Provincial Health Services Authority

REQUEST FOR ACCESS TO RECORDS

Personal information on this form is collected under British Columbia's *Freedom of Information and Protection of Privacy Act* and will be used to respond to your request.

About you

First Name: Alexandria

Last Name: Hill

Name of Company or Organization (*if applicable*): Doak Shirreff Lawyers LLP

Address: 200 - 537 Leon Avenue

City: Kelowna

Province: British Columbia

Postal Code: V1Y 2A9

Telephone Number: 250.979.2557

Email Address: AHill@doakshirreff.com

Details of the records you are seeking access to

Please give as much detail as possible. If you are seeking access to your own personal information, please include identifiers to help us find your records. If you are seeking access to another individual's personal information, you must include proof of your authorization in order for us to release information to you.

Please provide the following records from the Provincial Health Services Authority:
- all Adverse Events Following Immunization case report forms received by Provincial Health Services Authority between December 1, 2020 and November 8, 2023 (the "AEFIs")

For each AEFI, please include:
- the Provincial Health Services Authority investigation in Panorama;
- the Medical Health Officer recommendation; and
- a summary of how many AEFI reports were accepted as an AEFI compared to the total number of AEFI reports received.

Please redact any information that would disclose the identity of the patient from the records to be provided.

Date range of records search

Please include a start and end date for the records you are seeking access to.

Start Date: December 1, 2020

to

End Date: November 8, 2023

Signature

Date: November 10, 2023

Clear Form | Submit Form

Provincial Health Services Authority

June 6, 2024

Alexandria Hill
Doak Shirreff Lawyers LLP
Via email to ahill@doakshirreff.com

Dear Alexandria Hill:

Re: Response Letter
Freedom of Information and Protection of Privacy Act
Provincial Health Services Authority ("PHSA")
Our File No: F23-1799

We write in response to your request for records made under the *Freedom of Information and Protection of Privacy* Act [RSBC 1996] c. 165 (the "Act").

Request

You requested the following records (the "Request"):

> All AEFI Summary reports and the emails they were attached to.
> Date range of records search: December 1, 2017 to November 8, 2023.

Response

Some of the information in the enclosed records has been withheld pursuant to the following sections of the Act:

- Section 13(1) (Policy advice or recommendations): This section of the Act is applied to information that would reveal advice or recommendations developed by or for a public body.
- Section 15(1)(l) (Disclosure harmful to law enforcement): This section of the Act is applied to information that, if disclosed, could reasonably be expected to the harm the security of any property or system, including a building, a vehicle, a computer system or a communications system.
- Section 19(1) (Disclosure harmful to individual or public safety): This section of the Act is applied to information that would threaten anyone else's safety or mental or physical health.
- Section 22(1) (Disclosure harmful to personal privacy): This section of the Act is applied to information that would be harmful to a third party's personal privacy.

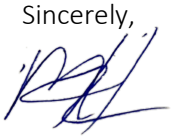
A copy of the Act is available online at:
http://www.bclaws.ca/Recon/document/ID/freeside/96165_00

Office of the Information and Privacy Commissioner for British Columbia

The Office of the Information and Privacy Commissioner for British Columbia (the "OIPC") is the regulator of access and privacy laws in the province. If you have a concern with any decision in the processing of the Request, you have the right to request a review of PHSA's decision from the OIPC. For ease of reference, information about the OIPC is included in Appendix A of this letter.

Additionally, should you have any questions about this letter, please contact me at matthew.hetu@phsa.ca or 604-707-5900 ext. 545835.

Sincerely,



Matthew Hetu
Information Access Advisor
Information Access Office
Provincial Health Services Authority

Appendix A: How to Request a Review

Under section 52 of the Act, you may request a review by the Office of the Information and Privacy Commissioner (OIPC) of any decision, action or failure to Act by PHSA in responding to your request.

If you wish to request a review, you must contact the OIPC in writing within 30 business days of your receipt of this letter and provide the OIPC with:

1. Your name, address and telephone number;
2. A copy of the original request that you sent;
3. A copy of this letter; and
4. The reasons or grounds upon which you are requesting the review.

All inquiries should be directed to:

Mail
Office of the Information and Privacy Commissioner for British Columbia
PO Box 9038, Stn. Prov. Govt.
Victoria, BC
V8W 9A4

Email
info@oipc.bc.ca

Tel
(250) 387-5629

Callers outside Victoria can contact the office toll-free by calling Enquiry BC at 1-800-663-7867 and requesting a transfer to (250) 387-5629.

Fax
(250) 387-1696

From: Noftall, Kyle [BCCDC]
To: Naus, Monika [BCCDC]; Amos, Heather [BCCDC]
Subject: RE: data for Thursday media avail
Date: Thursday, January 21, 2021 8:59:44 AM

Hi Monika and Heather,

Here are today's COVID-19 vaccine AEFI numbers:

- 56 AEFI reports (46.7 per 100,000 doses distributed); 32 following Moderna and 24 following Pfizer
- 13 anaphylaxis events reported (10.8 per 100,000 doses distributed); 5 following Moderna and 8 following Pfizer
- 16 other allergic events reported (13.4 per 100,000 doses distributed); 7 following Moderna and 9 following Pfizer

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

This e-mail message, including any attachments, is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged and/or confidential. If you are not the intended recipient or the employee or agent responsible for delivering the communication to the intended recipient, please notify us immediately by replying to this message and then delete this message from your system. You are hereby notified that any use, dissemination, distribution and/or reproduction of this message and/or any attachments by unintended recipients is unauthorized and may be unlawful.

From: Naus, Monika [BCCDC]
Sent: Thursday, January 21, 2021 8:29 AM
To: Noftall, Kyle [BCCDC]
Subject: FW: data for Thursday media avail

Kyle

I have an email from Bonnie asking for AEFI information. Should I use the information in the report from yesterday for this? Or are you planning to run a new one today?

Thank you,
Monika

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell 604.219.4524
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday)
mnds.assist@bccdc.ca Tel 604 707 2519
I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

From: Henry, Bonnie HLTH:EX [mailto:Bonnie.Henry@gov.bc.ca]
Sent: Wednesday, January 20, 2021 2:59 PM
To: Galanis, Eleni [BCCDC] <Eleni.Galanis@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Krajden, Mel [BCCDC] <Mel.Krajden@bccdc.ca>

Cc: Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>
Subject: data for Thursday media avail
EXTERNAL SENDER. If you suspect this message is malicious, please forward to spam@phsa.ca and **do not** open attachments or click on links.

Hi Monika, Mel and Eleni,
Could I get a quick update tomorrow of

1. Numbers of cases of MISC and ages/outcome
2. Numbers of AEFI and number of those that were 'allergic reactions'
3. Any vaccine wastage
4. Numbers of variants: SA (so far I am aware of 2, both NOT travel related) and UK (4, two travel and 2 contact of travel)

Thank you!
bonnie

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15(1), s.19(1) [redacted]
Mailing address: PO Box 9648, STN PROV GOVT
Victoria, BC
V8W 9P4
Bonnie.henry@gov.bc.ca
Phone: s.19(1) [redacted]

I gratefully acknowledge that I live and work on the traditional unceded territory of the Lekwungen Peoples, specifically the Songhees and Esquimalt First Nations. Hay'sxw'qu Si'em

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From: Naus, Monika [BCCDC]
To: Henry, Bonnie [EXT]
Cc: Amos, Heather [BCCDC]; Noftall, Kyle [BCCDC]; Gustafson, Reka [BCCDC]
Subject: Today"s AEFI report
Date: Thursday, January 21, 2021 10:09:24 AM
Attachments: COVID19_AEFI_Summary_Report_2021-01-21.html

Hi Bonnie
As requested, for your media briefing the full report based on reporting to today is enclosed.
In summary, we have had a total of 56 reports of adverse events (1 or more events/ report), for a rate of 46.7 reports per 100K doses distributed.
With respect to allergic/ anaphylaxis events:

- 10 anaphylaxis reports that meet the Brighton case definition have been reported, for a rate of 8 per 100K doses. This is a higher rate than reported in BC with influenza vaccine (for comparison) and higher than what has been reported in the US data (about 1 per 100K doses). One of these required hospitalization but recovered fully, and the others have not required hospitalization.
- 16 reports have been of other allergic events, including hives, some with onset days after immunization so the causal association of these later onset cases with the vaccine receipt is uncertain/ unlikely.

We do suspect that some of these events are being 'over-reported' because of the public domain information about these vaccines and the concern about allergy/ hypersensitivity to components including PEG and in the US, the recommendation to also not receive if one has a polysorbate hypersensitivity.
Other events of note, just fyi:

- The Bell's palsy was in a s.22(1) [redacted] This was a 'potential signal' in the vaccine trials but I've not heard it's being noted in postmarketing surveillance. The case reported is well within background 'expected' in BC. We will follow to outcome including causal assessment for other causes.
- We've had 4 cases of cellulitis reported but none meet the Brighton definition as none were microbiologically confirmed. We suspect these may be overcalled as cellulitis and are really large local reactions. One was not treated with antibiotics which raises questions about misreporting altogether so this needs to be teased out.

I forwarded your request on wastage to Noorjean and Julie Wilson as they're dealing with the logistics. You should hear from them directly.
Thank you,
Monika

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
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Sent: Wednesday, January 20, 2021 2:59 PM
To: Galanis, Eleni [BCCDC] <Eleni.Galanis@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Krajden, Mel [BCCDC] <Mel.Krajden@bccdc.ca>
Cc: Gustafson, Reka [BCCDC] <reka.gustafson@phsa.ca>
Subject: data for Thursday media avail
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bonnie

Dr Bonnie Henry
Provincial Health Officer
Office of the PHO
Ministry of Health
s.15(1), s.19(1) [redacted]
Mailing address: PO Box 9648, STN PROV GOVT
Victoria, BC
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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - January 21, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by January 18, 2021 there have been a total of 119,875 distributed doses. As of Jan 21, 2021, there have been 56 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 46.7 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 18 (32.1%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 75 adverse events reported, giving a ratio of 1.3 events per COVID-19 AEFI report.

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Jan 21, 2021 **(N=56)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2020-53	2021-1	2021-2	2021-3	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	7	9	23	14	**56**	**46.72**	**100.0**	6.50	**7.2**	100.0	**1.0**	32.30	**1.4**	100.0	**1.0**
Serious AEFI[g]	4	4	8	1	**18**	**15.02**	**32.1**	1.48	**10.1**	22.8	**1.4**	7.23	**2.1**	22.4	**1.4**
Events															
Anaphylaxis	2	3	6	1	**13**	**10.84**	**23.2**	0.47	**23.1**	7.3	**3.2**	2.70	**4.0**	8.3	**2.8**
Anaphylaxis Brighton levels 1/2/3[h]	2	1	5	1	**10**	**8.34**	**17.9**	0.19	**43.9**	2.8	**6.4**	NA	–	NA	–
Other allergic	2	2	7	3	**16**	**13.35**	**28.6**	2.09	**6.4**	32.1	**0.9**	5.64	**2.4**	17.5	**1.6**
Bell's Palsy	1	0	0	0	**1**	**0.83**	**1.8**	0.02	**41.5**	0.3	**6.0**	0.06	**13.8**	0.2	**9.0**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Meningitis	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.12	–	0.4	–

Meningitis	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.12	–	0.4	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	**0**	**0.00**	**0.0**	0.27	–	4.1	–	1.53	–	4.7	–
Thrombocytopenia	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Cellulitis	1	1	2	0	**4**	**3.34**	**7.1**	0.27	**12.4**	4.1	**1.7**	0.31	**10.8**	0.9	**7.9**
Recommendations															
No further immunizations	1	0	1	0	**3**	**2.50**	**5.4**	0.24	**10.4**	3.6	**1.5**	0.67	**3.7**	2.1	**2.6**
Outcomes															
Hospitalization	0	0	0	0	**1**	**0.83**	**1.8**	0.19	**4.4**	2.8	**0.6**	3.00	**0.3**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.18	–	0.6	–
Health Authority															
IHA	4	3	6	11	**25**	**111.61**	**44.6**	10.10	**11.1**	24.4	**1.8**	66.52	**1.7**	34.5	**1.3**
FHA	1	2	7	0	**11**	**31.32**	**19.6**	4.34	**7.2**	22.0	**0.9**	20.32	**1.5**	19.4	**1.0**
VCHA	2	2	1	0	**6**	**24.72**	**10.7**	2.28	**10.8**	10.4	**1.0**	10.19	**2.4**	9.7	**1.1**

FHA	1	2	7	0	**11**	**31.32**	**19.6**	4.34	**7.2**	22.0	**0.9**	20.32	**1.5**	19.4	**1.0**
VCHA	2	2	1	0	**6**	**24.72**	**10.7**	2.28	**10.8**	10.4	**1.0**	10.19	**2.4**	9.7	**1.1**
VIHA	0	1	6	3	**10**	**40.04**	**17.9**	9.55	**4.2**	25.9	**0.7**	38.38	**1.0**	20.7	**0.9**
NHA	0	1	3	0	**4**	**30.53**	**7.1**	26.36	**1.2**	17.4	**0.4**	115.42	**0.3**	15.7	**0.5**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	7	8	21	14	**53**	**1.62**	**94.6**	1.39	**1.2**	46.1	**2.1**	10.62	**0.2**	58.6	**1.6**
65+	0	1	2	0	**3**	**0.30**	**5.4**	0.95	**0.3**	8.8	**0.6**	5.09	**0.1**	6.3	**0.9**
Gender															
Female	7	8	22	14	**54**	**2.08**	**96.4**	2.32	**0.9**	60.4	**1.6**	16.58	**0.1**	69.8	**1.4**
Male	0	1	1	0	**2**	**0.08**	**3.6**	1.56	**0.1**	39.6	**0.1**	7.26	**0.0**	30.2	**0.1**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009

NHA	0	1	3	0	4	30.53	7.1	26.36	1.2	17.4	0.4	115.42	0.3	15.7	0.5
Age Group															
<18	0	0	0	0	0	0.00	0.0	5.03	–	45.1	–	21.73	–	35.1	–
18-64	7	8	21	14	53	1.62	94.6	1.39	1.2	46.1	2.1	10.62	0.2	58.6	1.6
65+	0	1	2	0	3	0.30	5.4	0.95	0.3	8.8	0.6	5.09	0.1	6.3	0.9
Gender															
Female	7	8	22	14	54	2.08	96.4	2.32	0.9	60.4	1.6	16.58	0.1	69.8	1.4
Male	0	1	1	0	2	0.08	3.6	1.56	0.1	39.6	0.1	7.26	0.0	30.2	0.1

Abbreviations:

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Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

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[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Seious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Jan 21, 2021 **(N=56)**

Vaccine information			Reports				Events																
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Seizure count	Seizure rate[b]	Other paralysis count	Other paralysis rate[b]	Cellu cou
COVID-19 mRNA	Moderna mRNA-1273	300042460	30	148.51	6	29.70	4	19.80	2	9.90	6	29.70	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2
		300042698	2	9.66	1	4.83	1	4.83	1	4.83	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
		Moderna mRNA-1273 total	**32**	**78.24**	**7**	**17.11**	**5**	**12.22**	**3**	**7.33**	**7**	**17.11**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**2**
	Pfizer mRNA BNT162b2	EK4175	4	102.56	4	102.56	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2
		EK4241	9	40.13	4	17.84	3	13.38	2	8.92	4	17.84	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0
		EK4245	9	36.92	2	8.21	2	8.21	2	8.21	5	20.51	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
		EL0203	1	3.54	1	3.54	1	3.54	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
		EL1406	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0
		Pfizer mRNA BNT162b2 total	**24**	**30.39**	**11**	**13.93**	**8**	**10.13**	**7**	**8.86**	**9**	**11.40**	**1**	**1.27**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**2**

	Events																		Outcomes			
rious EFI te[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Seizure count	Seizure rate[b]	Other paralysis count	Other paralysis rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
9.70	4	19.80	2	9.90	6	29.70	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	9.90	0	0.00	0	0.00
.83	1	4.83	1	4.83	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
7.11	**5**	**12.22**	**3**	**7.33**	**7**	**17.11**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**2**	**4.89**	**0**	**0.00**	**0**	**0.00**
2.56	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	51.28	0	0.00	0	0.00
7.84	3	13.38	2	8.92	4	17.84	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
.21	2	8.21	2	8.21	5	20.51	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
.54	1	3.54	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
3.93	**8**	**10.13**	**7**	**8.86**	**9**	**11.40**	**1**	**1.27**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**2**	**2.53**	**1**	**1.27**	**0**	**0.00**

		mRNA-1273 total																			
		EK4175	4	102.56	4	102.56	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2
		EK4241	9	40.13	4	17.84	3	13.38	2	8.92	4	17.84	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0
COVID-19 mRNA		EK4245	9	36.92	2	8.21	2	8.21	2	8.21	5	20.51	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
	Pfizer mRNA BNT162b2	EL0203	1	3.54	1	3.54	1	3.54	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
		EL1406	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0
		Pfizer mRNA BNT162b2 total	**24**	**30.39**	**11**	**13.93**	**8**	**10.13**	**7**	**8.86**	**9**	**11.40**	**1**	**1.27**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**2**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**56**	**46.72**	**18**	**15.02**	**13**	**10.84**	**10**	**8.34**	**16**	**13.35**	**1**	**0.83**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**4**

Abbreviations:
GBS = Guillain Barre Syndrome
Notes:
[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.
[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/
[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2.56	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	51.28	0	0.00	0	0.00
7.84	3	13.38	2	8.92	4	17.84	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
.21	2	8.21	2	8.21	5	20.51	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
.54	1	3.54	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
3.93	**8**	**10.13**	**7**	**8.86**	**9**	**11.40**	**1**	**1.27**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**2**	**2.53**	**1**	**1.27**	**0**	**0.00**
5.02	**13**	**10.84**	**10**	**8.34**	**16**	**13.35**	**1**	**0.83**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**4**	**3.34**	**1**	**0.83**	**0**	**0.00**

ot meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
)0 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.
Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]
Subject: RE: COVID AEFI numbers
Date: Monday, January 25, 2021 9:53:00 AM

Thanks Kyle

From: Noftall, Kyle [BCCDC]
Sent: Monday, January 25, 2021 9:44 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: COVID AEFI numbers

Hi Heather,

As of today, we have 70 COVID-19 AEFI reports. There have been 11 anaphylaxis reports meeting the anaphylaxis case definition and 23 other allergic events.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Naus, Monika [BCCDC]
To: Henry, Bonnie [EXT]
Cc: Rose, Caren [BCCDC]; Lavoie, Martin; Amos, Heather [BCCDC]; Gustafson, Reka [BCCDC]
Subject: COVID-19 AEFI report BC Jan 28
Date: Thursday, January 28, 2021 10:07:12 AM
Attachments: COVID19_AEFI_Summary_Report_2021-01-28.html

Good morning Bonnie
Here is today's cumulative AEFI report for BC.
Main points:
The most commonly reported events are allergic in nature, and include anaphylaxis which is a recognized and rare event that can occur with any vaccine. The reported rate of anaphylaxis in BC is about 1 case / 10,000 doses. All cases have been managed at the site and transferred for care to the ER; only one required hospitalization and all have recovered. A history of anaphylaxis to a dose of the vaccine is a contraindication to receipt of future doses.
We are seeing events reported as 'cellulitis' with an appreciably higher rate for the Moderna vaccine compared to Pfizer. We believe that these are likely not true cellulitis; none meet Brighton level 1 i.e., none were microbiologically confirmed. Some were not treated with antibiotics. The large differential rate between the products is consistent with the higher mRNA content (100 compared to 30 ug) per dose between the products; the mRNA acts as an adjuvant and this would be in keeping with what we see with adjuvanted vaccines and higher doses. These are likely large local reactions that are being managed as cellulitis preemptively by the care providers, but are not likely to be infections. This has been seen with other vaccines as well e.g., DPT-IPV compared to Tdap-IPV in younger children.
The one death was an inmate of a correctional facility with comorbidities. This is a coroner's case and results of that investigation are pending. We may not have this information for some time given the length of time these can take to complete.
We have two temporally associated thrombocytopenia reports. This is NOT being seen in the US analytic data comparing rates of this event in vaccinees and compared to non-vaccinees; there was some media coverage of an O+G who died following COVID-19 vaccine in the US from this condition, but as you know this is associated with a variety of causes and the VSD rapid cycle analysis data are pretty solid (see slide 24):
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-Shimabukuro.pdf
Thank you,
Monika

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell 604.219.4524
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday)
mnds.assist@bccdc.ca Tel 604 707 2519
I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - January 28, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by January 25, 2021 there have been a total of 144,250 distributed doses. As of January 28, 2021, there have been 142 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 98.4 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 42 (29.6%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 195 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Jan 28, 2021 **(N=142)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-1	2021-2	2021-3	2021-4	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	12	41	51	27	**142**	**98.44**	**100.0**	6.50	**15.1**	100.0	**1.0**	32.30	**3.0**	100.0	**1.0**
Serious AEFI[g]	4	11	14	8	**42**	**29.12**	**29.6**	1.48	**19.7**	22.8	**1.3**	7.23	**4.0**	22.4	**1.3**
Events															
Anaphylaxis	3	8	8	2	**24**	**16.64**	**16.9**	0.47	**35.4**	7.3	**2.3**	2.70	**6.2**	8.3	**2.0**
Anaphylaxis Brighton levels 1/2/3[h]	1	6	3	0	**13**	**9.01**	**9.2**	0.19	**47.4**	2.8	**3.3**	NA	–	NA	–
Other allergic	4	16	18	8	**51**	**35.36**	**35.9**	2.09	**16.9**	32.1	**1.1**	5.64	**6.3**	17.5	**2.1**
Bell's Palsy	0	0	0	0	**1**	**0.69**	**0.7**	0.02	**34.5**	0.3	**2.3**	0.06	**11.5**	0.2	**3.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Meningitis	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.12	–	0.4	–

Meningitis	0	0	0	0	0	0.00	0.0	0.00	–	0.0	–	0.12	–	0.4	–
Other paralysis	0	0	0	0	0	0.00	0.0	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	0	0.00	0.0	0.27	–	4.1	–	1.53	–	4.7	–
Thrombocytopenia	0	0	1	1	2	1.39	1.4	0.02	69.5	0.3	4.7	0.00	–	0.0	–
Cellulitis	1	3	4	5	14	9.71	9.9	0.27	36.0	4.1	2.4	0.31	31.3	0.9	11.0
Recommendations															
No further immunizations	0	1	0	0	3	2.08	2.1	0.24	8.7	3.6	0.6	0.67	3.1	2.1	1.0
Outcomes															
Hospitalization	0	0	0	0	1	0.69	0.7	0.19	3.6	2.8	0.2	3.00	0.2	9.3	0.1
Permanent disability	0	0	0	0	0	0.00	0.0	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	0	1	0	1	0.69	0.7	0.02	34.5	0.3	2.3	0.18	3.8	0.6	1.2
Health Authority															
IHA	3	8	19	14	49	179.65	34.5	10.10	17.8	24.4	1.4	66.52	2.7	34.5	1.0
FHA	3	17	14	4	41	91.36	28.9	4.34	21.1	22.0	1.3	20.32	4.5	19.4	1.5
VCHA	3	6	5	0	17	62.50	12.0	2.28	27.4	10.4	1.2	10.19	6.1	9.7	1.2

VCHA	3	6	5	0	**17**	**62.50**	**12.0**	2.28	**27.4**	10.4	**1.2**	10.19	**6.1**	9.7	**1.2**
VIHA	1	6	8	9	**24**	**80.40**	**16.9**	9.55	**8.4**	25.9	**0.7**	38.38	**2.1**	20.7	**0.8**
NHA	2	4	5	0	**11**	**73.09**	**7.7**	26.36	**2.8**	17.4	**0.4**	115.42	**0.6**	15.7	**0.5**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	10	39	46	19	**125**	**3.81**	**88.0**	1.39	**2.7**	46.1	**1.9**	10.62	**0.4**	58.6	**1.5**
65+	2	2	5	8	**17**	**1.72**	**12.0**	0.95	**1.8**	8.8	**1.4**	5.09	**0.3**	6.3	**1.9**
Gender															
Female	11	37	49	25	**133**	**5.12**	**93.7**	2.32	**2.2**	60.4	**1.6**	16.58	**0.3**	69.8	**1.3**
Male	1	4	2	2	**9**	**0.35**	**6.3**	1.56	**0.2**	39.6	**0.2**	7.26	**0.0**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

NHA	2	4	5	0	**11**	**73.09**	**7.7**	26.36	**2.8**	17.4	**0.4**	115.42	**0.6**	15.7	**0.5**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	10	39	46	19	**125**	**3.81**	**88.0**	1.39	**2.7**	46.1	**1.9**	10.62	**0.4**	58.6	**1.5**
65+	2	2	5	8	**17**	**1.72**	**12.0**	0.95	**1.8**	8.8	**1.4**	5.09	**0.3**	6.3	**1.9**
Gender															
Female	11	37	49	25	**133**	**5.12**	**93.7**	2.32	**2.2**	60.4	**1.6**	16.58	**0.3**	69.8	**1.3**
Male	1	4	2	2	**9**	**0.35**	**6.3**	1.56	**0.2**	39.6	**0.2**	7.26	**0.0**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Seious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Jan 28, 2021 **(N=142)**

Vaccine information			Reports				Events																
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Seizure count	Seizure rate[b]	Other paralysis count	Other paralysis rate[b]	Cell
COVID-19 mRNA	Moderna mRNA-1273	300042460	66	326.73	16	79.21	6	29.70	2	9.90	22	108.91	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	18	86.96	6	28.99	3	14.49	2	9.66	5	24.15	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Moderna mRNA-1273 total	**84**	**205.38**	**22**	**53.79**	**9**	**22.00**	**4**	**9.78**	**27**	**66.01**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**
	Pfizer mRNA BNT162b2	EK4175	7	179.49	4	102.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	13	57.97	5	22.30	3	13.38	2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	17	69.74	2	8.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	14	49.51	5	17.68	5	17.68	3	10.61	5	17.68	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1406	7	28.72	4	16.41	3	12.31	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Pfizer mRNA BNT162b2 total	**58**	**56.12**	**20**	**19.35**	**15**	**14.51**	**9**	**8.71**	**24**	**23.22**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	

	Events																		Outcomes			
rious EFI te[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Seizure count	Seizure rate[b]	Other paralysis count	Other paralysis rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
3.21	6	29.70	2	9.90	22	108.91	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	9	44.55	0	0.00	1	4.95
3.99	3	14.49	2	9.66	5	24.15	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	9.66	0	0.00	0	0.00
3.79	**9**	**22.00**	**4**	**9.78**	**27**	**66.01**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**11**	**26.89**	**0**	**0.00**	**1**	**2.44**
2.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	51.28	0	0.00	0	0.00
2.30	3	13.38	2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
7.68	5	17.68	3	10.61	5	17.68	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
3.41	3	12.31	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	0	0.00	0	0.00
3.35	**15**	**14.51**	**9**	**8.71**	**24**	**23.22**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**3**	**2.90**	**1**	**0.97**	**0**	**0.00**

		mRNA-1273 total																				
COVID-19 mRNA	**Pfizer mRNA BNT162b2**	EK4175	7	179.49	4	102.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2
		EK4241	13	57.97	5	22.30	3	13.38	2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0
		EK4245	17	69.74	2	8.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
		EL0203	14	49.51	5	17.68	5	17.68	3	10.61	5	17.68	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
		EL1406	7	28.72	4	16.41	3	12.31	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1
		Pfizer mRNA BNT162b2 total	**58**	**56.12**	**20**	**19.35**	**15**	**14.51**	**9**	**8.71**	**24**	**23.22**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**3**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**142**	**98.44**	**42**	**29.12**	**24**	**16.64**	**13**	**9.01**	**51**	**35.36**	**1**	**0.69**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**

Abbreviations:
GBS = Guillain Barre Syndrome
Notes:
[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.
[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i
[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	51.28	0	0.00	0	0.00
2.30	3	13.38	2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
7.68	5	17.68	3	10.61	5	17.68	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
5.41	3	12.31	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	0	0.00	0	0.00
9.35	**15**	**14.51**	**9**	**8.71**	**24**	**23.22**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**3**	**2.90**	**1**	**0.97**	**0**	**0.00**
3.12	**24**	**16.64**	**13**	**9.01**	**51**	**35.36**	**1**	**0.69**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**14**	**9.71**	**1**	**0.69**	**1**	**0.69**

ot meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
)0 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.
Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Feb.1 AEFI report
Date: Monday, February 01, 2021 10:49:03 AM
Attachments: COVID19_AEFI_Summary_Report_2021-02-01.html

Hi Heather,

Attached is today's COVID19 AEFI summary report. There are now 172 AEFI reports, with 15 meeting the anaphylaxis definition and 62 other allergic events.

Were you able to get access to the SharePoint site where these are being posted?

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - February 01, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by February 01, 2021 there have been a total of 144,250 distributed doses. As of February 01, 2021, there have been 172 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 119.2 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 48 (27.9%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 236 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Feb 01, 2021 **(N=172)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-2	2021-3	2021-4	2021-5	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	42	58	49	0	**172**	**119.24**	**100.0**	6.50	**18.3**	100.0	**1.0**	32.30	**3.7**	100.0	**1.0**
Serious AEFI[g]	11	18	10	0	**48**	**33.28**	**27.9**	1.48	**22.5**	22.8	**1.2**	7.23	**4.6**	22.4	**1.2**
Events															
Anaphylaxis	8	11	2	0	**27**	**18.72**	**15.7**	0.47	**39.8**	7.3	**2.2**	2.70	**6.9**	8.3	**1.9**
Anaphylaxis Brighton levels 1/2/3[h]	6	5	0	0	**15**	**10.40**	**8.7**	0.19	**54.7**	2.8	**3.1**	NA	–	NA	–
Other allergic	17	19	17	0	**62**	**42.98**	**36.0**	2.09	**20.6**	32.1	**1.1**	5.64	**7.6**	17.5	**2.1**
Bell's Palsy	0	0	0	0	**1**	**0.69**	**0.6**	0.02	**34.5**	0.3	**2.0**	0.06	**11.5**	0.2	**3.0**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Meningitis	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.12	–	0.4	–

Meningitis	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.12	–	0.4	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	**0**	**0.00**	**0.0**	0.27	–	4.1	–	1.53	–	4.7	–
Thrombocytopenia	0	1	1	0	**2**	**1.39**	**1.2**	0.02	**69.5**	0.3	**4.0**	0.00	–	0.0	–
Cellulitis	3	5	6	0	**16**	**11.09**	**9.3**	0.27	**41.1**	4.1	**2.3**	0.31	**35.8**	0.9	**10.3**
Recommendations															
No further immunizations	1	2	0	0	**5**	**3.47**	**2.9**	0.24	**14.5**	3.6	**0.8**	0.67	**5.2**	2.1	**1.4**
Outcomes															
Hospitalization	0	0	1	0	**2**	**1.39**	**1.2**	0.19	**7.3**	2.8	**0.4**	3.00	**0.5**	9.3	**0.1**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	1	0	0	**1**	**0.69**	**0.6**	0.02	**34.5**	0.3	**2.0**	0.18	**3.8**	0.6	**1.0**
Health Authority															
IHA	8	19	19	0	**54**	**197.98**	**31.4**	10.10	**19.6**	24.4	**1.3**	66.52	**3.0**	34.5	**0.9**
FHA	17	15	11	0	**49**	**109.19**	**28.5**	4.34	**25.2**	22.0	**1.3**	20.32	**5.4**	19.4	**1.5**
VCHA	6	9	0	0	**21**	**77.21**	**12.2**	2.28	**33.9**	10.4	**1.2**	10.19	**7.6**	9.7	**1.3**

VCHA	6	9	0	0	21	77.21	12.2	2.28	33.9	10.4	1.2	10.19	7.6	9.7	1.3
VIHA	6	8	18	0	33	110.55	19.2	9.55	11.6	25.9	0.7	38.38	2.9	20.7	0.9
NHA	5	7	1	0	15	99.67	8.7	26.36	3.8	17.4	0.5	115.42	0.9	15.7	0.6
Age Group															
<18	0	0	0	0	0	0.00	0.0	5.03	–	45.1	–	21.73	–	35.1	–
18-64	40	53	38	0	152	4.64	88.4	1.39	3.3	46.1	1.9	10.62	0.4	58.6	1.5
65+	2	5	11	0	20	2.03	11.6	0.95	2.1	8.8	1.3	5.09	0.4	6.3	1.8
Gender															
Female	38	56	46	0	162	6.24	94.2	2.32	2.7	60.4	1.6	16.58	0.4	69.8	1.3
Male	4	2	3	0	10	0.39	5.8	1.56	0.2	39.6	0.1	7.26	0.1	30.2	0.2

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

NHA	5	7	1	0	**15**	**99.67**	**8.7**	26.36	**3.8**	17.4	**0.5**	115.42	**0.9**	15.7	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	40	53	38	0	**152**	**4.64**	**88.4**	1.39	**3.3**	46.1	**1.9**	10.62	**0.4**	58.6	**1.5**
65+	2	5	11	0	**20**	**2.03**	**11.6**	0.95	**2.1**	8.8	**1.3**	5.09	**0.4**	6.3	**1.8**
Gender															
Female	38	56	46	0	**162**	**6.24**	**94.2**	2.32	**2.7**	60.4	**1.6**	16.58	**0.4**	69.8	**1.3**
Male	4	2	3	0	**10**	**0.39**	**5.8**	1.56	**0.2**	39.6	**0.1**	7.26	**0.1**	30.2	**0.2**

Abbreviations:
RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome
Notes:
[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.
[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.
[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.
[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.
[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.
[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[g] Seious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Feb 01, 2021 **(N=172)**

Vaccine information			Reports				Events																
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Seizure count	Seizure rate[b]	Other paralysis count	Other paralysis rate[b]	Cell
COVID-19 mRNA	Moderna mRNA-1273	300042460	72	356.44	18	89.11	7	34.65	3	14.85	25	123.76	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1
		300042698	29	140.10	7	33.82	3	14.49	2	9.66	8	38.65	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Moderna mRNA-1273 total	**101**	**246.94**	**25**	**61.12**	**10**	**24.45**	**5**	**12.22**	**33**	**80.68**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**
	Pfizer mRNA BNT162b2	EK4175	8	205.13	4	102.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	14	62.43	5	22.30	3	13.38	2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	18	73.85	2	8.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	17	60.12	6	21.22	5	17.68	3	10.61	8	28.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1406	14	57.44	6	24.62	5	20.51	1	4.10	5	20.51	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Pfizer mRNA BNT162b2 total	**71**	**68.70**	**23**	**22.25**	**17**	**16.45**	**10**	**9.68**	**29**	**28.06**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	

	Events																		Outcomes			
rious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Seizure count	Seizure rate[b]	Other paralysis count	Other paralysis rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
9.11	7	34.65	3	14.85	25	123.76	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	10	49.50	0	0.00	1	4.95
3.82	3	14.49	2	9.66	8	38.65	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	14.49	0	0.00	0	0.00
1.12	**10**	**24.45**	**5**	**12.22**	**33**	**80.68**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**13**	**31.78**	**0**	**0.00**	**1**	**2.44**
2.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	51.28	0	0.00	0	0.00
2.30	3	13.38	2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
1.22	5	17.68	3	10.61	8	28.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00
4.62	5	20.51	1	4.10	5	20.51	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	0	0.00	0	0.00
2.25	**17**	**16.45**	**10**	**9.68**	**29**	**28.06**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**3**	**2.90**	**2**	**1.94**	**0**	**0.00**

		mRNA-1273 total																			
		EK4175	8	205.13	4	102.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2
		EK4241	14	62.43	5	22.30	3	13.38	2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0
COVID-19 mRNA		EK4245	18	73.85	2	8.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
	Pfizer mRNA BNT162b2	EL0203	17	60.12	6	21.22	5	17.68	3	10.61	8	28.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
		EL1406	14	57.44	6	24.62	5	20.51	1	4.10	5	20.51	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1
		Pfizer mRNA BNT162b2 total	**71**	**68.70**	**23**	**22.25**	**17**	**16.45**	**10**	**9.68**	**29**	**28.06**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**3**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**172**	**119.24**	**48**	**33.28**	**27**	**18.72**	**15**	**10.40**	**62**	**42.98**	**1**	**0.69**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	51.28	0	0.00	0	0.00
2.30	3	13.38	2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
1.22	5	17.68	3	10.61	8	28.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00
4.62	5	20.51	1	4.10	5	20.51	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	0	0.00	0	0.00
2.25	**17**	**16.45**	**10**	**9.68**	**29**	**28.06**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**3**	**2.90**	**2**	**1.94**	**0**	**0.00**
3.28	**27**	**18.72**	**15**	**10.40**	**62**	**42.98**	**1**	**0.69**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**16**	**11.09**	**2**	**1.39**	**1**	**0.69**

ot meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
)0 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.
Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]
Subject: RE: Feb.1 AEFI report
Date: Monday, February 01, 2021 10:56:00 AM

Thanks Kyle!

From: Noftall, Kyle [BCCDC]
Sent: Monday, February 01, 2021 10:49 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Feb.1 AEFI report

Hi Heather,

Attached is today's COVID19 AEFI summary report. There are now 172 AEFI reports, with 15 meeting the anaphylaxis definition and 62 other allergic events.

Were you able to get access to the SharePoint site where these are being posted?

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: AEFI summary Feb.4
Date: Thursday, February 04, 2021 10:02:01 AM
Attachments: COVID19_AEFI_Summary_Report_2021-02-04.html

Hi Heather,

Today's COVID-19 AEFI report attached. There are 205 reports to date (142 reports per 100,000 doses distributed). Sixteen reports of anaphylaxis meeting the Brighton definition (11 reports per 100,000 doses distributed), and 76 reports with other allergic events (53 per 100,000 doses distributed).

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - February 04, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by February 01, 2021 there have been a total of 144,250 distributed doses. As of February 04, 2021, there have been 205 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 142.1 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 55 (26.8%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 293 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Feb 04, 2021 **(N=205)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-2	2021-3	2021-4	2021-5	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	44	61	57	18	**205**	**142.11**	**100.0**	6.50	**21.9**	100.0	**1.0**	32.30	**4.4**	100.0	**1.0**
Serious AEFI[g]	11	19	11	5	**55**	**38.13**	**26.8**	1.48	**25.8**	22.8	**1.2**	7.23	**5.3**	22.4	**1.2**
Events															
Anaphylaxis	8	11	2	2	**29**	**20.10**	**14.1**	0.47	**42.8**	7.3	**1.9**	2.70	**7.4**	8.3	**1.7**
Anaphylaxis Brighton levels 1/2/3[h]	6	5	0	1	**16**	**11.09**	**7.8**	0.19	**58.4**	2.8	**2.8**	NA	–	NA	–
Other allergic	18	22	22	5	**76**	**52.69**	**37.1**	2.09	**25.2**	32.1	**1.2**	5.64	**9.3**	17.5	**2.1**
Bell's Palsy	0	0	0	1	**2**	**1.39**	**1.0**	0.02	**69.5**	0.3	**3.3**	0.06	**23.2**	0.2	**5.0**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	0	0.00	0.0	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	0	0.00	0.0	0.27	–	4.1	–	1.53	–	4.7	–
Anaesthesia/ paraesthesia[1]	4	3	0	1	8	5.55	3.9	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	1	2	0	3	2.08	1.5	0.02	104.0	0.3	5.0	0.00	–	0.0	–
Cellulitis	3	5	7	2	19	13.17	9.3	0.27	48.8	4.1	2.3	0.31	42.5	0.9	10.3
Adenopathy/ lymphadenitis	4	2	5	0	11	7.63	5.4	0.07	109.0	1.0	5.4	0.43	17.7	1.3	4.2
Recommendations															
No further immunizations	1	2	0	0	5	3.47	2.4	0.25	13.9	3.9	0.6	0.67	5.2	2.1	1.1
Outcomes															
Hospitalization	0	1	1	0	3	2.08	1.5	0.19	10.9	2.8	0.5	3.00	0.7	9.3	0.2
Permanent disability	0	0	0	0	0	0.00	0.0	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	1	0	0	1	0.69	0.5	0.02	34.5	0.3	1.7	0.18	3.8	0.6	0.8
Health Authority															
IHA	10	21	23	5	68	249.31	33.2	10.10	24.7	24.4	1.4	66.52	3.7	34.5	1.0

IHA	10	21	23	5	**68**	**249.31**	**33.2**	10.10	**24.7**	24.4	**1.4**	66.52	**3.7**	34.5	**1.0**
FHA	16	15	11	0	**48**	**106.96**	**23.4**	4.34	**24.6**	22.0	**1.1**	20.32	**5.3**	19.4	**1.2**
VCHA	6	9	0	0	**22**	**80.88**	**10.7**	2.28	**35.5**	10.4	**1.0**	10.19	**7.9**	9.7	**1.1**
VIHA	6	9	22	12	**50**	**167.50**	**24.4**	9.55	**17.5**	25.9	**0.9**	38.38	**4.4**	20.7	**1.2**
NHA	6	7	1	1	**17**	**112.96**	**8.3**	26.36	**4.3**	17.4	**0.5**	115.42	**1.0**	15.7	**0.5**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	42	56	45	12	**178**	**5.43**	**86.8**	1.39	**3.9**	46.1	**1.9**	10.62	**0.5**	58.6	**1.5**
65+	2	5	12	6	**27**	**2.74**	**13.2**	0.95	**2.9**	8.8	**1.5**	5.09	**0.5**	6.3	**2.1**
Gender															
Female	40	59	53	18	**194**	**7.47**	**94.6**	2.32	**3.2**	60.4	**1.6**	16.58	**0.5**	69.8	**1.4**
Male	4	2	4	0	**11**	**0.43**	**5.4**	1.56	**0.3**	39.6	**0.1**	7.26	**0.1**	30.2	**0.2**

Abbreviations:
RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome
Notes:
[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.
[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.
[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	42	56	45	12	**178**	**5.43**	**86.8**	1.39	**3.9**	46.1	**1.9**	10.62	**0.5**	58.6	**1.5**
65+	2	5	12	6	**27**	**2.74**	**13.2**	0.95	**2.9**	8.8	**1.5**	5.09	**0.5**	6.3	**2.1**
Gender															
Female	40	59	53	18	**194**	**7.47**	**94.6**	2.32	**3.2**	60.4	**1.6**	16.58	**0.5**	69.8	**1.4**
Male	4	2	4	0	**11**	**0.43**	**5.4**	1.56	**0.3**	39.6	**0.1**	7.26	**0.1**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Feb 04, 2021 **(N=205)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	82	405.94	21	103.96	8	39.60	3	14.85	27	133.66	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	47	227.05	10	48.31	3	14.49	2	9.66	17	82.13	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		Moderna mRNA-1273 total	**129**	**315.40**	**31**	**75.79**	**11**	**26.89**	**5**	**12.22**	**44**	**107.58**	**1**	**2.44**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
	Pfizer mRNA BNT162b2	EK4175	8	205.13	4	102.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	15	66.89	5	22.30	3	13.38	2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	18	73.85	2	8.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	18	63.66	6	21.22	5	17.68	3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1406	17	69.74	7	28.72	6	24.62	2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Pfizer mRNA BNT162b2 total	**76**	**73.54**	**24**	**23.22**	**18**	**17.42**	**11**	**10.64**	**32**	**30.96**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	

	Events																		Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	27	133.66	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.95	11	54.46	1	4.95	1	4.95
	2	9.66	17	82.13	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	24.15	0	0.00	0	0.00
	5	**12.22**	**44**	**107.58**	**1**	**2.44**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**2.44**	**16**	**39.12**	**1**	**2.44**	**1**	**2.44**
	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	4	16.41	0	0.00	0	0.00	0	0.00
	3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	1	3.54	0	0.00
	2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	1	4.10	0	0.00	0	0.00
	11	**10.64**	**32**	**30.96**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**7**	**6.77**	**3**	**2.90**	**2**	**1.94**	**0**	**0.00**

		mRNA-1273 total																			
		EK4175	8	205.13	4	102.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EK4241	15	66.89	5	22.30	3	13.38	2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00
COVID-19 mRNA		EK4245	18	73.85	2	8.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	Pfizer mRNA BNT162b2	EL0203	18	63.66	6	21.22	5	17.68	3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1406	17	69.74	7	28.72	6	24.62	2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**76**	**73.54**	**24**	**23.22**	**18**	**17.42**	**11**	**10.64**	**32**	**30.96**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**205**	**142.11**	**55**	**38.13**	**29**	**20.10**	**16**	**11.09**	**76**	**52.69**	**2**	**1.39**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

Abbreviations:
GBS = Guillain Barre Syndrome
Notes:
[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.
[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i
[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
2	8.92	6	26.76	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	4	16.41	0	0.00	0	0.00	0	0.00
3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	1	3.54	0	0.00
2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	1	4.10	0	0.00	0	0.00
11	**10.64**	**32**	**30.96**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**7**	**6.77**	**3**	**2.90**	**2**	**1.94**	**0**	**0.00**
16	**11.09**	**76**	**52.69**	**2**	**1.39**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**8**	**5.55**	**19**	**13.17**	**3**	**2.08**	**1**	**0.69**

. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
played, the doses distributed for that lot number were not available at the time of the report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ed in the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Feb.8 AEFI Summary
Date: Monday, February 08, 2021 10:01:00 AM
Attachments: COVID19_AEFI_Summary_Report_2021-02-08.html

Hi Heather,
Today's AEFI summary is attached. There are 217 reports; 18 anaphylaxis meeting the case definition; 79 other allergic events. Doses distributed won't be accurate but will be updated later today.
Thanks,
Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - February 08, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by February 08, 2021 there have been a total of 144,250 distributed doses. As of February 08, 2021, there have been 217 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 150.4 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 58 (26.7%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 306 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Feb 08, 2021 **(N=217)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-3	2021-4	2021-5	2021-6	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	61	56	31	0	**217**	**150.43**	**100.0**	6.50	**23.1**	100.0	**1.0**	32.30	**4.7**	100.0	**1.0**
Serious AEFI[g]	19	11	8	0	**58**	**40.21**	**26.7**	1.48	**27.2**	22.8	**1.2**	7.23	**5.6**	22.4	**1.2**
Events															
Anaphylaxis	11	2	5	0	**32**	**22.18**	**14.7**	0.47	**47.2**	7.3	**2.0**	2.70	**8.2**	8.3	**1.8**
Anaphylaxis Brighton levels 1/2/3[h]	5	0	3	0	**18**	**12.48**	**8.3**	0.19	**65.7**	2.8	**3.0**	NA	–	NA	–
Other allergic	22	22	8	0	**79**	**54.77**	**36.4**	2.09	**26.2**	32.1	**1.1**	5.64	**9.7**	17.5	**2.1**
Bell's Palsy	0	0	1	0	**2**	**1.39**	**0.9**	0.02	**69.5**	0.3	**3.0**	0.06	**23.2**	0.2	**4.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	0	0.00	0.0	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	0	0.00	0.0	0.27	–	4.1	–	1.53	–	4.7	–
Anaesthesia/ paraesthesia[1]	3	0	3	0	9	6.24	4.1	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	1	2	0	0	3	2.08	1.4	0.02	104.0	0.3	4.7	0.00	–	0.0	–
Cellulitis	5	7	2	0	19	13.17	8.8	0.27	48.8	4.1	2.1	0.31	42.5	0.9	9.8
Adenopathy/ lymphadenitis	2	4	0	0	10	6.93	4.6	0.07	99.0	1.0	4.6	0.43	16.1	1.3	3.5
Recommendations															
No further immunizations	2	0	0	0	5	3.47	2.3	0.25	13.9	3.9	0.6	0.67	5.2	2.1	1.1
Outcomes															
Hospitalization	1	1	0	0	3	2.08	1.4	0.19	10.9	2.8	0.5	3.00	0.7	9.3	0.2
Permanent disability	0	0	0	0	0	0.00	0.0	0.00	–	0.0	–	0.00	–	0.0	–
Death	1	0	0	0	1	0.69	0.5	0.02	34.5	0.3	1.7	0.18	3.8	0.6	0.8
Health Authority															
IHA	21	22	8	0	70	256.65	32.3	10.10	25.4	24.4	1.3	66.52	3.9	34.5	0.9

Health Authority															
IHA	21	22	8	0	**70**	**256.65**	**32.3**	10.10	**25.4**	24.4	**1.3**	66.52	**3.9**	34.5	**0.9**
FHA	15	11	2	0	**50**	**111.42**	**23.0**	4.34	**25.7**	22.0	**1.0**	20.32	**5.5**	19.4	**1.2**
VCHA	9	0	0	0	**22**	**80.88**	**10.1**	2.28	**35.5**	10.4	**1.0**	10.19	**7.9**	9.7	**1.0**
VIHA	9	22	20	0	**58**	**194.30**	**26.7**	9.55	**20.3**	25.9	**1.0**	38.38	**5.1**	20.7	**1.3**
NHA	7	1	1	0	**17**	**112.96**	**7.8**	26.36	**4.3**	17.4	**0.4**	115.42	**1.0**	15.7	**0.5**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	56	44	20	0	**185**	**5.65**	**85.3**	1.39	**4.1**	46.1	**1.9**	10.62	**0.5**	58.6	**1.5**
65+	5	12	11	0	**32**	**3.25**	**14.7**	0.95	**3.4**	8.8	**1.7**	5.09	**0.6**	6.3	**2.3**
Gender															
Female	59	52	29	0	**204**	**7.86**	**94.0**	2.32	**3.4**	60.4	**1.6**	16.58	**0.5**	69.8	**1.3**
Male	2	4	2	0	**13**	**0.51**	**6.0**	1.56	**0.3**	39.6	**0.2**	7.26	**0.1**	30.2	**0.2**

Abbreviations:
RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome
Notes:
[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.
[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	56	44	20	0	**185**	**5.65**	**85.3**	1.39	**4.1**	46.1	**1.9**	10.62	**0.5**	58.6	**1.5**
65+	5	12	11	0	**32**	**3.25**	**14.7**	0.95	**3.4**	8.8	**1.7**	5.09	**0.6**	6.3	**2.3**
Gender															
Female	59	52	29	0	**204**	**7.86**	**94.0**	2.32	**3.4**	60.4	**1.6**	16.58	**0.5**	69.8	**1.3**
Male	2	4	2	0	**13**	**0.51**	**6.0**	1.56	**0.3**	39.6	**0.2**	7.26	**0.1**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Feb 08, 2021 **(N=217)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	84	415.84	21	103.96	8	39.60	3	14.85	27	133.66	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	52	251.21	10	48.31	3	14.49	2	9.66	19	91.79	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		Moderna mRNA-1273 total	**136**	**332.52**	**31**	**75.79**	**11**	**26.89**	**5**	**12.22**	**46**	**112.47**	**1**	**2.44**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
	Pfizer mRNA BNT162b2	EK4175	8	205.13	4	102.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	17	75.81	5	22.30	3	13.38	2	8.92	7	31.22	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	18	73.85	2	8.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	3	NA	3	NA	3	NA	2	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	
		EL0203	18	63.66	6	21.22	5	17.68	3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1406	17	69.74	7	28.72	6	24.62	2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Pfizer mRNA BNT162b2	**81**	**78.37**	**27**	**26.12**	**21**	**20.32**	**13**	**12.58**	**33**	**31.93**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	

	Events																		Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	27	133.66	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.95	11	54.46	1	4.95	1	4.95
	2	9.66	19	91.79	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	24.15	0	0.00	0	0.00
	5	**12.22**	**46**	**112.47**	**1**	**2.44**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**2.44**	**16**	**39.12**	**1**	**2.44**	**1**	**2.44**
	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	7	31.22	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00
	2	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	2	NA	0	NA	0	NA	0	NA
	3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	1	3.54	0	0.00
	2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	1	4.10	0	0.00	0	0.00
	13	**12.58**	**33**	**31.93**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**8**	**7.74**	**3**	**2.90**	**2**	**1.94**	**0**	**0.00**

		EK4175	8	205.13	4	102.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EK4241	17	75.81	5	22.30	3	13.38	2	8.92	7	31.22	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00
		EK4245	18	73.85	2	8.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
COVID-19 mRNA	**Pfizer mRNA BNT162b2**	EL0140	3	NA	3	NA	3	NA	2	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		EL0203	18	63.66	6	21.22	5	17.68	3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1406	17	69.74	7	28.72	6	24.62	2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**81**	**78.37**	**27**	**26.12**	**21**	**20.32**	**13**	**12.58**	**33**	**31.93**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**217**	**150.43**	**58**	**40.21**	**32**	**22.18**	**18**	**12.48**	**79**	**54.77**	**2**	**1.39**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

Abbreviations:
GBS = Guillain Barre Syndrome
Notes:
[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.
[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i
[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
2	8.92	7	31.22	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00
2	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	2	NA	0	NA	0	NA	0	NA
3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	1	3.54	0	0.00
2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	1	4.10	0	0.00	0	0.00
13	**12.58**	**33**	**31.93**	**1**	**0.97**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**8**	**7.74**	**3**	**2.90**	**2**	**1.94**	**0**	**0.00**
18	**12.48**	**79**	**54.77**	**2**	**1.39**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**9**	**6.24**	**19**	**13.17**	**3**	**2.08**	**1**	**0.69**

. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
layed, the doses distributed for that lot number were not available at the time of the report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ed in the anaphylaxis case definition.

References

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2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Naus, Monika [BCCDC]
Subject: RE: Feb.8 AEFI Summary
Date: Tuesday, February 09, 2021 8:47:47 AM
Attachments: COVID19_AEFI_Summary_Report_2021-02-08_updated.html

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Hi Heather,

I have an updated version of the report from yesterday attached here with updated doses distributed numbers and rates (the counts are all the same). The data source is Panorama (provincial public health information system), and data were extracted Feb.8. All rates are per 100,000 doses distributed.

A note on interpreting anaphylaxis – there are report counts/rates for just "Anaphylaxis" which means anything that was managed as anaphylaxis (e.g. given epinephrine). We also have report counts/rates for "Anaphylaxis Brighton levels 1/2/3" which are those anaphylaxis reports that meet the diagnostic certainty criteria in the Brighton Collaboration's anaphylaxis case definition. The latter are the numbers I've been quoting to you in my emails and are more likely to reflect a true anaphylactic reactions. Not saying you need to explain that at all, but thought it might be helpful as there are two anaphylaxis events included in the reports.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Amos, Heather [BCCDC]
Sent: Tuesday, February 09, 2021 8:21 AM
To: Naus, Monika [BCCDC]; Noftall, Kyle [BCCDC]
Subject: RE: Feb.8 AEFI Summary

Thanks Monika. I will add in the date, data source and rates from the same file.

From: Naus, Monika [BCCDC]
Sent: Tuesday, February 09, 2021 7:17 AM
To: Amos, Heather [BCCDC]; Noftall, Kyle [BCCDC]
Subject: Re: Feb.8 AEFI Summary

And P.S.
I know they like numbers, but rates are more informative. If you do provide numbers please also provide doses on which this is based.
On Blackberry so cannot read these out for you ...
Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases

BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell 604.219.4524

From: Monika.Naus@bccdc.ca
Sent: February 9, 2021 7:13 AM
To: heather.amos@bccdc.ca; Kyle.Noftall@bccdc.ca
Subject: Re: Feb.8 AEFI Summary

Hi Heather
If you provide numbers please do state the date reported by, and source i.e., the provincial public health information system. It would be good to reference the reporting process, which us by health care providers under regulations under the Public Health Act.
...such as hives
And data should be 'are' rather than 'is'.
Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell 604.219.4524

From: heather.amos@bccdc.ca
Sent: February 9, 2021 7:00 AM
To: Kyle.Noftall@bccdc.ca; Monika.Naus@bccdc.ca
Subject: Re: Feb.8 AEFI Summary

Hi

Thanks for these numbers. A reporter asked the Ministry of Health for more detailed data about AEFI (Bonnie just provided a high-level interview in the briefing yesterday). Is it okay to provide this information publicly? If so, please review below.

Does the Ministry have the data to say which vaccine people were having those reactions to?

For all adverse events:

81 Pfizer

136 Moderna

For anaphylaxis:

13 Pfizer

5 Moderna

- Is there data on if the allergic reaction was the same (ie: same symptoms/reactions) for all 18 persons?

18 reports of anaphylaxis and 79 reports of other allergic events such as ....

- Or whether there's a particular ingredient in the vaccines that those people were allergic to?

You should not get the vaccine if you have serious allergies to any of the ingredients in the vaccines. An ingredient in the vaccines that has been associated with a rare but serious allergy

(anaphylaxis) is polyethylene glycol (PEG).
Thank you,
Heather

From: Noftall, Kyle [BCCDC]
Sent: February 8, 2021 10:00 AM
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Feb.8 AEFI Summary

Hi Heather,

Today's AEFI summary is attached. There are 217 reports; 18 anaphylaxis meeting the case definition; 79 other allergic events. Doses distributed won't be accurate but will be updated later today.

Thanks,
Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - February 08, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by February 08, 2021 there have been a total of 171,475 distributed doses. As of February 08, 2021, there have been 217 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 126.5 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 58 (26.7%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 306 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Feb 08, 2021 **(N=217)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-3	2021-4	2021-5	2021-6	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	61	56	31	0	**217**	**126.55**	**100.0**	6.50	**19.5**	100.0	**1.0**	32.30	**3.9**	100.0	**1.0**
Serious AEFI[g]	19	11	8	0	**58**	**33.82**	**26.7**	1.48	**22.9**	22.8	**1.2**	7.23	**4.7**	22.4	**1.2**
Events															
Anaphylaxis	11	2	5	0	**32**	**18.66**	**14.7**	0.47	**39.7**	7.3	**2.0**	2.70	**6.9**	8.3	**1.8**
Anaphylaxis Brighton levels 1/2/3[h]	5	0	3	0	**18**	**10.50**	**8.3**	0.19	**55.3**	2.8	**3.0**	NA	–	NA	–
Other allergic	22	22	8	0	**79**	**46.07**	**36.4**	2.09	**22.0**	32.1	**1.1**	5.64	**8.2**	17.5	**2.1**
Bell's Palsy	0	0	1	0	**2**	**1.17**	**0.9**	0.02	**58.5**	0.3	**3.0**	0.06	**19.5**	0.2	**4.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	**0**	**0.00**	**0.0**	0.27	–	4.1	–	1.53	–	4.7	–
Anaesthesia/ paraesthesia[1]	3	0	3	0	**9**	**5.25**	**4.1**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	1	2	0	0	**3**	**1.75**	**1.4**	0.02	**87.5**	0.3	**4.7**	0.00	–	0.0	–
Cellulitis	5	7	2	0	**19**	**11.08**	**8.8**	0.27	**41.0**	4.1	**2.1**	0.31	**35.7**	0.9	**9.8**
Adenopathy/ lymphadenitis	2	4	0	0	**10**	**5.83**	**4.6**	0.07	**83.3**	1.0	**4.6**	0.43	**13.6**	1.3	**3.5**
Recommendations															
No further immunizations	2	0	0	0	**5**	**2.92**	**2.3**	0.25	**11.7**	3.9	**0.6**	0.67	**4.4**	2.1	**1.1**
Outcomes															
Hospitalization	1	1	0	0	**3**	**1.75**	**1.4**	0.19	**9.2**	2.8	**0.5**	3.00	**0.6**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	1	0	0	0	**1**	**0.58**	**0.5**	0.02	**29.0**	0.3	**1.7**	0.18	**3.2**	0.6	**0.8**
Health Authority															
IHA	21	22	8	0	**70**	**224.00**	**32.3**	10.10	**22.2**	24.4	**1.3**	66.52	**3.4**	34.5	**0.9**

Health Authority															
IHA	21	22	8	0	**70**	**224.00**	**32.3**	10.10	**22.2**	24.4	**1.3**	66.52	**3.4**	34.5	**0.9**
FHA	15	11	2	0	**50**	**96.57**	**23.0**	4.34	**22.3**	22.0	**1.0**	20.32	**4.8**	19.4	**1.2**
VCHA	9	0	0	0	**22**	**61.37**	**10.1**	2.28	**26.9**	10.4	**1.0**	10.19	**6.0**	9.7	**1.0**
VIHA	9	22	20	0	**58**	**174.96**	**26.7**	9.55	**18.3**	25.9	**1.0**	38.38	**4.6**	20.7	**1.3**
NHA	7	1	1	0	**17**	**87.40**	**7.8**	26.36	**3.3**	17.4	**0.4**	115.42	**0.8**	15.7	**0.5**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	56	44	20	0	**185**	**5.65**	**85.3**	1.39	**4.1**	46.1	**1.9**	10.62	**0.5**	58.6	**1.5**
65+	5	12	11	0	**32**	**3.25**	**14.7**	0.95	**3.4**	8.8	**1.7**	5.09	**0.6**	6.3	**2.3**
Gender															
Female	59	52	29	0	**204**	**7.86**	**94.0**	2.32	**3.4**	60.4	**1.6**	16.58	**0.5**	69.8	**1.3**
Male	2	4	2	0	**13**	**0.51**	**6.0**	1.56	**0.3**	39.6	**0.2**	7.26	**0.1**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	56	44	20	0	**185**	**5.65**	**85.3**	1.39	**4.1**	46.1	**1.9**	10.62	**0.5**	58.6	**1.5**
65+	5	12	11	0	**32**	**3.25**	**14.7**	0.95	**3.4**	8.8	**1.7**	5.09	**0.6**	6.3	**2.3**
Gender															
Female	59	52	29	0	**204**	**7.86**	**94.0**	2.32	**3.4**	60.4	**1.6**	16.58	**0.5**	69.8	**1.3**
Male	2	4	2	0	**13**	**0.51**	**6.0**	1.56	**0.3**	39.6	**0.2**	7.26	**0.1**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Feb 08, 2021 **(N=217)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	84	415.84	21	103.96	8	39.60	3	14.85	27	133.66	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	52	251.21	10	48.31	3	14.49	2	9.66	19	91.79	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		300042722	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Moderna mRNA-1273 total	**136**	**236.93**	**31**	**54.01**	**11**	**19.16**	**5**	**8.71**	**46**	**80.14**	**1**	**1.74**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
	Pfizer mRNA BNT162b2	EK4175	8	205.13	4	102.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	17	75.81	5	22.30	3	13.38	2	8.92	7	31.22	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	18	73.85	2	8.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	3	27.97	3	27.97	3	27.97	2	18.65	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	18	63.66	6	21.22	5	17.68	3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1406	17	69.74	7	28.72	6	24.62	2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Pfizer	**81**	**71.01**	**27**	**23.67**	**21**	**18.41**	**13**	**11.40**	**33**	**28.93**	**1**	**0.88**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	

	Events																		Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	27	133.66	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.95	11	54.46	1	4.95	1	4.95
	2	9.66	19	91.79	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	24.15	0	0.00	0	0.00
	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	5	**8.71**	**46**	**80.14**	**1**	**1.74**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**1.74**	**16**	**27.87**	**1**	**1.74**	**1**	**1.74**
	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	7	31.22	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00
	2	18.65	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	18.65	0	0.00	0	0.00	0	0.00
	3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	1	3.54	0	0.00
	2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	1	4.10	0	0.00	0	0.00
	13	**11.40**	**33**	**28.93**	**1**	**0.88**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**8**	**7.01**	**3**	**2.63**	**2**	**1.75**	**0**	**0.00**

		EK4175	8	205.13	4	102.56	2	51.28	2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EK4241	17	75.81	5	22.30	3	13.38	2	8.92	7	31.22	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00
COVID-19 mRNA		EK4245	18	73.85	2	8.21	2	8.21	2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	Pfizer mRNA BNT162b2	EL0140	3	27.97	3	27.97	3	27.97	2	18.65	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0203	18	63.66	6	21.22	5	17.68	3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1406	17	69.74	7	28.72	6	24.62	2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**81**	**71.01**	**27**	**23.67**	**21**	**18.41**	**13**	**11.40**	**33**	**28.93**	**1**	**0.88**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**217**	**126.55**	**58**	**33.82**	**32**	**18.66**	**18**	**10.50**	**79**	**46.07**	**2**	**1.17**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2	51.28	1	25.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
2	8.92	7	31.22	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00
2	8.21	9	36.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00
2	18.65	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	18.65	0	0.00	0	0.00	0	0.00
3	10.61	9	31.83	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	1	3.54	0	0.00
2	8.21	7	28.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	1	4.10	0	0.00	0	0.00
13	**11.40**	**33**	**28.93**	**1**	**0.88**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**8**	**7.01**	**3**	**2.63**	**2**	**1.75**	**0**	**0.00**
18	**10.50**	**79**	**46.07**	**2**	**1.17**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**9**	**5.25**	**19**	**11.08**	**3**	**1.75**	**1**	**0.58**

The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
played, the doses distributed for that lot number were not available at the time of the report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ed in the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]
Subject: RE: Feb.8 AEFI Summary
Date: Tuesday, February 09, 2021 8:55:08 AM

Thanks Kyle. I noted that there were two different numbers but figured it was related to case definition of true anaphylaxis ☺

From: Noftall, Kyle [BCCDC]
Sent: Tuesday, February 09, 2021 8:48 AM
To: Amos, Heather [BCCDC]; Naus, Monika [BCCDC]
Subject: RE: Feb.8 AEFI Summary

Hi Heather,

I have an updated version of the report from yesterday attached here with updated doses distributed numbers and rates (the counts are all the same). The data source is Panorama (provincial public health information system), and data were extracted Feb.8. All rates are per 100,000 doses distributed.

A note on interpreting anaphylaxis – there are report counts/rates for just "Anaphylaxis" which means anything that was managed as anaphylaxis (e.g. given epinephrine). We also have report counts/rates for "Anaphylaxis Brighton levels 1/2/3" which are those anaphylaxis reports that meet the diagnostic certainty criteria in the Brighton Collaboration's anaphylaxis case definition. The latter are the numbers I've been quoting to you in my emails and are more likely to reflect a true anaphylactic reactions. Not saying you need to explain that at all, but thought it might be helpful as there are two anaphylaxis events included in the reports.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Amos, Heather [BCCDC]
Sent: Tuesday, February 09, 2021 8:21 AM
To: Naus, Monika [BCCDC]; Noftall, Kyle [BCCDC]
Subject: RE: Feb.8 AEFI Summary

Thanks Monika. I will add in the date, data source and rates from the same file.

From: Naus, Monika [BCCDC]
Sent: Tuesday, February 09, 2021 7:17 AM
To: Amos, Heather [BCCDC]; Noftall, Kyle [BCCDC]
Subject: Re: Feb.8 AEFI Summary

And P.S.
I know they like numbers, but rates are more informative. If you do provide numbers please also provide doses on which this is based.
On Blackberry so cannot read these out for you ...
Thank you,

Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell 604.219.4524

From: Monika.Naus@bccdc.ca
Sent: February 9, 2021 7:13 AM
To: heather.amos@bccdc.ca; Kyle.Noftall@bccdc.ca
Subject: Re: Feb.8 AEFI Summary

Hi Heather
If you provide numbers please do state the date reported by, and source i.e., the provincial public health information system. It would be good to reference the reporting process, which us by health care providers under regulations under the Public Health Act.
...such as hives
And data should be 'are' rather than 'is'.
Thank you,
Monika

. . . . . .

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell 604.219.4524

From: heather.amos@bccdc.ca
Sent: February 9, 2021 7:00 AM
To: Kyle.Noftall@bccdc.ca; Monika.Naus@bccdc.ca
Subject: Re: Feb.8 AEFI Summary

Hi

Thanks for these numbers. A reporter asked the Ministry of Health for more detailed data about AEFI (Bonnie just provided a high-level interview in the briefing yesterday). Is it okay to provide this information publicly? If so, please review below.

s.13(1)

s.13(1)

[redacted]

Thank you,
Heather

From: Noftall, Kyle [BCCDC]
Sent: February 8, 2021 10:00 AM
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Feb.8 AEFI Summary

Hi Heather,

Today's AEFI summary is attached. There are 217 reports; 18 anaphylaxis meeting the case definition; 79 other allergic events. Doses distributed won't be accurate but will be updated later today.

Thanks,
Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Feb.11 COVID19 AEFI Summary
Date: Thursday, February 11, 2021 10:17:16 AM
Attachments: COVID19_AEFI_Summary_Report_2021-02-11.html

Hi Heather,

Today's COVID19 AEFI summary report attached. The total reports, serious, anaphylaxis and other allergic details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	248	144.63
Serious AEFI	61	35.57
Anaphylaxis	32	18.66
Anaphylaxis Brighton levels 1/2/3	18	10.50
Other allergic	94	54.82

Thank you,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - February 11, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by February 08, 2021 there have been a total of 171,475 distributed doses. As of February 11, 2021, there have been 248 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 144.6 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 61 (24.6%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 353 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Feb 11, 2021 **(N=248)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-3	2021-4	2021-5	2021-6	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	63	57	46	11	**248**	**144.63**	**100.0**	6.50	**22.3**	100.0	**1.0**	32.30	**4.5**	100.0	**1.0**
Serious AEFI[g]	19	11	10	1	**61**	**35.57**	**24.6**	1.48	**24.0**	22.8	**1.1**	7.23	**4.9**	22.4	**1.1**
Events															
Anaphylaxis	11	2	5	0	**32**	**18.66**	**12.9**	0.47	**39.7**	7.3	**1.8**	2.70	**6.9**	8.3	**1.6**
Anaphylaxis Brighton levels 1/2/3[h]	5	0	3	0	**18**	**10.50**	**7.3**	0.19	**55.3**	2.8	**2.6**	NA	–	NA	–
Other allergic	24	26	14	3	**94**	**54.82**	**37.9**	2.09	**26.2**	32.1	**1.2**	5.64	**9.7**	17.5	**2.2**
Bell's Palsy	0	0	1	0	**2**	**1.17**	**0.8**	0.02	**58.5**	0.3	**2.7**	0.06	**19.5**	0.2	**4.0**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	0	0.00	0.0	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	0	0.00	0.0	0.27	–	4.1	–	1.53	–	4.7	–
Anaesthesia/ paraesthesia[1]	3	2	3	1	12	7.00	4.8	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	1	1	0	0	2	1.17	0.8	0.02	58.5	0.3	2.7	0.00	–	0.0	–
Cellulitis	5	8	3	1	22	12.83	8.9	0.27	47.5	4.1	2.2	0.31	41.4	0.9	9.9
Adenopathy/ lymphadenitis	2	3	2	0	11	6.41	4.4	0.07	91.6	1.0	4.4	0.43	14.9	1.3	3.4
Recommendations															
No further immunizations	3	1	0	0	7	4.08	2.8	0.25	16.3	3.9	0.7	0.67	6.1	2.1	1.3
Outcomes															
Hospitalization	1	1	1	0	4	2.33	1.6	0.19	12.3	2.8	0.6	3.00	0.8	9.3	0.2
Permanent disability	0	0	0	0	0	0.00	0.0	0.00	–	0.0	–	0.00	–	0.0	–
Death	1	0	0	0	1	0.58	0.4	0.02	29.0	0.3	1.3	0.18	3.2	0.6	0.7
Health Authority															
IHA	20	17	9	6	71	227.20	28.6	10.10	22.5	24.4	1.2	66.52	3.4	34.5	0.8

Health Authority															
IHA	20	17	9	6	**71**	**227.20**	**28.6**	10.10	**22.5**	24.4	**1.2**	66.52	**3.4**	34.5	**0.8**
FHA	15	11	8	1	**57**	**110.09**	**23.0**	4.34	**25.4**	22.0	**1.0**	20.32	**5.4**	19.4	**1.2**
VCHA	12	6	5	0	**37**	**103.21**	**14.9**	2.28	**45.3**	10.4	**1.4**	10.19	**10.1**	9.7	**1.5**
VIHA	8	22	23	4	**65**	**196.08**	**26.2**	9.55	**20.5**	25.9	**1.0**	38.38	**5.1**	20.7	**1.3**
NHA	8	1	1	0	**18**	**92.54**	**7.3**	26.36	**3.5**	17.4	**0.4**	115.42	**0.8**	15.7	**0.5**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	58	48	33	11	**216**	**6.59**	**87.1**	1.39	**4.7**	46.1	**1.9**	10.62	**0.6**	58.6	**1.5**
65+	5	9	13	0	**32**	**3.25**	**12.9**	0.95	**3.4**	8.8	**1.5**	5.09	**0.6**	6.3	**2.0**
Gender															
Female	61	52	42	10	**230**	**8.86**	**92.7**	2.32	**3.8**	60.4	**1.5**	16.58	**0.5**	69.8	**1.3**
Male	2	5	4	1	**18**	**0.71**	**7.3**	1.56	**0.5**	39.6	**0.2**	7.26	**0.1**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	58	48	33	11	**216**	**6.59**	**87.1**	1.39	**4.7**	46.1	**1.9**	10.62	**0.6**	58.6	**1.5**
65+	5	9	13	0	**32**	**3.25**	**12.9**	0.95	**3.4**	8.8	**1.5**	5.09	**0.6**	6.3	**2.0**
Gender															
Female	61	52	42	10	**230**	**8.86**	**92.7**	2.32	**3.8**	60.4	**1.5**	16.58	**0.5**	69.8	**1.3**
Male	2	5	4	1	**18**	**0.71**	**7.3**	1.56	**0.5**	39.6	**0.2**	7.26	**0.1**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Feb 11, 2021 **(N=248)**

Vaccine information			Reports				Events														
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	85	420.79	22	108.91	8	39.60	3	14.85	28	138.61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	54	260.87	11	53.14	3	14.49	2	9.66	19	91.79	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		300042722	1	6.06	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Moderna mRNA-1273 total	**140**	**243.90**	**33**	**57.49**	**11**	**19.16**	**5**	**8.71**	**47**	**81.88**	**1**	**1.74**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
	Pfizer mRNA BNT162b2	EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	23	102.56	5	22.30	3	13.38	2	8.92	11	49.05	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	24	98.46	2	8.21	2	8.21	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	8	74.59	3	27.97	3	27.97	2	18.65	3	27.97	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	23	81.34	7	24.76	5	17.68	3	10.61	11	38.90	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1406	21	86.15	7	28.72	6	24.62	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Pfizer	**108**	**94.67**	**28**	**24.55**	**21**	**18.41**	**13**	**11.40**	**47**	**41.20**	**1**	**0.88**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	

	Events																					Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	28	138.61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.95	12	59.41	1	4.95	1	4.95
	2	9.66	19	91.79	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	1	4.83	7	33.82	0	0.00	0	0.00
	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	5	**8.71**	**47**	**81.88**	**1**	**1.74**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**2**	**3.48**	**19**	**33.10**	**1**	**1.74**	**1**	**1.74**
	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	11	49.05	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	4	16.41	0	0.00	0	0.00	0	0.00
	2	18.65	3	27.97	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	18.65	0	0.00	0	0.00	0	0.00
	3	10.61	11	38.90	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	2	7.07	0	0.00
	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	1	4.10	0	0.00	0	0.00
	13	**11.40**	**47**	**41.20**	**1**	**0.88**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**10**	**8.77**	**3**	**2.63**	**3**	**2.63**	**0**	**0.00**

COVID-19 mRNA	Pfizer mRNA BNT162b2	EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EK4241	23	102.56	5	22.30	3	13.38	2	8.92	11	49.05	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00
		EK4245	24	98.46	2	8.21	2	8.21	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0140	8	74.59	3	27.97	3	27.97	2	18.65	3	27.97	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0203	23	81.34	7	24.76	5	17.68	3	10.61	11	38.90	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1406	21	86.15	7	28.72	6	24.62	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**108**	**94.67**	**28**	**24.55**	**21**	**18.41**	**13**	**11.40**	**47**	**41.20**	**1**	**0.88**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**248**	**144.63**	**61**	**35.57**	**32**	**18.66**	**18**	**10.50**	**94**	**54.82**	**2**	**1.17**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

Abbreviations:
GBS = Guillain Barre Syndrome
Notes:
[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.
[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i
[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
2	8.92	11	49.05	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	4	16.41	0	0.00	0	0.00	0	0.00
2	18.65	3	27.97	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	18.65	0	0.00	0	0.00	0	0.00
3	10.61	11	38.90	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	2	7.07	0	0.00
2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.10	1	4.10	0	0.00	0	0.00
13	**11.40**	**47**	**41.20**	**1**	**0.88**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**10**	**8.77**	**3**	**2.63**	**3**	**2.63**	**0**	**0.00**
18	**10.50**	**94**	**54.82**	**2**	**1.17**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**12**	**7.00**	**22**	**12.83**	**4**	**2.33**	**1**	**0.58**

. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
played, the doses distributed for that lot number were not available at the time of the report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ied in the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]
Subject: RE: Feb.11 COVID19 AEFI Summary
Date: Thursday, February 11, 2021 11:44:45 AM

Thanks Kyle!

From: Noftall, Kyle [BCCDC]
Sent: Thursday, February 11, 2021 10:17 AM
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Feb.11 COVID19 AEFI Summary

Hi Heather,

Today's COVID19 AEFI summary report attached. The total reports, serious, anaphylaxis and other allergic details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	248	144.63
Serious AEFI	61	35.57
Anaphylaxis	32	18.66
Anaphylaxis Brighton levels 1/2/3	18	10.50
Other allergic	94	54.82

Thank you,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Youngs, Kirsten R GCPE:EX
To: Amos, Heather [BCCDC]; Smith, Devon FLNR:EX
Subject: RE: AEFI numbers
Date: Thursday, February 11, 2021 7:20:32 PM

EXTERNAL SENDER. If you suspect this message is malicious, please forward to spam@phsa.ca and **do not** open attachments or click on links.

Thank you!

From: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Sent: February 11, 2021 5:12 PM
To: Youngs, Kirsten R GCPE:EX <Kirsten.Youngs@gov.bc.ca>; Smith, Devon FLNR:EX <Devon.Smith@gov.bc.ca>
Subject: AEFI numbers

[EXTERNAL] This email came from an external source. Only open attachments or links that you are expecting from a known sender.

Hi,
Here are updated AEFI numbers for tomorrow if needed:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	248	144.63
Anaphylaxis Brighton levels 1/2/3	18	10.50
Other allergic	94	54.82

Heather
Heather Amos
Communications Officer
BC Centre for Disease Control
Provincial Health Services Authority

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After hours media line: 778-867-7472

I respectfully acknowledges that I live and work on the traditional, ancestral and unceded territories of the Sḵwx̱wú7mesh (Squamish), Sel̓íl̓witulh (Tsleil-Waututh), and xʷməθkʷəy̓əm (Musqueam) Nations.

From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: COVID19 AEFI Feb18
Date: Thursday, February 18, 2021 10:27:48 AM
Attachments: COVID19_AEFI_Summary_Report_2021-02-18.html

Hi Heather,

Today's AEFI summary report is attached. Pertinent details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	278	152.58
Serious AEFI	61	33.48
Anaphylaxis	32	17.56
Anaphylaxis Brighton levels 1/2/3	18	9.88
Other allergic	110	60.37

Note: Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - February 18, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by February 15, 2021 there have been a total of 182,200 distributed doses. As of February 18, 2021, there have been 278 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 152.6 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 61 (21.9%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 389 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Feb 18, 2021 **(N=278)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-4	2021-5	2021-6	2021-7	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	62	52	25	2	**278**	**152.58**	**100.0**	6.50	**23.5**	100.0	**1.0**	32.30	**4.7**	100.0	**1.0**
Serious AEFI[g]	10	10	2	0	**61**	**33.48**	**21.9**	1.48	**22.6**	22.8	**1.0**	7.23	**4.6**	22.4	**1.0**
Events															
Anaphylaxis	2	5	1	0	**32**	**17.56**	**11.5**	0.47	**37.4**	7.3	**1.6**	2.70	**6.5**	8.3	**1.4**
Anaphylaxis Brighton levels 1/2/3[h]	0	3	0	0	**18**	**9.88**	**6.5**	0.19	**52.0**	2.8	**2.3**	NA	–	NA	–
Other allergic	27	17	8	1	**110**	**60.37**	**39.6**	2.09	**28.9**	32.1	**1.2**	5.64	**10.7**	17.5	**2.3**
Bell's Palsy	0	1	0	0	**2**	**1.10**	**0.7**	0.02	**55.0**	0.3	**2.3**	0.06	**18.3**	0.2	**3.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	**0**	**0.00**	**0.0**	0.27	–	4.1	–	1.53	–	4.7	–
Anaesthesia/ paraesthesia[1]	3	3	2	0	**13**	**7.14**	**4.7**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	1	0	0	0	**2**	**1.10**	**0.7**	0.02	**55.0**	0.3	**2.3**	0.00	–	0.0	–
Cellulitis	7	3	1	0	**22**	**12.07**	**7.9**	0.27	**44.7**	4.1	**1.9**	0.31	**38.9**	0.9	**8.8**
Adenopathy/ lymphadenitis	3	3	0	0	**12**	**6.59**	**4.3**	0.07	**94.1**	1.0	**4.3**	0.43	**15.3**	1.3	**3.3**
Recommendations															
No further immunizations	1	0	0	0	**8**	**4.39**	**2.9**	0.25	**17.6**	3.9	**0.7**	0.67	**6.6**	2.1	**1.4**
Outcomes															
Hospitalization	1	1	0	0	**4**	**2.20**	**1.4**	0.19	**11.6**	2.8	**0.5**	3.00	**0.7**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	0	0	0	**1**	**0.55**	**0.4**	0.02	**27.5**	0.3	**1.3**	0.18	**3.1**	0.6	**0.7**
Health Authority															
IHA	17	9	9	1	**74**	**229.64**	**26.6**	10.10	**22.7**	24.4	**1.1**	66.52	**3.5**	34.5	**0.8**

Health Authority															
IHA	17	9	9	1	**74**	**229.64**	**26.6**	10.10	**22.7**	24.4	**1.1**	66.52	**3.5**	34.5	**0.8**
FHA	12	12	6	0	**68**	**120.04**	**24.5**	4.34	**27.7**	22.0	**1.1**	20.32	**5.9**	19.4	**1.3**
VCHA	8	6	0	1	**44**	**110.69**	**15.8**	2.28	**48.5**	10.4	**1.5**	10.19	**10.9**	9.7	**1.6**
VIHA	22	23	5	0	**66**	**199.10**	**23.7**	9.55	**20.8**	25.9	**0.9**	38.38	**5.2**	20.7	**1.1**
NHA	3	2	5	0	**26**	**127.29**	**9.4**	26.36	**4.8**	17.4	**0.5**	115.42	**1.1**	15.7	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	53	39	24	2	**245**	**7.48**	**88.1**	1.39	**5.4**	46.1	**1.9**	10.62	**0.7**	58.6	**1.5**
65+	9	13	1	0	**33**	**3.35**	**11.9**	0.95	**3.5**	8.8	**1.4**	5.09	**0.7**	6.3	**1.9**
Gender															
Female	57	48	24	2	**260**	**10.02**	**93.5**	2.32	**4.3**	60.4	**1.5**	16.58	**0.6**	69.8	**1.3**
Male	5	4	1	0	**18**	**0.71**	**6.5**	1.56	**0.5**	39.6	**0.2**	7.26	**0.1**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	53	39	24	2	**245**	**7.48**	**88.1**	1.39	**5.4**	46.1	**1.9**	10.62	**0.7**	58.6	**1.5**
65+	9	13	1	0	**33**	**3.35**	**11.9**	0.95	**3.5**	8.8	**1.4**	5.09	**0.7**	6.3	**1.9**
Gender															
Female	57	48	24	2	**260**	**10.02**	**93.5**	2.32	**4.3**	60.4	**1.5**	16.58	**0.6**	69.8	**1.3**
Male	5	4	1	0	**18**	**0.71**	**6.5**	1.56	**0.5**	39.6	**0.2**	7.26	**0.1**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Feb 18, 2021 **(N=278)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	93	460.40	22	108.91	7	34.65	3	14.85	33	163.37	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	57	275.36	10	48.31	3	14.49	2	9.66	20	96.62	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		300042722	1	6.06	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Moderna mRNA-1273 total	**151**	**263.07**	**32**	**55.75**	**10**	**17.42**	**5**	**8.71**	**53**	**92.33**	**1**	**1.74**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
	Pfizer mRNA BNT162b2	EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	27	120.40	5	22.30	3	13.38	2	8.92	11	49.05	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	25	102.56	2	8.21	2	8.21	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	11	70.51	4	25.64	4	25.64	2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	25	88.42	7	24.76	5	17.68	3	10.61	13	45.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1404	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1406	30	123.08	7	28.72	6	24.62	2	8.21	16	65.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	

	Events																			Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	33	163.37	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.95	13	64.36	1	4.95	1	4.95
	2	9.66	20	96.62	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	1	4.83	6	28.99	0	0.00	0	0.00
	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	5	**8.71**	**53**	**92.33**	**1**	**1.74**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**2**	**3.48**	**19**	**33.10**	**1**	**1.74**	**1**	**1.74**
	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	11	49.05	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00
	2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	12.82	0	0.00	0	0.00	0	0.00
	3	10.61	13	45.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	2	7.07	0	0.00
	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	2	8.21	16	65.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	1	4.10	0	0.00	0	0.00

COVID-19 mRNA	Pfizer mRNA BNT162b2	EK4241	27	120.40	5	22.30	3	13.38	2	8.92	11	49.05	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00
		EK4245	25	102.56	2	8.21	2	8.21	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0140	11	70.51	4	25.64	4	25.64	2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0203	25	88.42	7	24.76	5	17.68	3	10.61	13	45.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1404	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1406	30	123.08	7	28.72	6	24.62	2	8.21	16	65.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**127**	**101.76**	**29**	**23.24**	**22**	**17.63**	**13**	**10.42**	**57**	**45.67**	**1**	**0.80**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**278**	**152.58**	**61**	**33.48**	**32**	**17.56**	**18**	**9.88**	**110**	**60.37**	**2**	**1.10**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2	8.92	11	49.05	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00
2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	12.82	0	0.00	0	0.00	0	0.00
3	10.61	13	45.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	2	7.07	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	8.21	16	65.64	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	1	4.10	0	0.00	0	0.00
13	**10.42**	**57**	**45.67**	**1**	**0.80**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**11**	**8.81**	**3**	**2.40**	**3**	**2.40**	**0**	**0.00**
18	**9.88**	**110**	**60.37**	**2**	**1.10**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**13**	**7.14**	**22**	**12.07**	**4**	**2.20**	**1**	**0.55**

. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
played, the doses distributed for that lot number were not available at the time of the report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ied in the anaphylaxis case definition.

References

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2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
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From: Amos, Heather [BCCDC]
To: Youngs, Kirsten [EXT]; Devon GCPE:EX Smith
Subject: AEFI report
Date: Friday, February 19, 2021 8:53:14 AM

Hi

Not sure if you need this but latest numbers;

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	278	152.58
Anaphylaxis Brighton levels 1/2/3	18	9.88
Other allergic	110	60.37

Heather

Sent from my iPhone

From: Youngs, Kirsten R GCPE:EX
To: Amos, Heather [BCCDC]; Smith, Devon GCPE:EX
Subject: RE: AEFI report
Date: Friday, February 19, 2021 9:01:58 AM

EXTERNAL SENDER. If you suspect this message is malicious, please forward to spam@phsa.ca and **do not** open attachments or click on links.

We love numbers.
Thank you!
PS s.22(1) [redacted]

From: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Sent: February 19, 2021 8:53 AM
To: Youngs, Kirsten R GCPE:EX <Kirsten.Youngs@gov.bc.ca>; Smith, Devon GCPE:EX <Devon.P.Smith@gov.bc.ca>
Subject: AEFI report

[EXTERNAL] This email came from an external source. Only open attachments or links that you are expecting from a known sender.

Hi

Not sure if you need this but latest numbers;

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	278	152.58
Anaphylaxis Brighton levels 1/2/3	18	9.88
Other allergic	110	60.37

Heather
Sent from my iPhone

From: McLean, Cara [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Noftall, Kyle [BCCDC]
Subject: COVID19 AEFI FEB22
Date: Monday, February 22, 2021 9:31:54 AM
Attachments: COVID19_AEFI_Summary_Report_2021-02-22.html

Hi Heather,

Kyle is off today so I am sending the report out to you today. Here are the details:

	Cumulative COVID19 Count
Total AEFI	292
Serious AEFI	62
Anaphylaxis	33
Anaphylaxis Brighton levels 1/2/3	19
Other allergic	116

Thanks, have a great day !

Cara McLean, MSc
Epidemiologist, Communicable Diseases & Immunization Service
BC Centre for Disease Control
Provincial Health Services Authority
cara.mclean@bccdc.ca
Tel (604) 707-2400 ext 272402
Fax 604-707-2515

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - February 22, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by February 22, 2021 there have been a total of 182,200 distributed doses. As of February 22, 2021, there have been 292 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 160.3 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 62 (21.2%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 406 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Feb 22, 2021 **(N=292)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-5	2021-6	2021-7	2021-8	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	55	26	10	0	**292**	**160.26**	**100.0**	6.50	**24.7**	100.0	**1.0**	32.30	**5.0**	100.0	**1.0**
Serious AEFI[g]	10	2	1	0	**62**	**34.03**	**21.2**	1.48	**23.0**	22.8	**0.9**	7.23	**4.7**	22.4	**0.9**
Events															
Anaphylaxis	5	1	1	0	**33**	**18.11**	**11.3**	0.47	**38.5**	7.3	**1.5**	2.70	**6.7**	8.3	**1.4**
Anaphylaxis Brighton levels 1/2/3[h]	3	0	1	0	**19**	**10.43**	**6.5**	0.19	**54.9**	2.8	**2.3**	NA	–	NA	–
Other allergic	18	9	5	0	**116**	**63.67**	**39.7**	2.09	**30.5**	32.1	**1.2**	5.64	**11.3**	17.5	**2.3**
Bell's Palsy	1	0	0	0	**2**	**1.10**	**0.7**	0.02	**55.0**	0.3	**2.3**	0.06	**18.3**	0.2	**3.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	0	0.00	0.0	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	0	0.00	0.0	0.27	–	4.1	–	1.53	–	4.7	–
Anaesthesia/ paraesthesia[1]	3	2	0	0	13	7.14	4.5	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	0	2	1.10	0.7	0.02	55.0	0.3	2.3	0.00	–	0.0	–
Cellulitis	3	1	0	0	22	12.07	7.5	0.27	44.7	4.1	1.8	0.31	38.9	0.9	8.3
Adenopathy/ lymphadenitis	3	0	0	0	12	6.59	4.1	0.07	94.1	1.0	4.1	0.43	15.3	1.3	3.2
Recommendations															
No further immunizations	2	0	0	0	10	5.49	3.4	0.25	22.0	3.9	0.9	0.67	8.2	2.1	1.6
Outcomes															
Hospitalization	1	0	0	0	4	2.20	1.4	0.19	11.6	2.8	0.5	3.00	0.7	9.3	0.2
Permanent disability	0	0	0	0	0	0.00	0.0	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	0	0	0	1	0.55	0.3	0.02	27.5	0.3	1.0	0.18	3.1	0.6	0.5
Health Authority															
IHA	10	9	4	0	79	245.15	27.1	10.10	24.3	24.4	1.1	66.52	3.7	34.5	0.8

Health Authority															
IHA	10	9	4	0	**79**	**245.15**	**27.1**	10.10	**24.3**	24.4	**1.1**	66.52	**3.7**	34.5	**0.8**
FHA	12	6	0	0	**68**	**120.04**	**23.3**	4.34	**27.7**	22.0	**1.1**	20.32	**5.9**	19.4	**1.2**
VCHA	6	0	1	0	**44**	**110.69**	**15.1**	2.28	**48.5**	10.4	**1.5**	10.19	**10.9**	9.7	**1.6**
VIHA	23	5	1	0	**67**	**202.11**	**22.9**	9.55	**21.2**	25.9	**0.9**	38.38	**5.3**	20.7	**1.1**
NHA	4	6	4	0	**34**	**166.46**	**11.6**	26.36	**6.3**	17.4	**0.7**	115.42	**1.4**	15.7	**0.7**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	40	25	10	0	**257**	**7.84**	**88.0**	1.39	**5.6**	46.1	**1.9**	10.62	**0.7**	58.6	**1.5**
65+	15	1	0	0	**35**	**3.55**	**12.0**	0.95	**3.7**	8.8	**1.4**	5.09	**0.7**	6.3	**1.9**
Gender															
Female	51	25	9	0	**273**	**10.52**	**93.5**	2.32	**4.5**	60.4	**1.5**	16.58	**0.6**	69.8	**1.3**
Male	4	1	1	0	**19**	**0.75**	**6.5**	1.56	**0.5**	39.6	**0.2**	7.26	**0.1**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	40	25	10	0	**257**	**7.84**	**88.0**	1.39	**5.6**	46.1	**1.9**	10.62	**0.7**	58.6	**1.5**
65+	15	1	0	0	**35**	**3.55**	**12.0**	0.95	**3.7**	8.8	**1.4**	5.09	**0.7**	6.3	**1.9**
Gender															
Female	51	25	9	0	**273**	**10.52**	**93.5**	2.32	**4.5**	60.4	**1.5**	16.58	**0.6**	69.8	**1.3**
Male	4	1	1	0	**19**	**0.75**	**6.5**	1.56	**0.5**	39.6	**0.2**	7.26	**0.1**	30.2	**0.2**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Feb 22, 2021 **(N=292)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	99	490.10	22	108.91	7	34.65	3	14.85	35	173.27	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	59	285.02	10	48.31	3	14.49	2	9.66	20	96.62	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		300042722	4	24.24	0	0.00	0	0.00	0	0.00	2	12.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Moderna mRNA-1273 total	**162**	**282.23**	**32**	**55.75**	**10**	**17.42**	**5**	**8.71**	**57**	**99.30**	**1**	**1.74**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
	Pfizer mRNA BNT162b2	EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	28	124.86	5	22.30	3	13.38	2	8.92	12	53.51	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	25	102.56	2	8.21	2	8.21	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	11	70.51	4	25.64	4	25.64	2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	25	88.42	7	24.76	5	17.68	3	10.61	13	45.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1404	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1406	31	127.18	7	28.72	6	24.62	2	8.21	17	69.74	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	

	Events																		Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	35	173.27	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.95	13	64.36	1	4.95	1	4.95
	2	9.66	20	96.62	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	1	4.83	6	28.99	0	0.00	0	0.00
	0	0.00	2	12.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	5	**8.71**	**57**	**99.30**	**1**	**1.74**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**2**	**3.48**	**19**	**33.10**	**1**	**1.74**	**1**	**1.74**
	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	12	53.51	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00
	2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	12.82	0	0.00	0	0.00	0	0.00
	3	10.61	13	45.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	2	7.07	0	0.00
	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	2	8.21	17	69.74	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	1	4.10	0	0.00	0	0.00

COVID-19 mRNA	Pfizer mRNA BNT162b2	EK4245	25	102.56	2	8.21	2	8.21	2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0140	11	70.51	4	25.64	4	25.64	2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0203	25	88.42	7	24.76	5	17.68	3	10.61	13	45.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1404	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1406	31	127.18	7	28.72	6	24.62	2	8.21	17	69.74	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6017	1	NA	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		Pfizer mRNA BNT162b2 total	**130**	**104.17**	**30**	**24.04**	**23**	**18.43**	**14**	**11.22**	**59**	**47.28**	**1**	**0.80**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**292**	**160.26**	**62**	**34.03**	**33**	**18.11**	**19**	**10.43**	**116**	**63.67**	**2**	**1.10**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2	8.21	10	41.03	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	0	0.00	0	0.00	0	0.00
2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	12.82	0	0.00	0	0.00	0	0.00
3	10.61	13	45.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.54	0	0.00	2	7.07	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	8.21	17	69.74	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	1	4.10	0	0.00	0	0.00
1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
14	**11.22**	**59**	**47.28**	**1**	**0.80**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**11**	**8.81**	**3**	**2.40**	**3**	**2.40**	**0**	**0.00**
19	**10.43**	**116**	**63.67**	**2**	**1.10**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**13**	**7.14**	**22**	**12.07**	**4**	**2.20**	**1**	**0.55**

. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
played, the doses distributed for that lot number were not available at the time of the report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ied in the anaphylaxis case definition.

References

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2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: Youngs, Kirsten [EXT]; Devon GCPE:EX Smith
Subject: RE: AEFI report
Date: Monday, February 22, 2021 1:25:35 PM

Hi,

Here is today's. Should we just do these once per week? The Thursday/Friday briefing may be better because we can provide the rate info.

Total AEFI	292
Anaphylaxis Brighton levels 1/2/3	19
Other allergic	116

Heather

From: Amos, Heather [BCCDC]
Sent: Friday, February 19, 2021 8:53 AM
To: Youngs, Kirsten [EXT]; Devon GCPE:EX Smith
Subject: AEFI report

Hi

Not sure if you need this but latest numbers;

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	278	152.58
Anaphylaxis Brighton levels 1/2/3	18	9.88
Other allergic	110	60.37

Heather
Sent from my iPhone

From: Amos, Heather [BCCDC]
To: McLean, Cara [BCCDC]
Cc: Noftall, Kyle [BCCDC]
Subject: RE: COVID19 AEFI FEB22
Date: Monday, February 22, 2021 1:25:44 PM

Thank you Cara!

From: McLean, Cara [BCCDC]
Sent: Monday, February 22, 2021 9:32 AM
To: Amos, Heather [BCCDC]
Cc: Noftall, Kyle [BCCDC]
Subject: COVID19 AEFI FEB22

Hi Heather,

Kyle is off today so I am sending the report out to you today. Here are the details:

	Cumulative COVID19 Count
Total AEFI	292
Serious AEFI	62
Anaphylaxis	33
Anaphylaxis Brighton levels 1/2/3	19
Other allergic	116

Thanks, have a great day !

Cara McLean, MSc
Epidemiologist, Communicable Diseases & Immunization Service
BC Centre for Disease Control
Provincial Health Services Authority
cara.mclean@bccdc.ca
Tel (604) 707-2400 ext 272402
Fax 604-707-2515

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: COVID19 AEFI Report Feb.25
Date: Thursday, February 25, 2021 10:35:43 AM
Attachments: COVID19_AEFI_Summary_Report_2021-02-25.html

Hi Heather,

Today's AEFI report is attached. Key details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	321	139.90
Serious AEFI	79	34.43
Anaphylaxis	44	19.18
Anaphylaxis Brighton levels 1/2/3	25	10.90
Other allergic	125	54.48

Thank you,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - February 25, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by February 22, 2021 there have been a total of 229,450 distributed doses. As of February 25, 2021, there have been 321 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 139.9 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 79 (24.6%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 445 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Feb 25, 2021 **(N=321)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-5	2021-6	2021-7	2021-8	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	55	28	21	16	**321**	**139.90**	**100.0**	6.50	**21.5**	100.0	**1.0**	32.30	**4.3**	100.0	**1.0**
Serious AEFI[g]	10	4	7	8	**79**	**34.43**	**24.6**	1.48	**23.3**	22.8	**1.1**	7.23	**4.8**	22.4	**1.1**
Events															
Anaphylaxis	5	3	5	5	**44**	**19.18**	**13.7**	0.47	**40.8**	7.3	**1.9**	2.70	**7.1**	8.3	**1.7**
Anaphylaxis Brighton levels 1/2/3[h]	3	1	4	2	**25**	**10.90**	**7.8**	0.19	**57.4**	2.8	**2.8**	NA	–	NA	–
Other allergic	18	9	10	4	**125**	**54.48**	**38.9**	2.09	**26.1**	32.1	**1.2**	5.64	**9.7**	17.5	**2.2**
Bell's Palsy	1	0	1	0	**3**	**1.31**	**0.9**	0.02	**65.5**	0.3	**3.0**	0.06	**21.8**	0.2	**4.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	**0**	**0.00**	**0.0**	0.27	–	4.1	–	1.53	–	4.7	–
Anaesthesia/ paraesthesia[1]	3	2	2	3	**18**	**7.84**	**5.6**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	0	**2**	**0.87**	**0.6**	0.02	**43.5**	0.3	**2.0**	0.00	–	0.0	–
Cellulitis	3	1	0	0	**23**	**10.02**	**7.2**	0.27	**37.1**	4.1	**1.8**	0.31	**32.3**	0.9	**8.0**
Adenopathy/ lymphadenitis	3	0	0	1	**13**	**5.67**	**4.0**	0.07	**81.0**	1.0	**4.0**	0.43	**13.2**	1.3	**3.1**
Recommendations															
No further immunizations	2	1	3	2	**16**	**6.97**	**5.0**	0.25	**27.9**	3.9	**1.3**	0.67	**10.4**	2.1	**2.4**
Outcomes															
Hospitalization	1	0	2	1	**7**	**3.05**	**2.2**	0.19	**16.1**	2.8	**0.8**	3.00	**1.0**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	0	1	1	**3**	**1.31**	**0.9**	0.02	**65.5**	0.3	**3.0**	0.18	**7.3**	0.6	**1.5**
Health Authority															
IHA	10	9	5	11	**91**	**239.00**	**28.3**	10.10	**23.7**	24.4	**1.2**	66.52	**3.6**	34.5	**0.8**

Health Authority															
IHA	10	9	5	11	**91**	**239.00**	**28.3**	10.10	**23.7**	24.4	**1.2**	66.52	**3.6**	34.5	**0.8**
FHA	12	6	5	2	**75**	**94.82**	**23.4**	4.34	**21.8**	22.0	**1.1**	20.32	**4.7**	19.4	**1.2**
VCHA	6	1	6	1	**51**	**100.20**	**15.9**	2.28	**43.9**	10.4	**1.5**	10.19	**9.8**	9.7	**1.6**
VIHA	23	5	1	2	**69**	**176.92**	**21.5**	9.55	**18.5**	25.9	**0.8**	38.38	**4.6**	20.7	**1.0**
NHA	4	7	4	0	**35**	**156.42**	**10.9**	26.36	**5.9**	17.4	**0.6**	115.42	**1.4**	15.7	**0.7**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	40	26	19	12	**279**	**8.51**	**86.9**	1.39	**6.1**	46.1	**1.9**	10.62	**0.8**	58.6	**1.5**
65+	15	2	2	4	**42**	**4.26**	**13.1**	0.95	**4.5**	8.8	**1.5**	5.09	**0.8**	6.3	**2.1**
Gender															
Female	51	27	18	12	**296**	**11.40**	**92.2**	2.32	**4.9**	60.4	**1.5**	16.58	**0.7**	69.8	**1.3**
Male	4	1	3	4	**25**	**0.98**	**7.8**	1.56	**0.6**	39.6	**0.2**	7.26	**0.1**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	40	26	19	12	**279**	**8.51**	**86.9**	1.39	**6.1**	46.1	**1.9**	10.62	**0.8**	58.6	**1.5**
65+	15	2	2	4	**42**	**4.26**	**13.1**	0.95	**4.5**	8.8	**1.5**	5.09	**0.8**	6.3	**2.1**
Gender															
Female	51	27	18	12	**296**	**11.40**	**92.2**	2.32	**4.9**	60.4	**1.5**	16.58	**0.7**	69.8	**1.3**
Male	4	1	3	4	**25**	**0.98**	**7.8**	1.56	**0.6**	39.6	**0.2**	7.26	**0.1**	30.2	**0.3**

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Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Feb 25, 2021 **(N=321)**

Vaccine information			Reports				Events														
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b],[c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b],[d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	100	495.05	22	108.91	7	34.65	3	14.85	35	173.27	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	63	304.35	15	72.46	4	19.32	3	14.49	20	96.62	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		300042722	7	37.04	0	0.00	0	0.00	0	0.00	4	21.16	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Moderna mRNA-1273 total	**170**	**284.28**	**37**	**61.87**	**11**	**18.39**	**6**	**10.03**	**59**	**98.66**	**1**	**1.67**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
	Pfizer mRNA BNT162b2	EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	28	124.86	5	22.30	3	13.38	2	8.92	12	53.51	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	28	114.87	3	12.31	2	8.21	2	8.21	12	49.23	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	13	83.33	5	32.05	5	32.05	2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	29	102.56	9	31.83	6	21.22	3	10.61	15	53.05	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1404	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL1406	31	127.18	7	28.72	6	24.62	2	8.21	17	69.74	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	

	Events																		Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	35	173.27	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.95	13	64.36	1	4.95	1	4.95
	3	14.49	20	96.62	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	3	14.49	7	33.82	1	4.83	2	9.66
	0	0.00	4	21.16	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	6	**10.03**	**59**	**98.66**	**1**	**1.67**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**4**	**6.69**	**20**	**33.44**	**2**	**3.34**	**3**	**5.02**
	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	12	53.51	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
	2	8.21	12	49.23	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	4	16.41	0	0.00	0	0.00	0	0.00
	2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	12.82	0	0.00	0	0.00	0	0.00
	3	10.61	15	53.05	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	2	7.07	0	0.00	2	7.07	0	0.00
	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	2	8.21	17	69.74	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	1	4.10	0	0.00	0	0.00

COVID-19 mRNA	Pfizer mRNA BNT162b2	EK4245	28	114.87	3	12.31	2	8.21	2	8.21	12	49.23	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0140	13	83.33	5	32.05	5	32.05	2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0203	29	102.56	9	31.83	6	21.22	3	10.61	15	53.05	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00
		EL1404	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1406	31	127.18	7	28.72	6	24.62	2	8.21	17	69.74	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6017	13	28.99	9	20.07	9	20.07	6	13.38	3	6.69	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**151**	**89.01**	**42**	**24.76**	**33**	**19.45**	**19**	**11.20**	**66**	**38.90**	**2**	**1.18**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**321**	**139.90**	**79**	**34.43**	**44**	**19.18**	**25**	**10.90**	**125**	**54.48**	**3**	**1.31**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2	8.21	12	49.23	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	4	16.41	0	0.00	0	0.00	0	0.00
2	12.82	5	32.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	12.82	0	0.00	0	0.00	0	0.00
3	10.61	15	53.05	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	2	7.07	0	0.00	2	7.07	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	8.21	17	69.74	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	1	4.10	0	0.00	0	0.00
6	13.38	3	6.69	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	2.23	0	0.00	2	4.46	0	0.00
19	**11.20**	**66**	**38.90**	**2**	**1.18**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**14**	**8.25**	**3**	**1.77**	**5**	**2.95**	**0**	**0.00**
25	**10.90**	**125**	**54.48**	**3**	**1.31**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**18**	**7.84**	**23**	**10.02**	**7**	**3.05**	**3**	**1.31**

The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
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litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ed in the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: NLK Strategies, Nicola
Subject: RE: AEFI"s
Date: Tuesday, March 02, 2021 12:38:17 PM

Hi,

I don't have any for today but as of last Thursday: We use anaphylaxis Brighton levels to report on an anaphylaxis (i.e. the highlighted numbers).

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	321	139.90
Serious AEFI	79	34.43
Anaphylaxis	44	19.18
Anaphylaxis Brighton levels 1/2/3	25	10.90
Other allergic	125	54.48

Let me know if you need anything else. I can ask for them to pull new numbers but I can't guarantee I will hear back in time.

Heather

From: Nicola Lambrechts [mailto:nicola@nlkstrategies.ca]
Sent: Tuesday, March 02, 2021 12:35 PM
To: Amos, Heather [BCCDC]
Subject: AEFI's
EXTERNAL SENDER. If you suspect this message is malicious, please forward to spam@phsa.ca and **do not** open attachments or click on links.

Hi Heather - Hope you are well. Could you please send me the latest AEFI information for Dr. H's remarks? I have seen some numbers, but would like to verify.
Thank you,
Nicola

Nicola Lambrechts
NLK Strategies
604.970.9113
nicola@nlkstrategies.ca
www.nlkstrategies.ca

From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: COVID AEFI Report March 4
Date: Thursday, March 04, 2021 10:01:54 AM
Attachments: COVID19_AEFI_Summary_Report_2021-03-04.html

Hi Heather,
Attached is today's AEFI report. Key details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	407	128.59
Serious AEFI	94	29.70
Anaphylaxis	56	17.69
Anaphylaxis Brighton levels 1/2/3	32	10.11
Other allergic	172	54.34

Thanks,
Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
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I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - March 04, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 01, 2021 there have been a total of 316,500 distributed doses. As of March 04, 2021, there have been 407 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 128.6 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 94 (23.1%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 558 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 04, 2021 **(N=407)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-6	2021-7	2021-8	2021-9	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	34	28	53	30	**407**	**128.59**	**100.0**	6.50	**19.8**	100.0	**1.0**	32.30	**4.0**	100.0	**1.0**
Serious AEFI[g]	5	7	14	6	**94**	**29.70**	**23.1**	1.48	**20.1**	22.8	**1.0**	7.23	**4.1**	22.4	**1.0**
Events															
Anaphylaxis	4	5	11	5	**56**	**17.69**	**13.8**	0.47	**37.6**	7.3	**1.9**	2.70	**6.6**	8.3	**1.7**
Anaphylaxis Brighton levels 1/2/3[h]	1	4	7	1	**32**	**10.11**	**7.9**	0.19	**53.2**	2.8	**2.8**	NA	–	NA	–
Other allergic	12	17	24	14	**172**	**54.34**	**42.3**	2.09	**26.0**	32.1	**1.3**	5.64	**9.6**	17.5	**2.4**
Bell's Palsy	0	1	0	0	**3**	**0.95**	**0.7**	0.02	**47.5**	0.3	**2.3**	0.06	**15.8**	0.2	**3.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	**0**	**0.00**	**0.0**	0.27	–	4.1	–	1.53	–	4.7	–
Anaesthesia/ paraesthesia[1]	3	3	7	3	**28**	**8.85**	**6.9**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	0	**2**	**0.63**	**0.5**	0.02	**31.5**	0.3	**1.7**	0.00	–	0.0	–
Cellulitis	1	0	0	1	**24**	**7.58**	**5.9**	0.27	**28.1**	4.1	**1.4**	0.31	**24.5**	0.9	**6.6**
Adenopathy/ lymphadenitis	0	0	1	3	**16**	**5.06**	**3.9**	0.07	**72.3**	1.0	**3.9**	0.43	**11.8**	1.3	**3.0**
Recommendations															
No further immunizations	1	4	7	0	**23**	**7.27**	**5.7**	0.25	**29.1**	3.9	**1.5**	0.67	**10.9**	2.1	**2.7**
Outcomes															
Hospitalization	0	2	1	0	**7**	**2.21**	**1.7**	0.19	**11.6**	2.8	**0.6**	3.00	**0.7**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	1	0	0	**3**	**0.95**	**0.7**	0.02	**47.5**	0.3	**2.3**	0.18	**5.3**	0.6	**1.2**
Health Authority															
IHA	9	5	18	11	**110**	**197.82**	**27.0**	10.10	**19.6**	24.4	**1.1**	66.52	**3.0**	34.5	**0.8**

Health Authority															
IHA	9	5	18	11	**110**	**197.82**	**27.0**	10.10	**19.6**	24.4	**1.1**	66.52	**3.0**	34.5	**0.8**
FHA	7	9	16	3	**96**	**91.31**	**23.6**	4.34	**21.0**	22.0	**1.1**	20.32	**4.5**	19.4	**1.2**
VCHA	6	9	9	11	**82**	**123.61**	**20.1**	2.28	**54.2**	10.4	**1.9**	10.19	**12.1**	9.7	**2.1**
VIHA	5	1	8	5	**80**	**131.80**	**19.7**	9.55	**13.8**	25.9	**0.8**	38.38	**3.4**	20.7	**1.0**
NHA	7	4	2	0	**39**	**135.82**	**9.6**	26.36	**5.2**	17.4	**0.6**	115.42	**1.2**	15.7	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	30	25	45	28	**353**	**10.77**	**86.7**	1.39	**7.7**	46.1	**1.9**	10.62	**1.0**	58.6	**1.5**
65+	4	3	8	2	**54**	**5.48**	**13.3**	0.95	**5.8**	8.8	**1.5**	5.09	**1.1**	6.3	**2.1**
Gender															
Female	32	23	43	28	**370**	**14.25**	**90.9**	2.32	**6.1**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	2	5	10	2	**37**	**1.45**	**9.1**	1.56	**0.9**	39.6	**0.2**	7.26	**0.2**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	30	25	45	28	**353**	**10.77**	**86.7**	1.39	**7.7**	46.1	**1.9**	10.62	**1.0**	58.6	**1.5**
65+	4	3	8	2	**54**	**5.48**	**13.3**	0.95	**5.8**	8.8	**1.5**	5.09	**1.1**	6.3	**2.1**
Gender															
Female	32	23	43	28	**370**	**14.25**	**90.9**	2.32	**6.1**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	2	5	10	2	**37**	**1.45**	**9.1**	1.56	**0.9**	39.6	**0.2**	7.26	**0.2**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 04, 2021 **(N=407)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	109	539.60	22	108.91	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	65	314.01	16	77.29	4	19.32	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		300042722	13	60.47	1	4.65	1	4.65	1	4.65	8	37.21	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		3000489	4	19.90	1	4.98	1	4.98	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	
		Moderna mRNA-1273 total	**192**	**232.73**	**41**	**49.70**	**14**	**16.97**	**7**	**8.48**	**69**	**83.64**	**1**	**1.21**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
		EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	32	142.70	5	22.30	3	13.38	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	30	123.08	3	12.31	2	8.21	2	8.21	13	53.33	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	19	121.79	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	44	155.61	8	28.29	5	17.68	4	14.15	27	95.49	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	

	Events																		Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b],[d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	9.90	13	64.36	1	4.95	1	4.95
	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	3	14.49	8	38.65	1	4.83	2	9.66
	1	4.65	8	37.21	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00
	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
	7	**8.48**	**69**	**83.64**	**1**	**1.21**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**6**	**7.27**	**21**	**25.45**	**2**	**2.42**	**3**	**3.64**
	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
	2	8.21	13	53.33	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	20.51	0	0.00	0	0.00	0	0.00
	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
	4	14.15	27	95.49	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00

COVID-19 mRNA		EL0140	19	121.79	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0203	44	155.61	8	28.29	5	17.68	4	14.15	27	95.49	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00
	Pfizer mRNA BNT162b2	EL1406	33	135.38	7	28.72	6	24.62	2	8.21	18	73.85	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6017	35	78.04	16	35.67	15	33.44	7	15.61	13	28.99	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6775	15	23.31	4	6.22	4	6.22	4	6.22	9	13.99	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1404	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**217**	**92.74**	**53**	**22.65**	**42**	**17.95**	**25**	**10.68**	**104**	**44.44**	**2**	**0.85**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**409**	**129.23**	**94**	**29.70**	**56**	**17.69**	**32**	**10.11**	**173**	**54.66**	**3**	**0.95**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
4	14.15	27	95.49	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00
2	8.21	18	73.85	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	1	4.10	0	0.00	0	0.00
7	15.61	13	28.99	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	4	8.92	0	0.00	2	4.46	0	0.00
4	6.22	9	13.99	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
25	**10.68**	**104**	**44.44**	**2**	**0.85**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**22**	**9.40**	**3**	**1.28**	**5**	**2.14**	**0**	**0.00**
32	**10.11**	**173**	**54.66**	**3**	**0.95**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**28**	**8.85**	**24**	**7.58**	**7**	**2.21**	**3**	**0.95**

The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
played, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ied in the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: Youngs, Kirsten [EXT]; Marielle.Tounsi@gov.bc.ca
Subject: Fwd: COVID AEFI Report March 4
Date: Thursday, March 04, 2021 10:11:49 AM
Attachments: COVID19_AEFI_Summary_Report_2021-03-04.html

We use the yellow highlighted for anaphylaxis reports.

Sent from my iPhone

Begin forwarded message:

From: "Noftall, Kyle [BCCDC]" <Kyle.Noftall@bccdc.ca>
Date: March 4, 2021 at 10:01:54 AM PST
To: "Amos, Heather [BCCDC]" <heather.amos@bccdc.ca>
Cc: "Naus, Monika [BCCDC]" <Monika.Naus@bccdc.ca>
Subject: COVID AEFI Report March 4

Hi Heather,
Attached is today's AEFI report. Key details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	407	128.59
Serious AEFI	94	29.70
Anaphylaxis	56	17.69
Anaphylaxis Brighton levels 1/2/3	32	10.11
Other allergic	172	54.34

Thanks,
Kyle

Kyle Noftall, MPH
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I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - March 04, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 01, 2021 there have been a total of 316,500 distributed doses. As of March 04, 2021, there have been 407 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 128.6 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 94 (23.1%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 558 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 04, 2021 **(N=407)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-6	2021-7	2021-8	2021-9	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	34	28	53	30	**407**	**128.59**	**100.0**	6.50	**19.8**	100.0	**1.0**	32.30	**4.0**	100.0	**1.0**
Serious AEFI[g]	5	7	14	6	**94**	**29.70**	**23.1**	1.48	**20.1**	22.8	**1.0**	7.23	**4.1**	22.4	**1.0**
Events															
Anaphylaxis	4	5	11	5	**56**	**17.69**	**13.8**	0.47	**37.6**	7.3	**1.9**	2.70	**6.6**	8.3	**1.7**
Anaphylaxis Brighton levels 1/2/3[h]	1	4	7	1	**32**	**10.11**	**7.9**	0.19	**53.2**	2.8	**2.8**	NA	–	NA	–
Other allergic	12	17	24	14	**172**	**54.34**	**42.3**	2.09	**26.0**	32.1	**1.3**	5.64	**9.6**	17.5	**2.4**
Bell's Palsy	0	1	0	0	**3**	**0.95**	**0.7**	0.02	**47.5**	0.3	**2.3**	0.06	**15.8**	0.2	**3.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	0	**0**	**0.00**	**0.0**	0.27	–	4.1	–	1.53	–	4.7	–
Anaesthesia/ paraesthesia[1]	3	3	7	3	**28**	**8.85**	**6.9**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	0	**2**	**0.63**	**0.5**	0.02	**31.5**	0.3	**1.7**	0.00	–	0.0	–
Cellulitis	1	0	0	1	**24**	**7.58**	**5.9**	0.27	**28.1**	4.1	**1.4**	0.31	**24.5**	0.9	**6.6**
Adenopathy/ lymphadenitis	0	0	1	3	**16**	**5.06**	**3.9**	0.07	**72.3**	1.0	**3.9**	0.43	**11.8**	1.3	**3.0**
Recommendations															
No further immunizations	1	4	7	0	**23**	**7.27**	**5.7**	0.25	**29.1**	3.9	**1.5**	0.67	**10.9**	2.1	**2.7**
Outcomes															
Hospitalization	0	2	1	0	**7**	**2.21**	**1.7**	0.19	**11.6**	2.8	**0.6**	3.00	**0.7**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	1	0	0	**3**	**0.95**	**0.7**	0.02	**47.5**	0.3	**2.3**	0.18	**5.3**	0.6	**1.2**
Health Authority															
IHA	9	5	18	11	**110**	**197.82**	**27.0**	10.10	**19.6**	24.4	**1.1**	66.52	**3.0**	34.5	**0.8**

Health Authority															
IHA	9	5	18	11	**110**	**197.82**	**27.0**	10.10	**19.6**	24.4	**1.1**	66.52	**3.0**	34.5	**0.8**
FHA	7	9	16	3	**96**	**91.31**	**23.6**	4.34	**21.0**	22.0	**1.1**	20.32	**4.5**	19.4	**1.2**
VCHA	6	9	9	11	**82**	**123.61**	**20.1**	2.28	**54.2**	10.4	**1.9**	10.19	**12.1**	9.7	**2.1**
VIHA	5	1	8	5	**80**	**131.80**	**19.7**	9.55	**13.8**	25.9	**0.8**	38.38	**3.4**	20.7	**1.0**
NHA	7	4	2	0	**39**	**135.82**	**9.6**	26.36	**5.2**	17.4	**0.6**	115.42	**1.2**	15.7	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	30	25	45	28	**353**	**10.77**	**86.7**	1.39	**7.7**	46.1	**1.9**	10.62	**1.0**	58.6	**1.5**
65+	4	3	8	2	**54**	**5.48**	**13.3**	0.95	**5.8**	8.8	**1.5**	5.09	**1.1**	6.3	**2.1**
Gender															
Female	32	23	43	28	**370**	**14.25**	**90.9**	2.32	**6.1**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	2	5	10	2	**37**	**1.45**	**9.1**	1.56	**0.9**	39.6	**0.2**	7.26	**0.2**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	30	25	45	28	**353**	**10.77**	**86.7**	1.39	**7.7**	46.1	**1.9**	10.62	**1.0**	58.6	**1.5**
65+	4	3	8	2	**54**	**5.48**	**13.3**	0.95	**5.8**	8.8	**1.5**	5.09	**1.1**	6.3	**2.1**
Gender															
Female	32	23	43	28	**370**	**14.25**	**90.9**	2.32	**6.1**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	2	5	10	2	**37**	**1.45**	**9.1**	1.56	**0.9**	39.6	**0.2**	7.26	**0.2**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 04, 2021 **(N=407)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	109	539.60	22	108.91	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	65	314.01	16	77.29	4	19.32	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		300042722	13	60.47	1	4.65	1	4.65	1	4.65	8	37.21	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		3000489	4	19.90	1	4.98	1	4.98	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	
		Moderna mRNA-1273 total	**192**	**232.73**	**41**	**49.70**	**14**	**16.97**	**7**	**8.48**	**69**	**83.64**	**1**	**1.21**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
		EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	32	142.70	5	22.30	3	13.38	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	30	123.08	3	12.31	2	8.21	2	8.21	13	53.33	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	19	121.79	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	44	155.61	8	28.29	5	17.68	4	14.15	27	95.49	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	

	Events																		Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b],[d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	9.90	13	64.36	1	4.95	1	4.95
	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	3	14.49	8	38.65	1	4.83	2	9.66
	1	4.65	8	37.21	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00
	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
	7	**8.48**	**69**	**83.64**	**1**	**1.21**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**6**	**7.27**	**21**	**25.45**	**2**	**2.42**	**3**	**3.64**
	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
	2	8.21	13	53.33	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	20.51	0	0.00	0	0.00	0	0.00
	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
	4	14.15	27	95.49	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00

COVID-19 mRNA		EL0140	19	121.79	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0203	44	155.61	8	28.29	5	17.68	4	14.15	27	95.49	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00
	Pfizer mRNA BNT162b2	EL1406	33	135.38	7	28.72	6	24.62	2	8.21	18	73.85	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6017	35	78.04	16	35.67	15	33.44	7	15.61	13	28.99	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6775	15	23.31	4	6.22	4	6.22	4	6.22	9	13.99	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1404	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**217**	**92.74**	**53**	**22.65**	**42**	**17.95**	**25**	**10.68**	**104**	**44.44**	**2**	**0.85**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**409**	**129.23**	**94**	**29.70**	**56**	**17.69**	**32**	**10.11**	**173**	**54.66**	**3**	**0.95**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
4	14.15	27	95.49	1	3.54	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00
2	8.21	18	73.85	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	12.31	1	4.10	0	0.00	0	0.00
7	15.61	13	28.99	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	4	8.92	0	0.00	2	4.46	0	0.00
4	6.22	9	13.99	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
25	**10.68**	**104**	**44.44**	**2**	**0.85**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**22**	**9.40**	**3**	**1.28**	**5**	**2.14**	**0**	**0.00**
32	**10.11**	**173**	**54.66**	**3**	**0.95**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**28**	**8.85**	**24**	**7.58**	**7**	**2.21**	**3**	**0.95**

The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
played, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ied in the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Youngs, Kirsten R GCPE:EX
To: Amos, Heather [BCCDC]; Tounsi, Marielle GCPE:EX
Subject: RE: COVID AEFI Report March 4
Date: Thursday, March 04, 2021 10:20:50 AM

EXTERNAL SENDER. If you suspect this message is malicious, please forward to spam@phsa.ca and **do not** open attachments or click on links.

Thank you!

From: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Sent: March 4, 2021 10:12 AM
To: Youngs, Kirsten R GCPE:EX <Kirsten.Youngs@gov.bc.ca>; Tounsi, Marielle GCPE:EX <Marielle.Tounsi@gov.bc.ca>
Subject: Fwd: COVID AEFI Report March 4

[EXTERNAL] This email came from an external source. Only open attachments or links that you are expecting from a known sender.

We use the yellow highlighted for anaphylaxis reports.

Sent from my iPhone

Begin forwarded message:

From: "Noftall, Kyle [BCCDC]" <Kyle.Noftall@bccdc.ca>
Date: March 4, 2021 at 10:01:54 AM PST
To: "Amos, Heather [BCCDC]" <heather.amos@bccdc.ca>
Cc: "Naus, Monika [BCCDC]" <Monika.Naus@bccdc.ca>
Subject: COVID AEFI Report March 4

Hi Heather,
Attached is today's AEFI report. Key details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	407	128.59
Serious AEFI	94	29.70
Anaphylaxis	56	17.69
Anaphylaxis Brighton levels 1/2/3	32	10.11
Other allergic	172	54.34

Thanks,
Kyle

Kyle Noftall, MPH
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I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: March 11 COVID19 AEFI Report
Date: Thursday, March 11, 2021 10:48:07 AM
Attachments: COVID19_AEFI_Summary_Report_2021-03-11.html

Morning Heather,
Today's AEFI report is attached. Key details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	450	118.94
Serious AEFI	115	30.40
Anaphylaxis	71	18.77
Anaphylaxis Brighton levels 1/2/3	41	10.84
Other allergic	185	48.90

Thanks,
Kyle

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - March 11, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 08, 2021 there have been a total of 378,340 distributed doses. As of March 11, 2021, there have been 450 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 118.9 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 115 (25.6%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 615 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 11, 2021 **(N=450)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-07	2021-08	2021-09	2021-10	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	30	54	57	12	**450**	**118.94**	**100.0**	6.50	**18.3**	100.0	**1.0**	32.30	**3.7**	100.0	**1.0**
Serious AEFI[g]	8	15	21	4	**115**	**30.40**	**25.6**	1.48	**20.5**	22.8	**1.1**	7.23	**4.2**	22.4	**1.1**
Events															
Anaphylaxis	6	12	15	2	**71**	**18.77**	**15.8**	0.47	**39.9**	7.3	**2.2**	2.70	**7.0**	8.3	**1.9**
Anaphylaxis Brighton levels 1/2/3[h]	5	8	6	2	**41**	**10.84**	**9.1**	0.19	**57.1**	2.8	**3.2**	NA	–	NA	–
Other allergic	18	24	20	6	**185**	**48.90**	**41.1**	2.09	**23.4**	32.1	**1.3**	5.64	**8.7**	17.5	**2.3**
Bell's Palsy	1	0	1	0	**4**	**1.06**	**0.9**	0.02	**53.0**	0.3	**3.0**	0.06	**17.7**	0.2	**4.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	1	**1**	**0.26**	**0.2**	0.27	**1.0**	4.1	**0.0**	1.53	**0.2**	4.7	**0.0**
Anaesthesia/ paraesthesia[1]	3	7	4	1	**31**	**8.19**	**6.9**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	0	**2**	**0.53**	**0.4**	0.02	**26.5**	0.3	**1.3**	0.00	–	0.0	–
Cellulitis	0	0	1	0	**24**	**6.34**	**5.3**	0.27	**23.5**	4.1	**1.3**	0.31	**20.5**	0.9	**5.9**
Adenopathy/ lymphadenitis	0	1	3	1	**17**	**4.49**	**3.8**	0.07	**64.1**	1.0	**3.8**	0.43	**10.4**	1.3	**2.9**
Recommendations															
No further immunizations	5	9	2	0	**29**	**7.67**	**6.4**	0.25	**30.7**	3.9	**1.6**	0.67	**11.4**	2.1	**3.0**
Outcomes															
Hospitalization	2	1	2	1	**10**	**2.64**	**2.2**	0.19	**13.9**	2.8	**0.8**	3.00	**0.9**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	1	0	0	1	**3**	**0.79**	**0.7**	0.02	**39.5**	0.3	**2.3**	0.18	**4.4**	0.6	**1.2**
Health Authority															
IHA	6	17	18	7	**122**	**181.26**	**27.1**	10.10	**17.9**	24.4	**1.1**	66.52	**2.7**	34.5	**0.8**

Health Authority															
IHA	6	17	18	7	**122**	**181.26**	**27.1**	10.10	**17.9**	24.4	**1.1**	66.52	**2.7**	34.5	**0.8**
FHA	9	18	12	1	**110**	**87.98**	**24.4**	4.34	**20.3**	22.0	**1.1**	20.32	**4.3**	19.4	**1.3**
VCHA	9	9	11	0	**82**	**100.76**	**18.2**	2.28	**44.2**	10.4	**1.7**	10.19	**9.9**	9.7	**1.9**
VIHA	1	8	14	3	**92**	**127.07**	**20.4**	9.55	**13.3**	25.9	**0.8**	38.38	**3.3**	20.7	**1.0**
NHA	5	2	2	1	**44**	**136.54**	**9.8**	26.36	**5.2**	17.4	**0.6**	115.42	**1.2**	15.7	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	27	46	50	11	**390**	**11.90**	**86.7**	1.39	**8.6**	46.1	**1.9**	10.62	**1.1**	58.6	**1.5**
65+	3	8	7	1	**60**	**6.09**	**13.3**	0.95	**6.4**	8.8	**1.5**	5.09	**1.2**	6.3	**2.1**
Gender															
Female	25	44	48	9	**403**	**15.53**	**89.6**	2.32	**6.7**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	5	10	9	3	**47**	**1.85**	**10.4**	1.56	**1.2**	39.6	**0.3**	7.26	**0.3**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	27	46	50	11	**390**	**11.90**	**86.7**	1.39	**8.6**	46.1	**1.9**	10.62	**1.1**	58.6	**1.5**
65+	3	8	7	1	**60**	**6.09**	**13.3**	0.95	**6.4**	8.8	**1.5**	5.09	**1.2**	6.3	**2.1**
Gender															
Female	25	44	48	9	**403**	**15.53**	**89.6**	2.32	**6.7**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	5	10	9	3	**47**	**1.85**	**10.4**	1.56	**1.2**	39.6	**0.3**	7.26	**0.3**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 11, 2021 **(N=450)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	110	544.55	22	108.91	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	67	323.67	16	77.29	5	24.15	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		300042722	16	71.11	3	13.33	2	8.89	2	8.89	9	40.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		3000489	7	34.83	1	4.98	1	4.98	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	
		Moderna mRNA-1273 total	**201**	**240.72**	**43**	**51.50**	**16**	**19.16**	**8**	**9.58**	**70**	**83.83**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
		EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	32	142.70	5	22.30	3	13.38	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	31	127.18	3	12.31	2	8.21	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	19	121.79	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	45	159.15	10	35.37	6	21.22	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	

	Events																		Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	9.90	13	64.36	1	4.95	1	4.95
	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	3	14.49	8	38.65	1	4.83	1	4.83
	2	8.89	9	40.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.44	0	0.00
	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
	8	**9.58**	**70**	**83.83**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**5**	**5.99**	**21**	**25.15**	**3**	**3.59**	**2**	**2.40**
	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	20.51	0	0.00	0	0.00	0	0.00
	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00

19 mRNA		EL0203	45	159.15	10	35.37	6	21.22	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00
	Pfizer mRNA BNT162b2	EL1404	1	17.09	1	17.09	1	17.09	1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1406	37	151.79	7	28.72	6	24.62	2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6017	40	89.19	19	42.36	18	40.13	10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6775	29	45.07	12	18.65	8	12.43	5	7.77	15	23.31	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55
		ER1742	6	9.86	5	8.22	4	6.57	3	4.93	2	3.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**249**	**84.45**	**72**	**24.42**	**55**	**18.65**	**33**	**11.19**	**115**	**39.00**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**450**	**118.94**	**115**	**30.40**	**71**	**18.77**	**41**	**10.84**	**185**	**48.90**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00
1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	24.62	1	4.10	0	0.00	0	0.00
10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	11.15	0	0.00	2	4.46	0	0.00
5	7.77	15	23.31	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55	0	0.00	0	0.00	2	3.11	0	0.00
3	4.93	2	3.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	1.64
33	**11.19**	**115**	**39.00**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**	**26**	**8.82**	**3**	**1.02**	**7**	**2.37**	**1**	**0.34**
41	**10.84**	**185**	**48.90**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**	**31**	**8.19**	**24**	**6.34**	**10**	**2.64**	**3**	**0.79**

The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
played, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ied in the anaphylaxis case definition.

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3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]
Subject: RE: March 11 COVID19 AEFI Report
Date: Thursday, March 11, 2021 10:56:30 AM

Thanks!

From: Noftall, Kyle [BCCDC]
Sent: Thursday, March 11, 2021 10:48 AM
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: March 11 COVID19 AEFI Report

Morning Heather,

Today's AEFI report is attached. Key details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	450	118.94
Serious AEFI	115	30.40
Anaphylaxis	71	18.77
Anaphylaxis Brighton levels 1/2/3	41	10.84
Other allergic	185	48.90

Thanks,
Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Amos, Heather [BCCDC]
To: Youngs, Kirsten [EXT]; "Tounsi, Marielle GCPE:EX"
Subject: FW: March 11 COVID19 AEFI Report
Date: Thursday, March 11, 2021 10:57:30 AM
Attachments: COVID19_AEFI_Summary_Report_2021-03-11.html

Hi,

See updated numbers for AEFIs for today's briefing.

Heather

From: Noftall, Kyle [BCCDC]
Sent: Thursday, March 11, 2021 10:48 AM
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: March 11 COVID19 AEFI Report

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - March 11, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 08, 2021 there have been a total of 378,340 distributed doses. As of March 11, 2021, there have been 450 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 118.9 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 115 (25.6%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 615 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 11, 2021 **(N=450)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-07	2021-08	2021-09	2021-10	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	30	54	57	12	**450**	**118.94**	**100.0**	6.50	**18.3**	100.0	**1.0**	32.30	**3.7**	100.0	**1.0**
Serious AEFI[g]	8	15	21	4	**115**	**30.40**	**25.6**	1.48	**20.5**	22.8	**1.1**	7.23	**4.2**	22.4	**1.1**
Events															
Anaphylaxis	6	12	15	2	**71**	**18.77**	**15.8**	0.47	**39.9**	7.3	**2.2**	2.70	**7.0**	8.3	**1.9**
Anaphylaxis Brighton levels 1/2/3[h]	5	8	6	2	**41**	**10.84**	**9.1**	0.19	**57.1**	2.8	**3.2**	NA	–	NA	–
Other allergic	18	24	20	6	**185**	**48.90**	**41.1**	2.09	**23.4**	32.1	**1.3**	5.64	**8.7**	17.5	**2.3**
Bell's Palsy	1	0	1	0	**4**	**1.06**	**0.9**	0.02	**53.0**	0.3	**3.0**	0.06	**17.7**	0.2	**4.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	1	**1**	**0.26**	**0.2**	0.27	**1.0**	4.1	**0.0**	1.53	**0.2**	4.7	**0.0**
Anaesthesia/ paraesthesia[1]	3	7	4	1	**31**	**8.19**	**6.9**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	0	**2**	**0.53**	**0.4**	0.02	**26.5**	0.3	**1.3**	0.00	–	0.0	–
Cellulitis	0	0	1	0	**24**	**6.34**	**5.3**	0.27	**23.5**	4.1	**1.3**	0.31	**20.5**	0.9	**5.9**
Adenopathy/ lymphadenitis	0	1	3	1	**17**	**4.49**	**3.8**	0.07	**64.1**	1.0	**3.8**	0.43	**10.4**	1.3	**2.9**
Recommendations															
No further immunizations	5	9	2	0	**29**	**7.67**	**6.4**	0.25	**30.7**	3.9	**1.6**	0.67	**11.4**	2.1	**3.0**
Outcomes															
Hospitalization	2	1	2	1	**10**	**2.64**	**2.2**	0.19	**13.9**	2.8	**0.8**	3.00	**0.9**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	1	0	0	1	**3**	**0.79**	**0.7**	0.02	**39.5**	0.3	**2.3**	0.18	**4.4**	0.6	**1.2**
Health Authority															
IHA	6	17	18	7	**122**	**181.26**	**27.1**	10.10	**17.9**	24.4	**1.1**	66.52	**2.7**	34.5	**0.8**

Health Authority															
IHA	6	17	18	7	**122**	**181.26**	**27.1**	10.10	**17.9**	24.4	**1.1**	66.52	**2.7**	34.5	**0.8**
FHA	9	18	12	1	**110**	**87.98**	**24.4**	4.34	**20.3**	22.0	**1.1**	20.32	**4.3**	19.4	**1.3**
VCHA	9	9	11	0	**82**	**100.76**	**18.2**	2.28	**44.2**	10.4	**1.7**	10.19	**9.9**	9.7	**1.9**
VIHA	1	8	14	3	**92**	**127.07**	**20.4**	9.55	**13.3**	25.9	**0.8**	38.38	**3.3**	20.7	**1.0**
NHA	5	2	2	1	**44**	**136.54**	**9.8**	26.36	**5.2**	17.4	**0.6**	115.42	**1.2**	15.7	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	27	46	50	11	**390**	**11.90**	**86.7**	1.39	**8.6**	46.1	**1.9**	10.62	**1.1**	58.6	**1.5**
65+	3	8	7	1	**60**	**6.09**	**13.3**	0.95	**6.4**	8.8	**1.5**	5.09	**1.2**	6.3	**2.1**
Gender															
Female	25	44	48	9	**403**	**15.53**	**89.6**	2.32	**6.7**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	5	10	9	3	**47**	**1.85**	**10.4**	1.56	**1.2**	39.6	**0.3**	7.26	**0.3**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
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[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 11, 2021 **(N=450)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	110	544.55	22	108.91	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	67	323.67	16	77.29	5	24.15	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		300042722	16	71.11	3	13.33	2	8.89	2	8.89	9	40.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		3000489	7	34.83	1	4.98	1	4.98	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	
		Moderna mRNA-1273 total	**201**	**240.72**	**43**	**51.50**	**16**	**19.16**	**8**	**9.58**	**70**	**83.83**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
		EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	32	142.70	5	22.30	3	13.38	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	31	127.18	3	12.31	2	8.21	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	19	121.79	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	45	159.15	10	35.37	6	21.22	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	

	Events																		Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	9.90	13	64.36	1	4.95	1	4.95
	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	3	14.49	8	38.65	1	4.83	1	4.83
	2	8.89	9	40.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.44	0	0.00
	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
	8	**9.58**	**70**	**83.83**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**5**	**5.99**	**21**	**25.15**	**3**	**3.59**	**2**	**2.40**
	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	20.51	0	0.00	0	0.00	0	0.00
	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00

19 mRNA		EL0203	45	159.15	10	35.37	6	21.22	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00
	Pfizer mRNA BNT162b2	EL1404	1	17.09	1	17.09	1	17.09	1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1406	37	151.79	7	28.72	6	24.62	2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6017	40	89.19	19	42.36	18	40.13	10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6775	29	45.07	12	18.65	8	12.43	5	7.77	15	23.31	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55
		ER1742	6	9.86	5	8.22	4	6.57	3	4.93	2	3.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**249**	**84.45**	**72**	**24.42**	**55**	**18.65**	**33**	**11.19**	**115**	**39.00**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**450**	**118.94**	**115**	**30.40**	**71**	**18.77**	**41**	**10.84**	**185**	**48.90**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00
1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	24.62	1	4.10	0	0.00	0	0.00
10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	11.15	0	0.00	2	4.46	0	0.00
5	7.77	15	23.31	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55	0	0.00	0	0.00	2	3.11	0	0.00
3	4.93	2	3.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	1.64
33	**11.19**	**115**	**39.00**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**	**26**	**8.82**	**3**	**1.02**	**7**	**2.37**	**1**	**0.34**
41	**10.84**	**185**	**48.90**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**	**31**	**8.19**	**24**	**6.34**	**10**	**2.64**	**3**	**0.79**

The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
played, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ied in the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Naus, Monika [BCCDC]
To: Henry, Bonnie [EXT]
Cc: Amos, Heather [BCCDC]; Gustafson, Reka [BCCDC]
Subject: AEFI report from today
Date: Thursday, March 11, 2021 1:47:21 PM
Attachments: COVID19_AEFI_Summary_Report_2021-03-11.html

Hi Bonnie
This is today's report. You will also see my note about the AstraZeneca suspension. Nothing concerning based on BC rates but we are continuing to see anaphylaxis reported at higher rates than the Canadian average; we are apparently not the highest P/T but in the top 3. We are reviewing these on a case by case basis and are doing the Brighton leveling; it's clear that some people are being overtreated e.g., 'vomiting 5 minutes after receiving vaccine; received adrenaline'.
We have had 4 Bell's reported and this is signaling against influenza vaccine (PRR) with 2 expected, 4 reported. But as you know this signal as questioned in both mRNA trials and not seen in the US VSD to date.
Apologies that I've been in back to back meetings all day and trying to get the information together about the AstraZeneca lot hold.
We will be producing a public facing report (the enclosed is for public health, and accessible on SharePoint for MHOs/ others) shortly, and updating – we can do weekly for now and then perhaps drop down to q2 weeks.
Thank you,
Monika

. . . . . .

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I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - March 11, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 08, 2021 there have been a total of 378,340 distributed doses. As of March 11, 2021, there have been 450 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 118.9 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 115 (25.6%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 615 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 11, 2021 **(N=450)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-07	2021-08	2021-09	2021-10	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	30	54	57	12	**450**	**118.94**	**100.0**	6.50	**18.3**	100.0	**1.0**	32.30	**3.7**	100.0	**1.0**
Serious AEFI[g]	8	15	21	4	**115**	**30.40**	**25.6**	1.48	**20.5**	22.8	**1.1**	7.23	**4.2**	22.4	**1.1**
Events															
Anaphylaxis	6	12	15	2	**71**	**18.77**	**15.8**	0.47	**39.9**	7.3	**2.2**	2.70	**7.0**	8.3	**1.9**
Anaphylaxis Brighton levels 1/2/3[h]	5	8	6	2	**41**	**10.84**	**9.1**	0.19	**57.1**	2.8	**3.2**	NA	–	NA	–
Other allergic	18	24	20	6	**185**	**48.90**	**41.1**	2.09	**23.4**	32.1	**1.3**	5.64	**8.7**	17.5	**2.3**
Bell's Palsy	1	0	1	0	**4**	**1.06**	**0.9**	0.02	**53.0**	0.3	**3.0**	0.06	**17.7**	0.2	**4.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	1	**1**	**0.26**	**0.2**	0.27	**1.0**	4.1	**0.0**	1.53	**0.2**	4.7	**0.0**
Anaesthesia/ paraesthesia[1]	3	7	4	1	**31**	**8.19**	**6.9**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	0	**2**	**0.53**	**0.4**	0.02	**26.5**	0.3	**1.3**	0.00	–	0.0	–
Cellulitis	0	0	1	0	**24**	**6.34**	**5.3**	0.27	**23.5**	4.1	**1.3**	0.31	**20.5**	0.9	**5.9**
Adenopathy/ lymphadenitis	0	1	3	1	**17**	**4.49**	**3.8**	0.07	**64.1**	1.0	**3.8**	0.43	**10.4**	1.3	**2.9**
Recommendations															
No further immunizations	5	9	2	0	**29**	**7.67**	**6.4**	0.25	**30.7**	3.9	**1.6**	0.67	**11.4**	2.1	**3.0**
Outcomes															
Hospitalization	2	1	2	1	**10**	**2.64**	**2.2**	0.19	**13.9**	2.8	**0.8**	3.00	**0.9**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	1	0	0	1	**3**	**0.79**	**0.7**	0.02	**39.5**	0.3	**2.3**	0.18	**4.4**	0.6	**1.2**
Health Authority															
IHA	6	17	18	7	**122**	**181.26**	**27.1**	10.10	**17.9**	24.4	**1.1**	66.52	**2.7**	34.5	**0.8**

Health Authority															
IHA	6	17	18	7	**122**	**181.26**	**27.1**	10.10	**17.9**	24.4	**1.1**	66.52	**2.7**	34.5	**0.8**
FHA	9	18	12	1	**110**	**87.98**	**24.4**	4.34	**20.3**	22.0	**1.1**	20.32	**4.3**	19.4	**1.3**
VCHA	9	9	11	0	**82**	**100.76**	**18.2**	2.28	**44.2**	10.4	**1.7**	10.19	**9.9**	9.7	**1.9**
VIHA	1	8	14	3	**92**	**127.07**	**20.4**	9.55	**13.3**	25.9	**0.8**	38.38	**3.3**	20.7	**1.0**
NHA	5	2	2	1	**44**	**136.54**	**9.8**	26.36	**5.2**	17.4	**0.6**	115.42	**1.2**	15.7	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	27	46	50	11	**390**	**11.90**	**86.7**	1.39	**8.6**	46.1	**1.9**	10.62	**1.1**	58.6	**1.5**
65+	3	8	7	1	**60**	**6.09**	**13.3**	0.95	**6.4**	8.8	**1.5**	5.09	**1.2**	6.3	**2.1**
Gender															
Female	25	44	48	9	**403**	**15.53**	**89.6**	2.32	**6.7**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	5	10	9	3	**47**	**1.85**	**10.4**	1.56	**1.2**	39.6	**0.3**	7.26	**0.3**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	27	46	50	11	**390**	**11.90**	**86.7**	1.39	**8.6**	46.1	**1.9**	10.62	**1.1**	58.6	**1.5**
65+	3	8	7	1	**60**	**6.09**	**13.3**	0.95	**6.4**	8.8	**1.5**	5.09	**1.2**	6.3	**2.1**
Gender															
Female	25	44	48	9	**403**	**15.53**	**89.6**	2.32	**6.7**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	5	10	9	3	**47**	**1.85**	**10.4**	1.56	**1.2**	39.6	**0.3**	7.26	**0.3**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 11, 2021 **(N=450)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	110	544.55	22	108.91	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	67	323.67	16	77.29	5	24.15	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		300042722	16	71.11	3	13.33	2	8.89	2	8.89	9	40.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		3000489	7	34.83	1	4.98	1	4.98	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	
		Moderna mRNA-1273 total	**201**	**240.72**	**43**	**51.50**	**16**	**19.16**	**8**	**9.58**	**70**	**83.83**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
		EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	32	142.70	5	22.30	3	13.38	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	31	127.18	3	12.31	2	8.21	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	19	121.79	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	45	159.15	10	35.37	6	21.22	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	

	Events																		Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	9.90	13	64.36	1	4.95	1	4.95
	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	3	14.49	8	38.65	1	4.83	1	4.83
	2	8.89	9	40.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.44	0	0.00
	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
	8	**9.58**	**70**	**83.83**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**5**	**5.99**	**21**	**25.15**	**3**	**3.59**	**2**	**2.40**
	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	20.51	0	0.00	0	0.00	0	0.00
	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00

19 mRNA		EL0203	45	159.15	10	35.37	6	21.22	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00
	Pfizer mRNA BNT162b2	EL1404	1	17.09	1	17.09	1	17.09	1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL1406	37	151.79	7	28.72	6	24.62	2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6017	40	89.19	19	42.36	18	40.13	10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6775	29	45.07	12	18.65	8	12.43	5	7.77	15	23.31	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55
		ER1742	6	9.86	5	8.22	4	6.57	3	4.93	2	3.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**249**	**84.45**	**72**	**24.42**	**55**	**18.65**	**33**	**11.19**	**115**	**39.00**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**450**	**118.94**	**115**	**30.40**	**71**	**18.77**	**41**	**10.84**	**185**	**48.90**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00
1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	24.62	1	4.10	0	0.00	0	0.00
10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	11.15	0	0.00	2	4.46	0	0.00
5	7.77	15	23.31	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55	0	0.00	0	0.00	2	3.11	0	0.00
3	4.93	2	3.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	1.64
33	**11.19**	**115**	**39.00**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**	**26**	**8.82**	**3**	**1.02**	**7**	**2.37**	**1**	**0.34**
41	**10.84**	**185**	**48.90**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**	**31**	**8.19**	**24**	**6.34**	**10**	**2.64**	**3**	**0.79**

The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
played, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ied in the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: NLK Strategies, Nicola
Subject: RE: AEFI report
Date: Monday, March 15, 2021 9:07:03 AM
Attachments: FW March 11 COVID19 AEFI Report.msg

See attached. Would you like me to see if I can an update today?

From: Nicola Lambrechts [mailto:nicola@nlkstrategies.ca]
Sent: Monday, March 15, 2021 9:06 AM
To: Amos, Heather [BCCDC]
Subject: AEFI report
EXTERNAL SENDER. If you suspect this message is malicious, please forward to spam@phsa.ca and **do not** open attachments or click on links.

Hi Heather - Would you mind please sending me the weekly AEFI report? DBH would like to speak to it in her remarks this afternoon.
Thank you,
Nicola

Nicola Lambrechts
NLK Strategies
604.970.9113
nicola@nlkstrategies.ca
www.nlkstrategies.ca

From: Amos, Heather [BCCDC]
To: Youngs, Kirsten [EXT]; "Tounsi, Marielle GCPE:EX"
Subject: FW: March 11 COVID19 AEFI Report
Date: Thursday, March 11, 2021 10:57:30 AM
Attachments: COVID19_AEFI_Summary_Report_2021-03-11.html

Hi,

See updated numbers for AEFIs for today's briefing.

Heather

From: Noftall, Kyle [BCCDC]
Sent: Thursday, March 11, 2021 10:48 AM
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: March 11 COVID19 AEFI Report

Morning Heather,

Today's AEFI report is attached. Key details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	450	118.94
Serious AEFI	115	30.40
Anaphylaxis	71	18.77
Anaphylaxis Brighton levels 1/2/3	41	10.84
Other allergic	185	48.90

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

This e-mail message, including any attachments, is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged and/or confidential. If you are not the intended recipient or the employee or agent responsible for delivering the communication to the intended recipient, please notify us immediately by replying to this message and then delete this message from your system. You are hereby notified that any use, dissemination, distribution and/or reproduction of this message and/or any attachments by unintended recipients is unauthorized and may be unlawful.

BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - March 11, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 08, 2021 there have been a total of 378,340 distributed doses. As of March 11, 2021, there have been 450 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 118.9 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 115 (25.6%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 615 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 11, 2021 **(N=450)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-07	2021-08	2021-09	2021-10	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	30	54	57	12	**450**	**118.94**	**100.0**	6.50	**18.3**	100.0	**1.0**	32.30	**3.7**	100.0	**1.0**
Serious AEFI[g]	8	15	21	4	**115**	**30.40**	**25.6**	1.48	**20.5**	22.8	**1.1**	7.23	**4.2**	22.4	**1.1**
Events															
Anaphylaxis	6	12	15	2	**71**	**18.77**	**15.8**	0.47	**39.9**	7.3	**2.2**	2.70	**7.0**	8.3	**1.9**
Anaphylaxis Brighton levels 1/2/3[h]	5	8	6	2	**41**	**10.84**	**9.1**	0.19	**57.1**	2.8	**3.2**	NA	–	NA	–
Other allergic	18	24	20	6	**185**	**48.90**	**41.1**	2.09	**23.4**	32.1	**1.3**	5.64	**8.7**	17.5	**2.3**
Bell's Palsy	1	0	1	0	**4**	**1.06**	**0.9**	0.02	**53.0**	0.3	**3.0**	0.06	**17.7**	0.2	**4.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–

Other paralysis	0	0	0	0	**0**	**0.00**	**0.0**	0.05	–	0.8	–	0.00	–	0.0	–
Seizure	0	0	0	1	**1**	**0.26**	**0.2**	0.27	**1.0**	4.1	**0.0**	1.53	**0.2**	4.7	**0.0**
Anaesthesia/ paraesthesia[1]	3	7	4	1	**31**	**8.19**	**6.9**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	0	**2**	**0.53**	**0.4**	0.02	**26.5**	0.3	**1.3**	0.00	–	0.0	–
Cellulitis	0	0	1	0	**24**	**6.34**	**5.3**	0.27	**23.5**	4.1	**1.3**	0.31	**20.5**	0.9	**5.9**
Adenopathy/ lymphadenitis	0	1	3	1	**17**	**4.49**	**3.8**	0.07	**64.1**	1.0	**3.8**	0.43	**10.4**	1.3	**2.9**
Recommendations															
No further immunizations	5	9	2	0	**29**	**7.67**	**6.4**	0.25	**30.7**	3.9	**1.6**	0.67	**11.4**	2.1	**3.0**
Outcomes															
Hospitalization	2	1	2	1	**10**	**2.64**	**2.2**	0.19	**13.9**	2.8	**0.8**	3.00	**0.9**	9.3	**0.2**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	1	0	0	1	**3**	**0.79**	**0.7**	0.02	**39.5**	0.3	**2.3**	0.18	**4.4**	0.6	**1.2**
Health Authority															
IHA	6	17	18	7	**122**	**181.26**	**27.1**	10.10	**17.9**	24.4	**1.1**	66.52	**2.7**	34.5	**0.8**

Health Authority															
IHA	6	17	18	7	**122**	**181.26**	**27.1**	10.10	**17.9**	24.4	**1.1**	66.52	**2.7**	34.5	**0.8**
FHA	9	18	12	1	**110**	**87.98**	**24.4**	4.34	**20.3**	22.0	**1.1**	20.32	**4.3**	19.4	**1.3**
VCHA	9	9	11	0	**82**	**100.76**	**18.2**	2.28	**44.2**	10.4	**1.7**	10.19	**9.9**	9.7	**1.9**
VIHA	1	8	14	3	**92**	**127.07**	**20.4**	9.55	**13.3**	25.9	**0.8**	38.38	**3.3**	20.7	**1.0**
NHA	5	2	2	1	**44**	**136.54**	**9.8**	26.36	**5.2**	17.4	**0.6**	115.42	**1.2**	15.7	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	27	46	50	11	**390**	**11.90**	**86.7**	1.39	**8.6**	46.1	**1.9**	10.62	**1.1**	58.6	**1.5**
65+	3	8	7	1	**60**	**6.09**	**13.3**	0.95	**6.4**	8.8	**1.5**	5.09	**1.2**	6.3	**2.1**
Gender															
Female	25	44	48	9	**403**	**15.53**	**89.6**	2.32	**6.7**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	5	10	9	3	**47**	**1.85**	**10.4**	1.56	**1.2**	39.6	**0.3**	7.26	**0.3**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.1	–
18-64	27	46	50	11	**390**	**11.90**	**86.7**	1.39	**8.6**	46.1	**1.9**	10.62	**1.1**	58.6	**1.5**
65+	3	8	7	1	**60**	**6.09**	**13.3**	0.95	**6.4**	8.8	**1.5**	5.09	**1.2**	6.3	**2.1**
Gender															
Female	25	44	48	9	**403**	**15.53**	**89.6**	2.32	**6.7**	60.4	**1.5**	16.58	**0.9**	69.8	**1.3**
Male	5	10	9	3	**47**	**1.85**	**10.4**	1.56	**1.2**	39.6	**0.3**	7.26	**0.3**	30.2	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 11, 2021 **(N=450)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Ana para
COVID-19 mRNA	Moderna mRNA-1273	300042460	110	544.55	22	108.91	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		300042698	67	323.67	16	77.29	5	24.15	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	
		300042722	16	71.11	3	13.33	2	8.89	2	8.89	9	40.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		3000489	7	34.83	1	4.98	1	4.98	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	
		Moderna mRNA-1273 total	**201**	**240.72**	**43**	**51.50**	**16**	**19.16**	**8**	**9.58**	**70**	**83.83**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	
		EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4241	32	142.70	5	22.30	3	13.38	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	
		EK4245	31	127.18	3	12.31	2	8.21	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0140	19	121.79	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	
		EL0203	45	159.15	10	35.37	6	21.22	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	

	Events																				Outcomes			
xis	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Other paralysis count	Other paralysis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	9.90	13	64.36	1	4.95	1	4.95
	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	0	0.00	0	0.00	3	14.49	8	38.65	1	4.83	1	4.83
	2	8.89	9	40.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.44	0	0.00
	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
	8	**9.58**	**70**	**83.83**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**5**	**5.99**	**21**	**25.15**	**3**	**3.59**	**2**	**2.40**
	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	20.51	0	0.00	0	0.00	0	0.00
	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00

19 mRNA		EL0203	45	159.15	10	35.37	6	21.22	4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00
		EL1404	1	17.09	1	17.09	1	17.09	1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	Pfizer mRNA BNT162b2	EL1406	37	151.79	7	28.72	6	24.62	2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6017	40	89.19	19	42.36	18	40.13	10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6775	29	45.07	12	18.65	8	12.43	5	7.77	15	23.31	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55
		ER1742	6	9.86	5	8.22	4	6.57	3	4.93	2	3.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Pfizer mRNA BNT162b2 total	**249**	**84.45**	**72**	**24.42**	**55**	**18.65**	**33**	**11.19**	**115**	**39.00**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**450**	**118.94**	**115**	**30.40**	**71**	**18.77**	**41**	**10.84**	**185**	**48.90**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/i

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

4	14.15	26	91.95	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00
1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	24.62	1	4.10	0	0.00	0	0.00
10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	11.15	0	0.00	2	4.46	0	0.00
5	7.77	15	23.31	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55	0	0.00	0	0.00	2	3.11	0	0.00
3	4.93	2	3.29	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	1.64
33	**11.19**	**115**	**39.00**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**	**26**	**8.82**	**3**	**1.02**	**7**	**2.37**	**1**	**0.34**
41	**10.84**	**185**	**48.90**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**	**31**	**8.19**	**24**	**6.34**	**10**	**2.64**	**3**	**0.79**

The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
played, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
litis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
ied in the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
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3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: March 11 COVID19 AEFI Report
Date: Monday, March 15, 2021 9:34:02 AM
Attachments: COVID19_AEFI_Summary_Report_2021-03-15.html

Hi Heather,

Today's report is attached (as you mention, the rates won't be accurate).

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	469	123.96
Serious AEFI	124	32.77
Anaphylaxis	79	20.88
Anaphylaxis Brighton levels 1/2/3	46	12.16
Other allergic	189	49.96

Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

Kyle Noftall, MPH
Communicable Disease Epidemiologist
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Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Amos, Heather [BCCDC]
Sent: Monday, March 15, 2021 9:25 AM
To: Noftall, Kyle [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: March 11 COVID19 AEFI Report

Hi Kyle,

GCPE has asked if there is any way we could provide an update on AEFI reports for Dr. Henry's briefing today. I understand the rate will not be updated.

Heather

From: Noftall, Kyle [BCCDC]
Sent: Thursday, March 11, 2021 10:48 AM
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: March 11 COVID19 AEFI Report

Morning Heather,

Today's AEFI report is attached. Key details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	450	118.94
Serious AEFI	115	30.40
Anaphylaxis	71	18.77
Anaphylaxis Brighton levels 1/2/3	41	10.84
Other allergic	185	48.90

Thanks,
Kyle

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I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - March 15, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 15, 2021 there have been a total of 378,340 distributed doses. As of March 15, 2021, there have been 469 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 124.0 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 124 (26.4%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 646 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 15, 2021 **(N=469)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-08	2021-09	2021-10	2021-11	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	56	61	25	0	**469**	**123.96**	**100.0**	6.50	**19.1**	100.0	**1.0**	32.36	**3.8**	100.0	**1.0**
Serious AEFI[g]	16	23	9	0	**124**	**32.77**	**26.4**	1.48	**22.1**	22.8	**1.2**	7.23	**4.5**	22.3	**1.2**
Events															
Anaphylaxis	13	17	7	0	**79**	**20.88**	**16.8**	0.47	**44.4**	7.3	**2.3**	2.70	**7.7**	8.3	**2.0**
Anaphylaxis Brighton levels 1/2/3[h]	8	8	5	0	**46**	**12.16**	**9.8**	0.19	**64.0**	2.8	**3.5**	NA	–	NA	–
Other allergic	25	22	7	0	**189**	**49.96**	**40.3**	2.09	**23.9**	32.1	**1.3**	5.70	**8.8**	17.6	**2.3**
Bell's Palsy	0	1	0	0	**4**	**1.06**	**0.9**	0.02	**53.0**	0.3	**3.0**	0.06	**17.7**	0.2	**4.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Transverse myelitis	1	0	0	0	**1**	**0.26**	**0.2**	0.00	–	0.0	–	0.00	–	0.0	–

Transverse myelitis	1	0	0	0	1	0.26	0.2	0.00	–	0.0	–	0.00	–	0.0	–
Seizure	0	0	1	0	1	0.26	0.2	0.27	1.0	4.1	0.0	1.53	0.2	4.7	0.0
Anaesthesia/ paraesthesia[1]	7	4	6	0	36	9.52	7.7	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	0	2	0.53	0.4	0.02	26.5	0.3	1.3	0.00	–	0.0	–
Cellulitis	0	1	0	0	24	6.34	5.1	0.27	23.5	4.1	1.2	0.31	20.5	0.9	5.7
Adenopathy/ lymphadenitis	1	3	2	0	18	4.76	3.8	0.07	68.0	1.0	3.8	0.43	11.1	1.3	2.9
Recommendations															
No further immunizations	9	3	2	0	34	8.99	7.2	0.25	36.0	3.9	1.8	0.67	13.4	2.1	3.4
Outcomes															
Hospitalization	1	3	2	0	12	3.17	2.6	0.19	16.7	2.8	0.9	3.00	1.1	9.3	0.3
Permanent disability	0	0	0	0	0	0.00	0.0	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	0	1	0	3	0.79	0.6	0.02	39.5	0.3	2.0	0.18	4.4	0.6	1.0
Health Authority															
IHA	17	18	9	0	124	184.24	26.4	10.10	18.2	24.4	1.1	66.52	2.8	34.5	0.8

Death	0	0	1	0	3	0.79	0.6	0.02	39.5	0.3	2.0	0.18	4.4	0.6	1.0
Health Authority															
IHA	17	18	9	0	124	184.24	26.4	10.10	18.2	24.4	1.1	66.52	2.8	34.5	0.8
FHA	19	16	10	0	124	99.18	26.4	4.34	22.9	22.0	1.2	20.32	4.9	19.3	1.4
VCHA	9	11	1	0	83	101.99	17.7	2.28	44.7	10.4	1.7	10.19	10.0	9.7	1.8
VIHA	8	14	3	0	92	127.07	19.6	9.55	13.3	25.9	0.8	38.38	3.3	20.6	1.0
NHA	3	2	2	0	46	142.75	9.8	26.36	5.4	17.4	0.6	116.81	1.2	15.9	0.6
Age Group															
<18	0	0	0	0	0	0.00	0.0	5.03	–	45.1	–	21.73	–	35.0	–
18-64	48	53	23	0	407	12.42	86.8	1.39	8.9	46.1	1.9	10.62	1.2	58.5	1.5
65+	8	8	2	0	62	6.29	13.2	0.95	6.6	8.8	1.5	5.24	1.2	6.4	2.1
Gender															
Female	45	52	22	0	421	16.22	89.8	2.32	7.0	60.4	1.5	16.63	1.0	69.9	1.3
Male	11	9	3	0	48	1.89	10.2	1.56	1.2	39.6	0.3	7.26	0.3	30.1	0.3

Abbreviations:
RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.0	–
18-64	48	53	23	0	**407**	**12.42**	**86.8**	1.39	**8.9**	46.1	**1.9**	10.62	**1.2**	58.5	**1.5**
65+	8	8	2	0	**62**	**6.29**	**13.2**	0.95	**6.6**	8.8	**1.5**	5.24	**1.2**	6.4	**2.1**
Gender															
Female	45	52	22	0	**421**	**16.22**	**89.8**	2.32	**7.0**	60.4	**1.5**	16.63	**1.0**	69.9	**1.3**
Male	11	9	3	0	**48**	**1.89**	**10.2**	1.56	**1.2**	39.6	**0.3**	7.26	**0.3**	30.1	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 15, 2021 **(N=469)**

Vaccine information			Reports				Events													
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizure rate[b]
COVID-19	Moderna mRNA-1273	300042460	110	544.55	23	113.86	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		300042698	68	328.50	16	77.29	5	24.15	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	1	4.83	0	0.00
		300042722	19	84.44	4	17.78	3	13.33	3	13.33	10	44.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		3000489	7	34.83	1	4.98	1	4.98	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		Moderna mRNA-1273 total	**205**	**245.51**	**45**	**53.89**	**17**	**20.36**	**9**	**10.78**	**71**	**85.03**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**1**	**1.20**	**0**	**0.00**
		EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EK4241	32	142.70	5	22.30	3	13.38	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00
		EK4245	31	127.18	3	12.31	2	8.21	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0140	20	128.21	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0203	47	166.22	10	35.37	6	21.22	4	14.15	27	95.49	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00

Events																		Outcomes			
Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	9.90	13	64.36	1	4.95	1	4.95
3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	1	4.83	0	0.00	3	14.49	8	38.65	1	4.83	1	4.83
3	13.33	10	44.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.44	0	0.00
0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
9	**10.78**	**71**	**85.03**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**1**	**1.20**	**0**	**0.00**	**5**	**5.99**	**21**	**25.15**	**3**	**3.59**	**2**	**2.40**
2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	20.51	0	0.00	0	0.00	0	0.00
2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
4	14.15	27	95.49	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00

		EL1404	1	17.09	1	17.09	1	17.09	1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	Pfizer mRNA BNT162b2	EL1406	37	151.79	7	28.72	6	24.62	2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6017	40	89.19	19	42.36	18	40.13	10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6775	35	54.39	14	21.76	10	15.54	6	9.32	16	24.86	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55
		ER1742	11	18.08	9	14.79	8	13.15	5	8.22	3	4.93	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		ER1742-CC01	1	NA	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		Pfizer mRNA BNT162b2 total	**264**	**89.54**	**79**	**26.79**	**62**	**21.03**	**37**	**12.55**	**118**	**40.02**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**469**	**123.96**	**124**	**32.77**	**79**	**20.88**	**46**	**12.16**	**189**	**49.96**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**	**1**	**0.26**

Abbreviations:
GBS = Guillain Barre Syndrome
Notes:
[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, pe
[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	24.62	1	4.10	0	0.00	0	0.00
10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	13.38	0	0.00	2	4.46	0	0.00
6	9.32	16	24.86	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55	2	3.11	0	0.00	3	4.66	0	0.00
5	8.22	3	4.93	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	3.29	0	0.00	1	1.64	1	1.64
1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
37	**12.55**	**118**	**40.02**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**	**31**	**10.51**	**3**	**1.02**	**9**	**3.05**	**1**	**0.34**
46	**12.16**	**189**	**49.96**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**	**1**	**0.26**	**36**	**9.52**	**24**	**6.34**	**12**	**3.17**	**3**	**0.79**

e data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
ed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
n the anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]
Subject: RE: March 11 COVID19 AEFI Report
Date: Monday, March 15, 2021 9:51:09 AM

Thanks!

From: Noftall, Kyle [BCCDC]
Sent: Monday, March 15, 2021 9:34 AM
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: March 11 COVID19 AEFI Report

Hi Heather,

Today's report is attached (as you mention, the rates won't be accurate).

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	469	123.96
Serious AEFI	124	32.77
Anaphylaxis	79	20.88
Anaphylaxis Brighton levels 1/2/3	46	12.16
Other allergic	189	49.96

Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

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From: Amos, Heather [BCCDC]
Sent: Monday, March 15, 2021 9:25 AM
To: Noftall, Kyle [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: March 11 COVID19 AEFI Report

Hi Kyle,

GCPE has asked if there is any way we could provide an update on AEFI reports for Dr. Henry's briefing today. I understand the rate will not be updated.

Heather

From: Noftall, Kyle [BCCDC]
Sent: Thursday, March 11, 2021 10:48 AM

To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: March 11 COVID19 AEFI Report

Morning Heather,

Today's AEFI report is attached. Key details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	450	118.94
Serious AEFI	115	30.40
Anaphylaxis	71	18.77
Anaphylaxis Brighton levels 1/2/3	41	10.84
Other allergic	185	48.90

Thanks,

Kyle

Kyle Noftall, MPH
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Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Sc̓ic̓ilwətaʔ/Selilwitulh Nations.

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From: Amos, Heather [BCCDC]
To: NLK Strategies, Nicola
Subject: RE: AEFI report
Date: Monday, March 15, 2021 9:55:32 AM
Attachments: COVID19_AEFI_Summary_Report_2021-03-15.html

Hi,

We don't get updated rates in time on Mondays so here are the counts:

	Cumulative COVID19 Count
Total AEFI	469
Serious AEFI	124
Anaphylaxis	79
Anaphylaxis Brighton levels 1/2/3	46
Other allergic	189

Heather

From: Nicola Lambrechts [mailto:nicola@nlkstrategies.ca]
Sent: Monday, March 15, 2021 9:15 AM
To: Amos, Heather [BCCDC]
Subject: Re: AEFI report
EXTERNAL SENDER. If you suspect this message is malicious, please forward to spam@phsa.ca and **do not** open attachments or click on links.

Sure! Thank you.

Nicola Lambrechts
nicola@nlkstrategies.ca
604-970-9113

On Mar 15, 2021, at 9:07 AM, Amos, Heather [BCCDC] <heather.amos@bccdc.ca> wrote:

See attached. Would you like me to see if I can an update today?

From: Nicola Lambrechts [mailto:nicola@nlkstrategies.ca]
Sent: Monday, March 15, 2021 9:06 AM
To: Amos, Heather [BCCDC]
Subject: AEFI report
EXTERNAL SENDER. If you suspect this message is malicious, please forward to spam@phsa.ca and **do not** open attachments or click on links.

Hi Heather - Would you mind please sending me the weekly AEFI report? DBH would like to speak to it in her remarks this afternoon.
Thank you,
Nicola

Nicola Lambrechts
NLK Strategies
604.970.9113
nicola@nlkstrategies.ca
www.nlkstrategies.ca

<mime-attachment>

BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - March 15, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 15, 2021 there have been a total of 378,340 distributed doses. As of March 15, 2021, there have been 469 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 124.0 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 124 (26.4%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 646 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 15, 2021 **(N=469)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-08	2021-09	2021-10	2021-11	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	56	61	25	0	**469**	**123.96**	**100.0**	6.50	**19.1**	100.0	**1.0**	32.36	**3.8**	100.0	**1.0**
Serious AEFI[g]	16	23	9	0	**124**	**32.77**	**26.4**	1.48	**22.1**	22.8	**1.2**	7.23	**4.5**	22.3	**1.2**
Events															
Anaphylaxis	13	17	7	0	**79**	**20.88**	**16.8**	0.47	**44.4**	7.3	**2.3**	2.70	**7.7**	8.3	**2.0**
Anaphylaxis Brighton levels 1/2/3[h]	8	8	5	0	**46**	**12.16**	**9.8**	0.19	**64.0**	2.8	**3.5**	NA	–	NA	–
Other allergic	25	22	7	0	**189**	**49.96**	**40.3**	2.09	**23.9**	32.1	**1.3**	5.70	**8.8**	17.6	**2.3**
Bell's Palsy	0	1	0	0	**4**	**1.06**	**0.9**	0.02	**53.0**	0.3	**3.0**	0.06	**17.7**	0.2	**4.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Transverse myelitis	1	0	0	0	**1**	**0.26**	**0.2**	0.00	–	0.0	–	0.00	–	0.0	–

Transverse myelitis	1	0	0	0	1	0.26	0.2	0.00	–	0.0	–	0.00	–	0.0	–
Seizure	0	0	1	0	1	0.26	0.2	0.27	1.0	4.1	0.0	1.53	0.2	4.7	0.0
Anaesthesia/ paraesthesia[1]	7	4	6	0	36	9.52	7.7	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	0	2	0.53	0.4	0.02	26.5	0.3	1.3	0.00	–	0.0	–
Cellulitis	0	1	0	0	24	6.34	5.1	0.27	23.5	4.1	1.2	0.31	20.5	0.9	5.7
Adenopathy/ lymphadenitis	1	3	2	0	18	4.76	3.8	0.07	68.0	1.0	3.8	0.43	11.1	1.3	2.9
Recommendations															
No further immunizations	9	3	2	0	34	8.99	7.2	0.25	36.0	3.9	1.8	0.67	13.4	2.1	3.4
Outcomes															
Hospitalization	1	3	2	0	12	3.17	2.6	0.19	16.7	2.8	0.9	3.00	1.1	9.3	0.3
Permanent disability	0	0	0	0	0	0.00	0.0	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	0	1	0	3	0.79	0.6	0.02	39.5	0.3	2.0	0.18	4.4	0.6	1.0
Health Authority															
IHA	17	18	9	0	124	184.24	26.4	10.10	18.2	24.4	1.1	66.52	2.8	34.5	0.8

Death	0	0	1	0	3	0.79	0.6	0.02	39.5	0.3	2.0	0.18	4.4	0.6	1.0
Health Authority															
IHA	17	18	9	0	124	184.24	26.4	10.10	18.2	24.4	1.1	66.52	2.8	34.5	0.8
FHA	19	16	10	0	124	99.18	26.4	4.34	22.9	22.0	1.2	20.32	4.9	19.3	1.4
VCHA	9	11	1	0	83	101.99	17.7	2.28	44.7	10.4	1.7	10.19	10.0	9.7	1.8
VIHA	8	14	3	0	92	127.07	19.6	9.55	13.3	25.9	0.8	38.38	3.3	20.6	1.0
NHA	3	2	2	0	46	142.75	9.8	26.36	5.4	17.4	0.6	116.81	1.2	15.9	0.6
Age Group															
<18	0	0	0	0	0	0.00	0.0	5.03	–	45.1	–	21.73	–	35.0	–
18-64	48	53	23	0	407	12.42	86.8	1.39	8.9	46.1	1.9	10.62	1.2	58.5	1.5
65+	8	8	2	0	62	6.29	13.2	0.95	6.6	8.8	1.5	5.24	1.2	6.4	2.1
Gender															
Female	45	52	22	0	421	16.22	89.8	2.32	7.0	60.4	1.5	16.63	1.0	69.9	1.3
Male	11	9	3	0	48	1.89	10.2	1.56	1.2	39.6	0.3	7.26	0.3	30.1	0.3

Abbreviations:
RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.0	–
18-64	48	53	23	0	**407**	**12.42**	**86.8**	1.39	**8.9**	46.1	**1.9**	10.62	**1.2**	58.5	**1.5**
65+	8	8	2	0	**62**	**6.29**	**13.2**	0.95	**6.6**	8.8	**1.5**	5.24	**1.2**	6.4	**2.1**
Gender															
Female	45	52	22	0	**421**	**16.22**	**89.8**	2.32	**7.0**	60.4	**1.5**	16.63	**1.0**	69.9	**1.3**
Male	11	9	3	0	**48**	**1.89**	**10.2**	1.56	**1.2**	39.6	**0.3**	7.26	**0.3**	30.1	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 15, 2021 **(N=469)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizure rate[b]
COVID-19	Moderna mRNA-1273	300042460	110	544.55	23	113.86	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		300042698	68	328.50	16	77.29	5	24.15	3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	1	4.83	0	0.00
		300042722	19	84.44	4	17.78	3	13.33	3	13.33	10	44.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		3000489	7	34.83	1	4.98	1	4.98	0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		Moderna mRNA-1273 total	**205**	**245.51**	**45**	**53.89**	**17**	**20.36**	**9**	**10.78**	**71**	**85.03**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**1**	**1.20**	**0**	**0.00**
		EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EK4241	32	142.70	5	22.30	3	13.38	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00
		EK4245	31	127.18	3	12.31	2	8.21	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0140	20	128.21	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EL0203	47	166.22	10	35.37	6	21.22	4	14.15	27	95.49	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00

Events																		Outcomes			
Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	9.90	13	64.36	1	4.95	1	4.95
3	14.49	22	106.28	1	4.83	0	0.00	0	0.00	1	4.83	0	0.00	3	14.49	8	38.65	1	4.83	1	4.83
3	13.33	10	44.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.44	0	0.00
0	0.00	1	4.98	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
9	**10.78**	**71**	**85.03**	**1**	**1.20**	**0**	**0.00**	**0**	**0.00**	**1**	**1.20**	**0**	**0.00**	**5**	**5.99**	**21**	**25.15**	**3**	**3.59**	**2**	**2.40**
2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	20.51	0	0.00	0	0.00	0	0.00
2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
4	14.15	27	95.49	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00

		EL1404	1	17.09	1	17.09	1	17.09	1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	Pfizer mRNA BNT162b2	EL1406	37	151.79	7	28.72	6	24.62	2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6017	40	89.19	19	42.36	18	40.13	10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		EP6775	35	54.39	14	21.76	10	15.54	6	9.32	16	24.86	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55
		ER1742	11	18.08	9	14.79	8	13.15	5	8.22	3	4.93	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
		ER1742-CC01	1	NA	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		Pfizer mRNA BNT162b2 total	**264**	**89.54**	**79**	**26.79**	**62**	**21.03**	**37**	**12.55**	**118**	**40.02**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**469**	**123.96**	**124**	**32.77**	**79**	**20.88**	**46**	**12.16**	**189**	**49.96**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**	**1**	**0.26**

Abbreviations:

GBS = Guillain Barre Syndrome

Notes:

[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.

[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, pe

[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	24.62	1	4.10	0	0.00	0	0.00
10	22.30	14	31.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	13.38	0	0.00	2	4.46	0	0.00
6	9.32	16	24.86	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55	2	3.11	0	0.00	3	4.66	0	0.00
5	8.22	3	4.93	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	3.29	0	0.00	1	1.64	1	1.64
1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
37	**12.55**	**118**	**40.02**	**3**	**1.02**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.34**	**31**	**10.51**	**3**	**1.02**	**9**	**3.05**	**1**	**0.34**
46	**12.16**	**189**	**49.96**	**4**	**1.06**	**0**	**0.00**	**0**	**0.00**	**1**	**0.26**	**1**	**0.26**	**36**	**9.52**	**24**	**6.34**	**12**	**3.17**	**3**	**0.79**

e data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
ed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
n the anaphylaxis case definition.

References

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3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: NLK_Strategies, Nicola
Cc: Youngs, Kirsten [EXT]
Subject: FW: Mar.18 AEFI Summary
Date: Thursday, March 18, 2021 11:00:00 AM
Attachments: COVID19_AEFI_Daily_Report_2021-03-18.html

Today's AEFI report.

From: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>
Sent: Thursday, March 18, 2021 10:57 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Mar.18 AEFI Summary

Hi Heather,

Today's summary attached.

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	497	88.90
Serious AEFI	136	24.33
Anaphylaxis	89	15.92
Anaphylaxis Brighton levels 1/2/3	50	8.94
Other allergic	201	35.95

Thanks,
Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - March 18, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 15, 2021 there have been a total of 559,055 distributed doses. As of March 18, 2021, there have been 497 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 88.9 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 136 (27.4%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 679 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 18, 2021 **(N=497)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-08	2021-09	2021-10	2021-11	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	55	63	33	18	**497**	**88.90**	**100.0**	6.50	**13.7**	100.0	**1.0**	32.36	**2.7**	100.0	**1.0**
Serious AEFI[g]	16	21	13	9	**136**	**24.33**	**27.4**	1.48	**16.4**	22.8	**1.2**	7.23	**3.4**	22.3	**1.2**
Events															
Anaphylaxis	13	15	11	8	**89**	**15.92**	**17.9**	0.47	**33.9**	7.3	**2.5**	2.70	**5.9**	8.3	**2.2**
Anaphylaxis Brighton levels 1/2/3[h]	8	8	6	3	**50**	**8.94**	**10.1**	0.19	**47.1**	2.8	**3.6**	NA	–	NA	–
Other allergic	25	25	10	5	**201**	**35.95**	**40.4**	2.09	**17.2**	32.1	**1.3**	5.70	**6.3**	17.6	**2.3**
Bell's Palsy	0	1	0	0	**4**	**0.72**	**0.8**	0.02	**36.0**	0.3	**2.7**	0.06	**12.0**	0.2	**4.0**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Transverse myelitis	1	0	0	0	**1**	**0.18**	**0.2**	0.00	–	0.0	–	0.00	–	0.0	–

Transverse myelitis	1	0	0	0	**1**	**0.18**	**0.2**	0.00	–	0.0	–	0.00	–	0.0	–
Seizure	0	0	1	0	**1**	**0.18**	**0.2**	0.27	**0.7**	4.1	**0.0**	1.53	**0.1**	4.7	**0.0**
Anaesthesia/ paraesthesia[i]	6	4	7	1	**37**	**6.62**	**7.4**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	0	1	**3**	**0.54**	**0.6**	0.02	**27.0**	0.3	**2.0**	0.00	–	0.0	–
Cellulitis	0	1	0	0	**25**	**4.47**	**5.0**	0.27	**16.6**	4.1	**1.2**	0.31	**14.4**	0.9	**5.6**
Adenopathy/ lymphadenitis	1	3	2	0	**18**	**3.22**	**3.6**	0.07	**46.0**	1.0	**3.6**	0.43	**7.5**	1.3	**2.8**
Recommendations															
No further immunizations	9	3	2	0	**34**	**6.08**	**6.8**	0.25	**24.3**	3.9	**1.7**	0.67	**9.1**	2.1	**3.2**
Outcomes															
Hospitalization	1	3	2	1	**13**	**2.33**	**2.6**	0.19	**12.3**	2.8	**0.9**	3.00	**0.8**	9.3	**0.3**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	0	1	0	**3**	**0.54**	**0.6**	0.02	**27.0**	0.3	**2.0**	0.18	**3.0**	0.6	**1.0**
Health Authority															
IHA	16	18	10	6	**130**	**139.88**	**26.2**	10.10	**13.8**	24.4	**1.1**	66.52	**2.1**	34.5	**0.8**

Health Authority															
IHA	16	18	10	6	**130**	**139.88**	**26.2**	10.10	**13.8**	24.4	**1.1**	66.52	**2.1**	34.5	**0.8**
FHA	19	17	15	7	**137**	**73.45**	**27.6**	4.34	**16.9**	22.0	**1.3**	20.32	**3.6**	19.3	**1.4**
VCHA	9	11	1	0	**84**	**67.21**	**16.9**	2.28	**29.5**	10.4	**1.6**	10.19	**6.6**	9.7	**1.7**
VIHA	8	14	3	3	**95**	**104.52**	**19.1**	9.55	**10.9**	25.9	**0.7**	38.38	**2.7**	20.6	**0.9**
NHA	3	3	4	2	**51**	**80.05**	**10.3**	26.36	**3.0**	17.4	**0.6**	116.81	**0.7**	15.9	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.0	–
18-64	47	55	28	13	**426**	**13.00**	**85.7**	1.39	**9.4**	46.1	**1.9**	10.62	**1.2**	58.5	**1.5**
65+	8	8	5	5	**71**	**7.20**	**14.3**	0.95	**7.6**	8.8	**1.6**	5.24	**1.4**	6.4	**2.2**
Gender															
Female	45	53	30	16	**446**	**17.18**	**89.7**	2.32	**7.4**	60.4	**1.5**	16.63	**1.0**	69.9	**1.3**
Male	10	10	3	2	**51**	**2.00**	**10.3**	1.56	**1.3**	39.6	**0.3**	7.26	**0.3**	30.1	**0.3**

Abbreviations:
RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome
Notes:
[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.
[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.0	–
18-64	47	55	28	13	**426**	**13.00**	**85.7**	1.39	**9.4**	46.1	**1.9**	10.62	**1.2**	58.5	**1.5**
65+	8	8	5	5	**71**	**7.20**	**14.3**	0.95	**7.6**	8.8	**1.6**	5.24	**1.4**	6.4	**2.2**
Gender															
Female	45	53	30	16	**446**	**17.18**	**89.7**	2.32	**7.4**	60.4	**1.5**	16.63	**1.0**	69.9	**1.3**
Male	10	10	3	2	**51**	**2.00**	**10.3**	1.56	**1.3**	39.6	**0.3**	7.26	**0.3**	30.1	**0.3**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 18, 2021 **(N=497)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizu rate
COVID-19 mRNA	Moderna mRNA-1273	300042460	109	539.60	23	113.86	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		300042698	68	328.50	15	72.46	4	19.32	3	14.49	23	111.11	1	4.83	0	0.00	0	0.00	1	4.83	0	0.0
		300042722	22	97.78	5	22.22	3	13.33	3	13.33	12	53.33	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		3000489	11	54.73	3	14.93	2	9.95	1	4.98	2	9.95	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		3001176	3	5.32	3	5.32	3	5.32	1	1.77	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		Moderna mRNA-1273 total	**214**	**152.97**	**50**	**35.74**	**20**	**14.30**	**11**	**7.86**	**75**	**53.61**	**1**	**0.71**	**0**	**0.00**	**0**	**0.00**	**1**	**0.71**	**0**	**0.0**
		EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EK4241	33	147.16	5	22.30	3	13.38	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.0
		EK4245	31	127.18	3	12.31	2	8.21	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EL0140	20	128.21	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0

Events																		Outcomes			
Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.95	13	64.36	1	4.95	1	4.95
3	14.49	23	111.11	1	4.83	0	0.00	0	0.00	1	4.83	0	0.00	3	14.49	8	38.65	1	4.83	1	4.83
3	13.33	12	53.33	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.44	1	4.44	0	0.00
1	4.98	2	9.95	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
1	1.77	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	1.77	0	0.00
0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
11	**7.86**	**75**	**53.61**	**1**	**0.71**	**0**	**0.00**	**0**	**0.00**	**1**	**0.71**	**0**	**0.00**	**4**	**2.86**	**22**	**15.73**	**4**	**2.86**	**2**	**1.43**
2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	20.51	0	0.00	0	0.00	0	0.00
2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00

mRNA		EL0140	20	128.21	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EL0203	47	166.22	10	35.37	6	21.22	4	14.15	27	95.49	2	7.07	0	0.00	0	0.00	0	0.00	0	0.0
	Pfizer mRNA BNT162b2	EL1404	2	34.19	1	17.09	1	17.09	1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EL1406	37	151.79	7	28.72	6	24.62	2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EP6017	42	91.65	19	41.46	18	39.28	10	21.82	15	32.73	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EP6775	37	57.50	14	21.76	10	15.54	6	9.32	18	27.97	0	0.00	0	0.00	0	0.00	0	0.00	1	1.5
		ER1742	25	20.55	17	13.97	16	13.15	8	6.57	8	6.57	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		Pfizer mRNA BNT162b2 total	**283**	**79.35**	**86**	**24.11**	**69**	**19.35**	**39**	**10.93**	**126**	**35.33**	**3**	**0.84**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.2**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**497**	**100.09**	**136**	**27.39**	**89**	**17.92**	**50**	**10.07**	**201**	**40.48**	**4**	**0.81**	**0**	**0.00**	**0**	**0.00**	**1**	**0.20**	**1**	**0.2**
COVID-19 Non-replicating Viral	**COVISHIELD**	4120Z003	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		4120Z029	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		COVISHIELD total	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.0**
	COVID-19	**COVID-19**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.0**

2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
4	14.15	27	95.49	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00
1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	24.62	1	4.10	0	0.00	0	0.00
10	21.82	15	32.73	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	13.09	0	0.00	2	4.36	0	0.00
6	9.32	18	27.97	0	0.00	0	0.00	0	0.00	0	0.00	1	1.55	2	3.11	0	0.00	3	4.66	0	0.00
8	6.57	8	6.57	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	4	3.29	0	0.00	1	0.82	1	0.82
39	**10.93**	**126**	**35.33**	**3**	**0.84**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.28**	**33**	**9.25**	**3**	**0.84**	**9**	**2.52**	**1**	**0.28**
50	**10.07**	**201**	**40.48**	**4**	**0.81**	**0**	**0.00**	**0**	**0.00**	**1**	**0.20**	**1**	**0.20**	**37**	**7.45**	**25**	**5.03**	**13**	**2.62**	**3**	**0.60**
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00

		Pfizer mRNA BNT162b2 total	283	79.35	86	24.11	69	19.35	39	10.93	126	35.33	3	0.84	0	0.00	0	0.00	0	0.00	1	0.2
	COVID-19 mRNA total	COVID-19 mRNA total	497	100.09	136	27.39	89	17.92	50	10.07	201	40.48	4	0.81	0	0.00	0	0.00	1	0.20	1	0.2
COVID-19 Non-replicating Viral Vector	COVISHIELD	4120Z003	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		4120Z029	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		COVISHIELD total	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
	COVID-19 Non-replicating Viral Vector total	COVID-19 Non-replicating Viral Vector total	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0

Abbreviations:
GBS = Guillain Barre Syndrome
Notes:
[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, pe
[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

39	**10.93**	**126**	**35.33**	**3**	**0.84**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.28**	**33**	**9.25**	**3**	**0.84**	**9**	**2.52**	**1**	**0.28**
50	**10.07**	**201**	**40.48**	**4**	**0.81**	**0**	**0.00**	**0**	**0.00**	**1**	**0.20**	**1**	**0.20**	**37**	**7.45**	**25**	**5.03**	**13**	**2.62**	**3**	**0.60**
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
0	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
e doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
verse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]
Subject: RE: Mar.18 AEFI Summary
Date: Thursday, March 18, 2021 11:00:00 AM

Thanks!

From: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>
Sent: Thursday, March 18, 2021 10:57 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Mar.18 AEFI Summary

Hi Heather,

Today's summary attached.

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	497	88.90
Serious AEFI	136	24.33
Anaphylaxis	89	15.92
Anaphylaxis Brighton levels 1/2/3	50	8.94
Other allergic	201	35.95

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Subject: March 25 AEFI report
Date: Thursday, March 25, 2021 10:27:12 AM
Attachments: COVID19_AEFI_Daily_Report_2021-03-25.html

Morning Heather,
Today's AEFI report attached.

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	523	84.37
Serious AEFI	144	23.23
Anaphylaxis	94	15.16
Anaphylaxis Brighton levels 1/2/3	53	8.55
Other allergic	209	33.72

Thanks,
Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - March 25, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020, and by March 22, 2021 there have been a total of 619,895 distributed doses. As of March 25, 2021, there have been 523 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 84.4 reports per 100,000 distributed doses (Table 1, Table 2). Of the reports to date, 144 (27.5%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 714 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Mar 25, 2021 **(N=523)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-09	2021-10	2021-11	2021-12	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	63	36	35	6	**523**	**84.37**	**100.0**	6.50	**13.0**	100.0	**1.0**	32.36	**2.6**	100.0	**1.0**
Serious AEFI[g]	21	13	15	2	**144**	**23.23**	**27.5**	1.48	**15.7**	22.8	**1.2**	7.23	**3.2**	22.3	**1.2**
Events															
Anaphylaxis	15	11	13	0	**94**	**15.16**	**18.0**	0.47	**32.3**	7.3	**2.5**	2.70	**5.6**	8.3	**2.2**
Anaphylaxis Brighton levels 1/2/3[h]	8	6	5	0	**53**	**8.55**	**10.1**	0.19	**45.0**	2.8	**3.6**	NA	–	NA	–
Other allergic	25	10	11	2	**209**	**33.72**	**40.0**	2.09	**16.1**	32.1	**1.2**	5.70	**5.9**	17.6	**2.3**
Bell's Palsy	1	0	0	0	**4**	**0.65**	**0.8**	0.02	**32.5**	0.3	**2.7**	0.06	**10.8**	0.2	**4.0**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Transverse myelitis	0	0	0	0	**1**	**0.16**	**0.2**	0.00	–	0.0	–	0.00	–	0.0	–

Transverse myelitis	0	0	0	0	**1**	**0.16**	**0.2**	0.00	–	0.0	–	0.00	–	0.0	–
Seizure	0	1	0	0	**1**	**0.16**	**0.2**	0.27	**0.6**	4.1	**0.0**	1.53	**0.1**	4.7	**0.0**
Anaesthesia/ paraesthesia[1]	4	7	3	0	**40**	**6.45**	**7.6**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	0	0	1	0	**3**	**0.48**	**0.6**	0.02	**24.0**	0.3	**2.0**	0.00	–	0.0	–
Cellulitis	1	0	0	0	**25**	**4.03**	**4.8**	0.27	**14.9**	4.1	**1.2**	0.31	**13.0**	0.9	**5.3**
Adenopathy/ lymphadenitis	3	3	0	0	**19**	**3.07**	**3.6**	0.07	**43.9**	1.0	**3.6**	0.43	**7.1**	1.3	**2.8**
Recommendations															
No further immunizations	3	2	0	0	**34**	**5.48**	**6.5**	0.25	**21.9**	3.9	**1.7**	0.67	**8.2**	2.1	**3.1**
Outcomes															
Hospitalization	3	2	2	2	**16**	**2.58**	**3.1**	0.19	**13.6**	2.8	**1.1**	3.00	**0.9**	9.3	**0.3**
Permanent disability	0	0	0	0	**0**	**0.00**	**0.0**	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	1	0	0	**3**	**0.48**	**0.6**	0.02	**24.0**	0.3	**2.0**	0.18	**2.7**	0.6	**1.0**
Health Authority															
IHA	18	10	11	1	**136**	**131.45**	**26.0**	10.10	**13.0**	24.4	**1.1**	66.52	**2.0**	34.5	**0.8**

IHA	18	10	11	1	**136**	**131.45**	**26.0**	10.10	**13.0**	24.4	**1.1**	66.52	**2.0**	34.5	**0.8**
FHA	17	15	16	2	**148**	**71.29**	**28.3**	4.34	**16.4**	22.0	**1.3**	20.32	**3.5**	19.3	**1.5**
VCHA	11	1	0	0	**84**	**59.91**	**16.1**	2.28	**26.3**	10.4	**1.5**	10.19	**5.9**	9.7	**1.7**
VIHA	14	5	6	2	**102**	**99.42**	**19.5**	9.55	**10.4**	25.9	**0.8**	38.38	**2.6**	20.6	**0.9**
NHA	3	5	2	1	**53**	**80.24**	**10.1**	26.36	**3.0**	17.4	**0.6**	116.81	**0.7**	15.9	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.0	–
18-64	55	31	23	3	**442**	**13.49**	**84.5**	1.39	**9.7**	46.1	**1.8**	10.62	**1.3**	58.5	**1.4**
65+	8	5	12	3	**81**	**8.22**	**15.5**	0.95	**8.7**	8.8	**1.8**	5.24	**1.6**	6.4	**2.4**
Gender															
Female	53	33	29	4	**466**	**17.95**	**89.1**	2.32	**7.7**	60.4	**1.5**	16.63	**1.1**	69.9	**1.3**
Male	10	3	6	2	**57**	**2.24**	**10.9**	1.56	**1.4**	39.6	**0.3**	7.26	**0.3**	30.1	**0.4**

Abbreviations:
RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome
Notes:
[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.
[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.
[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.0	–
18-64	55	31	23	3	**442**	**13.49**	**84.5**	1.39	**9.7**	46.1	**1.8**	10.62	**1.3**	58.5	**1.4**
65+	8	5	12	3	**81**	**8.22**	**15.5**	0.95	**8.7**	8.8	**1.8**	5.24	**1.6**	6.4	**2.4**
Gender															
Female	53	33	29	4	**466**	**17.95**	**89.1**	2.32	**7.7**	60.4	**1.5**	16.63	**1.1**	69.9	**1.3**
Male	10	3	6	2	**57**	**2.24**	**10.9**	1.56	**1.4**	39.6	**0.3**	7.26	**0.3**	30.1	**0.4**

Abbreviations:
RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome
Notes:
[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.
[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.
[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.
[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.
[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.
[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.
[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Mar 25, 2021 **(N=523)**

Vaccine information			Reports				Events															
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizu rate
COVID-19 mRNA	Moderna mRNA-1273	300042460	109	539.60	23	113.86	7	34.65	3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		300042698	68	328.50	15	72.46	4	19.32	3	14.49	23	111.11	1	4.83	0	0.00	0	0.00	1	4.83	0	0.0
		300042722	23	102.22	6	26.67	3	13.33	3	13.33	12	53.33	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		3000489	15	74.63	3	14.93	2	9.95	1	4.98	2	9.95	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		3001176	4	7.09	3	5.32	3	5.32	1	1.77	1	1.77	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		Unknown	1	NA	1	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
		Moderna mRNA-1273 total	**220**	**157.26**	**51**	**36.45**	**20**	**14.30**	**11**	**7.86**	**76**	**54.32**	**1**	**0.71**	**0**	**0.00**	**0**	**0.00**	**1**	**0.71**	**0**	**0.0**
		EK4175	9	230.77	4	102.56	2	51.28	2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EK4241	33	147.16	5	22.30	3	13.38	2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.0
		EK4245	31	127.18	3	12.31	2	8.21	2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EL0140	20	128.21	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0

Events																		Outcomes			
Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
3	14.85	38	188.12	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.95	13	64.36	1	4.95	1	4.95
3	14.49	23	111.11	1	4.83	0	0.00	0	0.00	1	4.83	0	0.00	3	14.49	8	38.65	1	4.83	1	4.83
3	13.33	12	53.33	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.44	2	8.89	0	0.00
1	4.98	2	9.95	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
1	1.77	1	1.77	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	1.77	0	0.00
0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA
11	**7.86**	**76**	**54.32**	**1**	**0.71**	**0**	**0.00**	**0**	**0.00**	**1**	**0.71**	**0**	**0.00**	**4**	**2.86**	**22**	**15.73**	**5**	**3.57**	**2**	**1.43**
2	51.28	2	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	25.64	2	51.28	0	0.00	0	0.00
2	8.92	14	62.43	1	4.46	0	0.00	0	0.00	0	0.00	0	0.00	1	4.46	0	0.00	1	4.46	0	0.00
2	8.21	14	57.44	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	20.51	0	0.00	0	0.00	0	0.00
2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00

COVID-19 mRNA		EL0140	20	128.21	6	38.46	5	32.05	2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EL0203	48	169.76	10	35.37	6	21.22	4	14.15	27	95.49	2	7.07	0	0.00	0	0.00	0	0.00	0	0.0
	Pfizer mRNA BNT162b2	EL1404	2	34.19	1	17.09	1	17.09	1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EL1406	38	155.90	7	28.72	6	24.62	2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EP6017	46	100.38	21	45.83	20	43.64	12	26.19	16	34.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EP6775	40	41.19	15	15.45	11	11.33	6	6.18	19	19.57	0	0.00	0	0.00	0	0.00	0	0.00	1	1.0
		ER1742	36	24.04	21	14.02	18	12.02	9	6.01	13	8.68	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		Pfizer mRNA BNT162b2 total	**303**	**72.58**	**93**	**22.28**	**74**	**17.72**	**42**	**10.06**	**133**	**31.86**	**3**	**0.72**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.2**
	COVID-19 mRNA total	**COVID-19 mRNA total**	**523**	**93.83**	**144**	**25.83**	**94**	**16.86**	**53**	**9.51**	**209**	**37.50**	**4**	**0.72**	**0**	**0.00**	**0**	**0.00**	**1**	**0.18**	**1**	**0.1**
COVID-19 Non-replicating Viral	COVISHIELD	4120Z003	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		4120Z029	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		COVISHIELD total	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.0**
	COVID-19	COVID-19	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0

2	12.82	8	51.28	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	19.23	0	0.00	0	0.00	0	0.00
4	14.15	27	95.49	2	7.07	0	0.00	0	0.00	0	0.00	0	0.00	5	17.68	0	0.00	2	7.07	0	0.00
1	17.09	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	8.21	20	82.05	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	7	28.72	1	4.10	0	0.00	0	0.00
12	26.19	16	34.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	7	15.28	0	0.00	2	4.36	0	0.00
6	6.18	19	19.57	0	0.00	0	0.00	0	0.00	0	0.00	1	1.03	3	3.09	0	0.00	3	3.09	0	0.00
9	6.01	13	8.68	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	4	2.67	0	0.00	3	2.00	1	0.67
42	**10.06**	**133**	**31.86**	**3**	**0.72**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.24**	**36**	**8.62**	**3**	**0.72**	**11**	**2.63**	**1**	**0.24**
53	**9.51**	**209**	**37.50**	**4**	**0.72**	**0**	**0.00**	**0**	**0.00**	**1**	**0.18**	**1**	**0.18**	**40**	**7.18**	**25**	**4.49**	**16**	**2.87**	**3**	**0.54**
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00

		Pfizer mRNA BNT162b2 total	303	72.58	93	22.28	74	17.72	42	10.06	133	31.86	3	0.72	0	0.00	0	0.00	0	0.00	1	0.2
	COVID-19 mRNA total	COVID-19 mRNA total	523	93.83	144	25.83	94	16.86	53	9.51	209	37.50	4	0.72	0	0.00	0	0.00	1	0.18	1	0.1
COVID-19 Non-replicating Viral Vector	COVISHIELD	4120Z003	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		4120Z029	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		COVISHIELD total	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
	COVID-19 Non-replicating Viral Vector total	COVID-19 Non-replicating Viral Vector total	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0

Abbreviations:
GBS = Guillain Barre Syndrome
Notes:
[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses distributed. If 'NA' is displayed, the doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, pe
[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

42	**10.06**	**133**	**31.86**	**3**	**0.72**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**0.24**	**36**	**8.62**	**3**	**0.72**	**11**	**2.63**	**1**	**0.24**
53	**9.51**	**209**	**37.50**	**4**	**0.72**	**0**	**0.00**	**0**	**0.00**	**1**	**0.18**	**1**	**0.18**	**40**	**7.18**	**25**	**4.49**	**16**	**2.87**	**3**	**0.54**
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
0	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
e doses distributed for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
verse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
anaphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Amos, Heather [BCCDC]
To: Youngs, Kirsten [EXT]; Nicola Lambrechts
Subject: FW: March 25 AEFI report
Date: Thursday, March 25, 2021 10:51:00 AM

Today's AEFI report.

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	523	84.37
Serious AEFI	144	23.23
Anaphylaxis	94	15.16
Anaphylaxis Brighton levels 1/2/3	53	8.55
Other allergic	209	33.72

From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]
Subject: RE: March 25 AEFI report
Date: Thursday, March 25, 2021 10:51:00 AM

Thank you!

From: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>
Sent: Thursday, March 25, 2021 10:27 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Subject: March 25 AEFI report

Morning Heather,

Today's AEFI report attached.

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	523	84.37
Serious AEFI	144	23.23
Anaphylaxis	94	15.16
Anaphylaxis Brighton levels 1/2/3	53	8.55
Other allergic	209	33.72

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Naus, Monika [BCCDC]
Subject: April 8 Public COVID19 AEFI report
Date: Thursday, April 08, 2021 10:34:29 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-04-08.docx
COVID19_AEFI_Weekly_Report_2021-04-08.pdf

Hi Heather,
Attached is the final version of this week's (and first!) public COVID-19 AEFI report. I've included a Word and PDF, but only the PDF would be posted to the website. You were still deciding where on the website it would make sense to include this report, as the COVID-19 Data section was being reworked.
Monika was going to send you some key messages related to the report as well.
Thanks,
Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to April 03, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including April 03, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in the reports received in BC to date. These results are in keeping with observed events elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of the vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed and reported as anaphylaxis out of an abundance of caution. Serious events have not been reported at rates higher than expected compared to background rates.

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[5] When an AEFI report is received at a local public health unit, it is reviewed and recorded in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[6] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[7]

Definitions

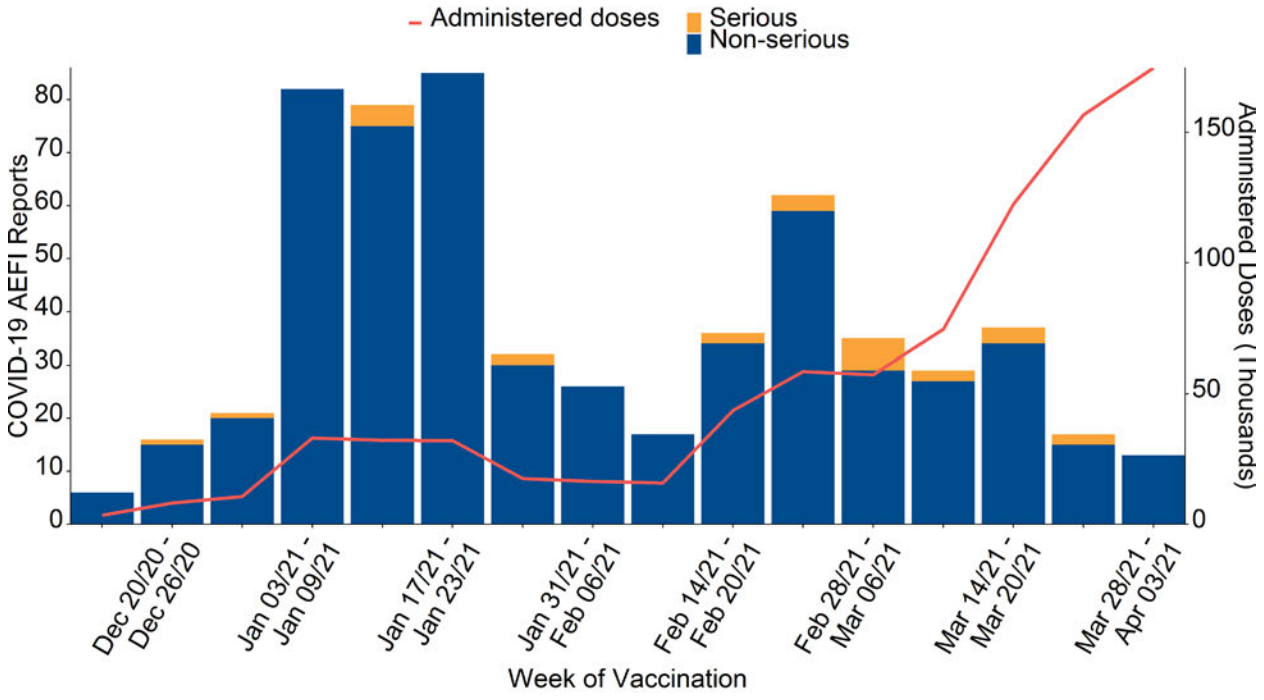
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[8]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of April 03, 2021, there have been 857,644 COVID-19 vaccine doses administered in BC and 593 COVID-19 AEFI reports (69.1 reports per 100,000 doses administered)
- 26 reports (4.4%) met the serious definition, for a rate of 3.0 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 - Apr.03, 2021 **(N=593)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including April 03, 2021, a total of 857,644 doses have been administered. During this period, there have been 593 AEFI reports following a COVID-19 vaccine, for a reporting rate of 69.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive,

investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 - Apr.03, 2021 **(N=593)**

		COVID-19 Vaccine		
	All COVID-19 Vaccines	**COVISHIELD**	**Moderna mRNA**	**Pfizer mRNA**
Total reports	**593**	**10**	**239**	**344**
Non-serious reports	567	9	230	328
Serious reports	26	1	9	16
Proportion serious	4.4%	10%	3.8%	4.7%
Dose 1 reports	507	10	213	284
Dose 2 reports	86	0	26	60
Total doses administered	**857,644**	**34,058**	**144,338**	**679,248**
Dose 1 administered	770,236	34,058	127,228	608,950
Dose 2 administered	87,408	0	17,110	70,298
Total reporting rate	**69.1**	**29.4**	**165.6**	**50.6**
Serious rate	3.0	2.9	6.2	2.4
Dose 1 rate	65.8	29.4	167.4	46.6
Dose 2 rate	98.4	--	152.0	85.4

Note: Rates calculated per 100,000 doses administered

Serious Reports

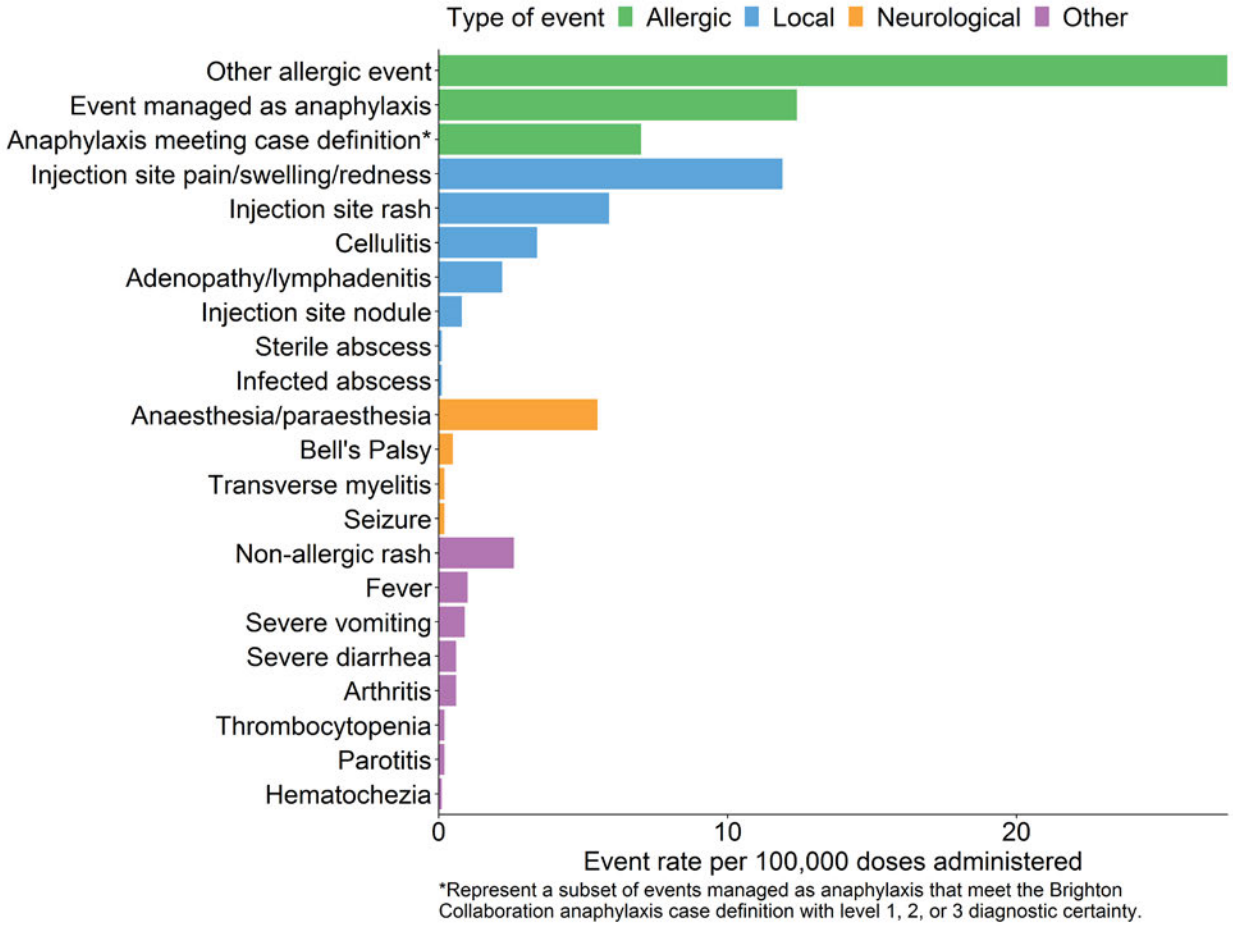
Twenty-six reports (4.4%) were considered serious (refer to serious AEFI definition above). Of these, 23 individuals were admitted to hospital. These included nine individuals hospitalized after anaphylaxis or other allergic event, eight for neurological investigations/monitoring (including two for transverse myelitis, one for a seizure, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), five for chest pain/cardiac events, and one for a pregnancy related complication.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[5] Death may also be recorded as the outcome of a specific reportable event. Three serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death. The other death, which was still being investigated at the time of this report, was the outcome of a cardiac event that occurred in an elderly individual with multiple underlying medical conditions.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 593 AEFI reports received up to April 03, 2021 contained a total of 809 adverse events for a ratio of 1.4 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[9]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 - Apr.03, 2021 **(N=809)**



Event Descriptions

One hundred six reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 60 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[9] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Twenty-nine reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[10] None of these reports were confirmed by microbial testing.

Seven reports contained a diagnosed neurological event. Four individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. One individual, with a history of a seizure disorder, was admitted to hospital for seizures.

There were two reports of thrombocytopenia, although one was unconfirmed with no platelet count provided and still under investigation at the time of this report. The other report was for an individual who had a prior episode of thrombocytopenia pre-vaccination and was found to have a low platelet count roughly two weeks after vaccination when seen in the emergency department for signs of bleeding.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on April 08, 2021. Only AEFIs reported and doses administered up to April 03, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

References

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to April 03, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including April 03, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in the reports received in BC to date. These results are in keeping with observed events elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of the vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed and reported as anaphylaxis out of an abundance of caution. Serious events have not been reported at rates higher than expected compared to background rates.

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[5] When an AEFI report is received at a local public health unit, it is reviewed and recorded in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[6] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[7]

Definitions

1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[8]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of April 03, 2021, there have been 857,644 COVID-19 vaccine doses administered in BC and 593 COVID-19 AEFI reports (69.1 reports per 100,000 doses administered)
- 26 reports (4.4%) met the serious definition, for a rate of 3.0 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

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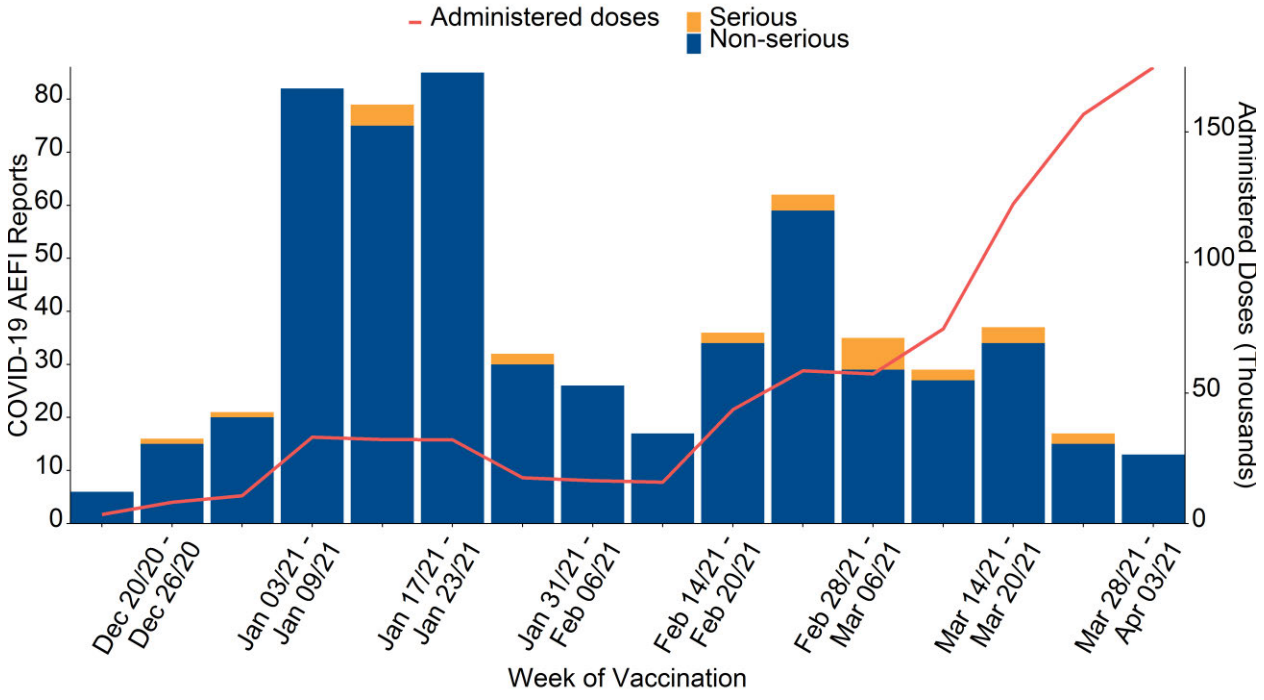

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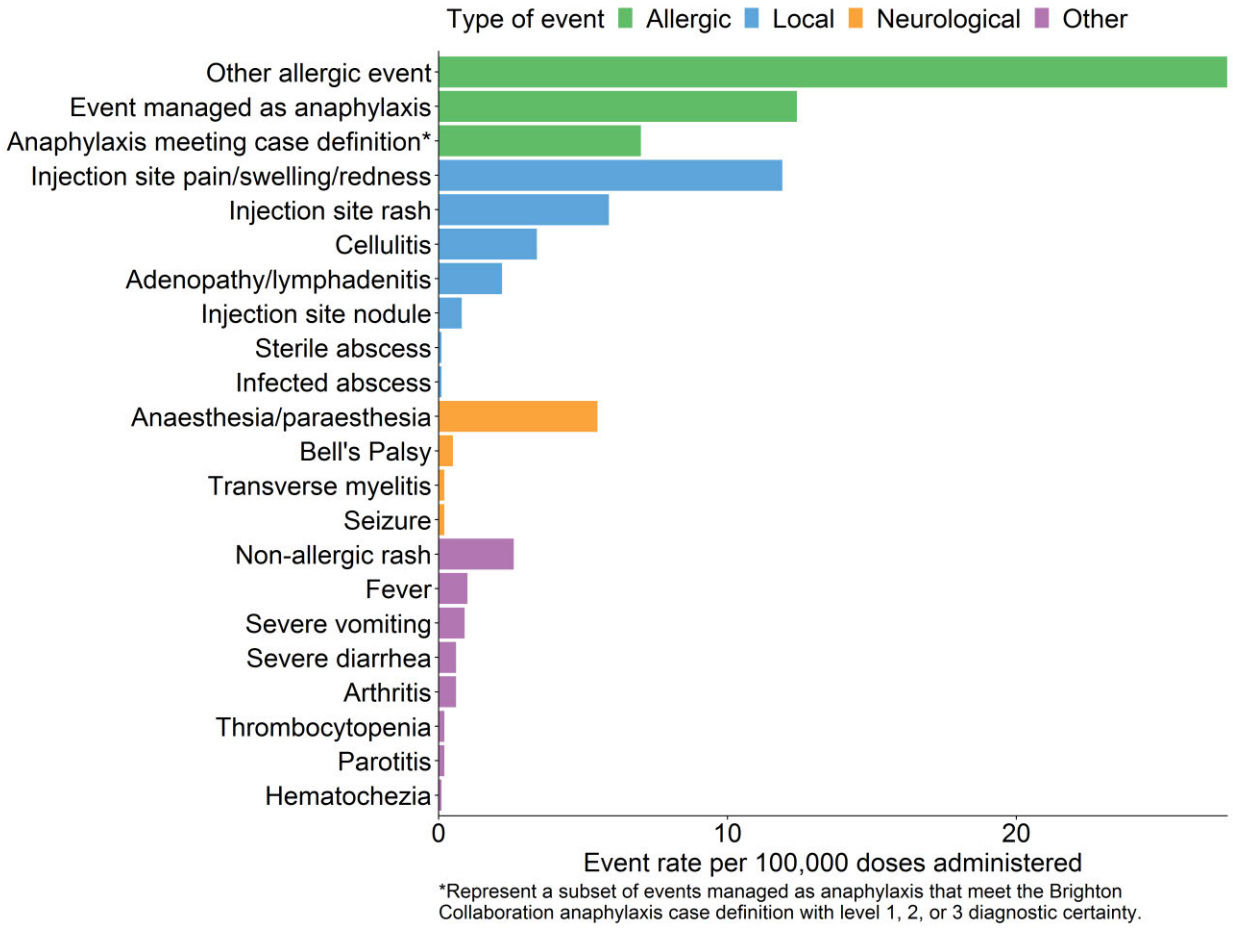

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References

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Routine AEFI report April 8
Date: Thursday, April 08, 2021 10:49:08 AM
Attachments: COVID19_AEFI_Daily_Report_2021-04-08.html

Hi Heather,

Attached is today's daily AEFI report (non-public) with relevant details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	599	62.98
Serious AEFI	169	17.77
Anaphylaxis	106	11.15
Anaphylaxis Brighton levels 1/2/3	60	6.31
Other allergic	235	24.71

Just a note that I've updated the report so rates are now calculated per doses administered (rather than doses distributed) and those doses administered data will be updated daily.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

This e-mail message, including any attachments, is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged and/or confidential. If you are not the intended recipient or the employee or agent responsible for delivering the communication to the intended recipient, please notify us immediately by replying to this message and then delete this message from your system. You are hereby notified that any use, dissemination, distribution and/or reproduction of this message and/or any attachments by unintended recipients is unauthorized and may be unlawful.

BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - April 08, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020. By April 08, 2021 there have been a total of 951,025 doses administered and 599 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 63.0 reports per 100,000 administered doses (Table 1, Table 2). Of the reports to date, 169 (28.2%) met one or more of the criteria to be considered serious (refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 814 adverse events reported, giving a ratio of 1.4 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Apr 08, 2021 **(N=599)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-11	2021-12	2021-13	2021-14	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b],[c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d],[e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	42	27	38	6	**599**	**62.98**	**100.0**	6.50	**9.7**	100.0	**1.0**	32.36	**1.9**	100.0	**1.0**
Serious AEFI[g]	17	9	13	1	**169**	**17.77**	**28.2**	1.46	**12.2**	22.5	**1.3**	7.23	**2.5**	22.3	**1.3**
Events															
Anaphylaxis	13	5	8	0	**106**	**11.15**	**17.7**	0.47	**23.7**	7.3	**2.4**	2.70	**4.1**	8.3	**2.1**
Anaphylaxis Brighton levels 1/2/3[h]	5	1	6	0	**60**	**6.31**	**10.0**	0.19	**33.2**	2.8	**3.6**	NA	–	NA	–
Other allergic	14	10	12	1	**235**	**24.71**	**39.2**	2.09	**11.8**	32.1	**1.2**	5.70	**4.3**	17.6	**2.2**
Bell's Palsy	0	0	0	0	**4**	**0.42**	**0.7**	0.02	**21.0**	0.3	**2.3**	0.06	**7.0**	0.2	**3.5**
GBS	0	0	0	0	**0**	**0.00**	**0.0**	0.03	–	0.5	–	0.12	–	0.4	–
Encephalitis	0	0	0	0	**0**	**0.00**	**0.0**	0.02	–	0.3	–	0.00	–	0.0	–
Transverse myelitis	0	0	0	0	**2**	**0.21**	**0.3**	0.00	–	0.0	–	0.00	–	0.0	–

Transverse myelitis	0	0	0	0	**2**	**0.21**	**0.3**	0.00	–	0.0	–	0.00	–	0.0	–
Seizure	0	0	0	0	**2**	**0.21**	**0.3**	0.27	**0.8**	4.1	**0.1**	1.53	**0.1**	4.7	**0.1**
Anaesthesia/ paraesthesia[1]	4	2	4	1	**48**	**5.05**	**8.0**	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	1	0	0	0	**2**	**0.21**	**0.3**	0.02	**10.5**	0.3	**1.0**	0.00	–	0.0	–
Cellulitis	0	1	2	0	**29**	**3.05**	**4.8**	0.25	**12.2**	3.9	**1.2**	0.31	**9.8**	0.9	**5.3**
Adenopathy/ lymphadenitis	0	0	0	0	**19**	**2.00**	**3.2**	0.07	**28.6**	1.0	**3.2**	0.43	**4.7**	1.3	**2.5**
Recommendations															
No further immunizations	1	0	0	0	**38**	**4.00**	**6.3**	0.25	**16.0**	3.9	**1.6**	0.67	**6.0**	2.1	**3.0**
Outcomes															
Hospitalization	4	3	2	1	**24**	**2.52**	**4.0**	0.19	**13.3**	2.8	**1.4**	3.00	**0.8**	9.3	**0.4**
Permanent disability	0	0	1	0	**1**	**0.11**	**0.2**	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	0	0	0	**3**	**0.32**	**0.5**	0.02	**16.0**	0.3	**1.7**	0.18	**1.8**	0.6	**0.8**
Health Authority															
IHA	11	4	9	2	**149**	**99.26**	**24.9**	10.10	**9.8**	24.4	**1.0**	66.52	**1.5**	34.5	**0.7**

Health Authority															
IHA	11	4	9	2	**149**	**99.26**	**24.9**	10.10	**9.8**	24.4	**1.0**	66.52	**1.5**	34.5	**0.7**
FHA	16	15	16	0	**179**	**52.24**	**29.9**	4.34	**12.0**	22.0	**1.4**	20.32	**2.6**	19.3	**1.5**
VCHA	0	0	1	0	**86**	**37.57**	**14.4**	2.28	**16.5**	10.4	**1.4**	10.19	**3.7**	9.7	**1.5**
VIHA	10	5	10	4	**124**	**72.98**	**20.7**	9.55	**7.6**	25.9	**0.8**	38.38	**1.9**	20.6	**1.0**
NHA	5	3	2	0	**61**	**102.70**	**10.2**	26.36	**3.9**	17.4	**0.6**	116.81	**0.9**	15.9	**0.6**
Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	**–**	45.1	**–**	21.73	**–**	35.0	**–**
18-64	31	17	26	4	**498**	**15.20**	**83.1**	1.39	**10.9**	46.1	**1.8**	10.62	**1.4**	58.5	**1.4**
65+	11	10	12	2	**101**	**10.25**	**16.9**	0.95	**10.8**	8.8	**1.9**	5.24	**2.0**	6.4	**2.6**
Gender															
Female	34	20	33	5	**529**	**20.38**	**88.3**	2.32	**8.8**	60.4	**1.5**	16.63	**1.2**	69.9	**1.3**
Male	8	7	5	1	**70**	**2.75**	**11.7**	1.56	**1.8**	39.6	**0.3**	7.26	**0.4**	30.1	**0.4**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

Age Group															
<18	0	0	0	0	**0**	**0.00**	**0.0**	5.03	–	45.1	–	21.73	–	35.0	–
18-64	31	17	26	4	**498**	**15.20**	**83.1**	1.39	**10.9**	46.1	**1.8**	10.62	**1.4**	58.5	**1.4**
65+	11	10	12	2	**101**	**10.25**	**16.9**	0.95	**10.8**	8.8	**1.9**	5.24	**2.0**	6.4	**2.6**
Gender															
Female	34	20	33	5	**529**	**20.38**	**88.3**	2.32	**8.8**	60.4	**1.5**	16.63	**1.2**	69.9	**1.3**
Male	8	7	5	1	**70**	**2.75**	**11.7**	1.56	**1.8**	39.6	**0.3**	7.26	**0.4**	30.1	**0.4**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Apr 08, 2021 **(N=599)**

Vaccine information			Reports				Events														
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizu rate
		300042460	110	541.45	24	118.13	8	39.38	3	14.77	38	187.04	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		300042698	69	334.09	15	72.63	4	19.37	3	14.53	23	111.36	1	4.84	0	0.00	0	0.00	1	4.84	0	0.0
		300042722	25	109.52	8	35.05	3	13.14	3	13.14	12	52.57	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		3000489	18	103.53	4	23.01	2	11.50	1	5.75	5	28.76	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
	Moderna mRNA-1273	3001176	16	29.51	6	11.07	4	7.38	2	3.69	5	9.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		3001530	2	13.30	1	6.65	1	6.65	1	6.65	1	6.65	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		3001652	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		3001654	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		Moderna mRNA-1273 total	**240**	**142.97**	**58**	**34.55**	**22**	**13.11**	**13**	**7.74**	**84**	**50.04**	**1**	**0.60**	**0**	**0.00**	**0**	**0.00**	**1**	**0.60**	**0**	**0.0**
		EK4175	9	192.93	4	85.74	2	42.87	2	42.87	2	42.87	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EK4241	34	149.30	5	21.96	3	13.17	2	8.78	14	61.48	1	4.39	0	0.00	0	0.00	0	0.00	0	0.0

Events																		Outcomes			
Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
3	14.77	38	187.04	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	4.92	13	63.99	1	4.92	1	4.92
3	14.53	23	111.36	1	4.84	0	0.00	0	0.00	1	4.84	0	0.00	3	14.53	8	38.74	1	4.84	1	4.84
3	13.14	12	52.57	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	8.76	3	13.14	0	0.00
1	5.75	5	28.76	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	5.75	0	0.00	0	0.00
2	3.69	5	9.22	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	3.69	1	1.84	2	3.69	0	0.00
1	6.65	1	6.65	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
13	**7.74**	**84**	**50.04**	**1**	**0.60**	**0**	**0.00**	**0**	**0.00**	**1**	**0.60**	**0**	**0.00**	**6**	**3.57**	**25**	**14.89**	**7**	**4.17**	**2**	**1.19**
2	42.87	2	42.87	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	21.44	2	42.87	0	0.00	0	0.00
2	8.78	14	61.48	1	4.39	0	0.00	0	0.00	0	0.00	0	0.00	1	4.39	0	0.00	1	4.39	0	0.00

COVID-19 mRNA	Pfizer mRNA BNT162b2	EK4175	9	192.93	4	85.74	2	42.87	2	42.87	2	42.87	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EK4241	34	149.30	5	21.96	3	13.17	2	8.78	14	61.48	1	4.39	0	0.00	0	0.00	0	0.00	0	0.0
		EK4245	32	125.81	4	15.73	2	7.86	2	7.86	14	55.04	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EL0140	21	119.30	6	34.09	5	28.41	2	11.36	8	45.45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EL0203	48	162.26	11	37.18	6	20.28	4	13.52	27	91.27	2	6.76	0	0.00	0	0.00	1	3.38	0	0.0
		EL1404	2	28.48	1	14.24	1	14.24	1	14.24	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EL1406	39	147.96	7	26.56	6	22.76	2	7.59	20	75.88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EN1196	2	4.16	1	2.08	0	0.00	0	0.00	1	2.08	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EN1198	10	14.64	4	5.86	3	4.39	2	2.93	2	2.93	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EP6017	51	91.20	22	39.34	20	35.76	12	21.46	17	30.40	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EP6775	48	49.15	18	18.43	12	12.29	7	7.17	21	21.50	0	0.00	0	0.00	0	0.00	0	0.00	2	2.0
		ER1742	47	21.49	21	9.60	19	8.69	10	4.57	20	9.14	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EW3344	5	4.29	2	1.72	2	1.72	1	0.86	2	1.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		EX0904	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		Pfizer mRNA BNT162b2	**348**	**46.46**	**106**	**14.15**	**81**	**10.81**	**47**	**6.27**	**148**	**19.76**	**3**	**0.40**	**0**	**0.00**	**0**	**0.00**	**1**	**0.13**	**2**	**0.2**

2	42.87	2	42.87	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	21.44	2	42.87	0	0.00	0	0.00
2	8.78	14	61.48	1	4.39	0	0.00	0	0.00	0	0.00	0	0.00	1	4.39	0	0.00	1	4.39	0	0.00
2	7.86	14	55.04	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	19.66	0	0.00	0	0.00	0	0.00
2	11.36	8	45.45	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	17.04	0	0.00	0	0.00	0	0.00
4	13.52	27	91.27	2	6.76	0	0.00	0	0.00	1	3.38	0	0.00	5	16.90	0	0.00	3	10.14	0	0.00
1	14.24	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	7.59	20	75.88	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	7	26.56	1	3.79	0	0.00	0	0.00
0	0.00	1	2.08	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	2.93	2	2.93	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	1.46	0	0.00	1	1.46	0	0.00
12	21.46	17	30.40	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	8	14.31	0	0.00	3	5.36	0	0.00
7	7.17	21	21.50	0	0.00	0	0.00	0	0.00	0	0.00	2	2.05	5	5.12	0	0.00	5	5.12	0	0.00
10	4.57	20	9.14	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	2.74	0	0.00	3	1.37	1	0.46
1	0.86	2	1.72	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
47	**6.27**	**148**	**19.76**	**3**	**0.40**	**0**	**0.00**	**0**	**0.00**	**1**	**0.13**	**2**	**0.27**	**42**	**5.61**	**3**	**0.40**	**16**	**2.14**	**1**	**0.13**

		Pfizer mRNA BNT162b2 total	348	46.46	106	14.15	81	10.81	47	6.27	148	19.76	3	0.40	0	0.00	0	0.00	1	0.13	2	0.2
	COVID-19 mRNA total	COVID-19 mRNA total	588	64.12	164	17.89	103	11.23	60	6.54	232	25.30	4	0.44	0	0.00	0	0.00	2	0.22	2	0.2
COVID-19 Non-replicating Viral Vector	COVISHIELD	4120Z003	9	34.02	5	18.90	3	11.34	0	0.00	2	7.56	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		4120Z029	2	26.30	0	0.00	0	0.00	0	0.00	1	13.15	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
		COVISHIELD total	11	32.30	5	14.68	3	8.81	0	0.00	3	8.81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0
	COVID-19 Non-replicating Viral Vector total	COVID-19 Non-replicating Viral Vector total	11	32.30	5	14.68	3	8.81	0	0.00	3	8.81	0	0.00	0	0.00	0	0.00	0	0.00	0	0.0

Abbreviations:
GBS = Guillain Barre Syndrome
Notes:
[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses administered. If 'NA' is displayed, the doses administered for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, pe
[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

47	**6.27**	**148**	**19.76**	**3**	**0.40**	**0**	**0.00**	**0**	**0.00**	**1**	**0.13**	**2**	**0.27**	**42**	**5.61**	**3**	**0.40**	**16**	**2.14**	**1**	**0.13**
60	**6.54**	**232**	**25.30**	**4**	**0.44**	**0**	**0.00**	**0**	**0.00**	**2**	**0.22**	**2**	**0.22**	**48**	**5.23**	**28**	**3.05**	**23**	**2.51**	**3**	**0.33**
0	0.00	2	7.56	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.78	1	3.78	0	0.00
0	0.00	1	13.15	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	**0.00**	**3**	**8.81**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**2.94**	**1**	**2.94**	**0**	**0.00**
0	**0.00**	**3**	**8.81**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**1**	**2.94**	**1**	**2.94**	**0**	**0.00**

are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
the doses administered for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
verse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
anaphylaxis case definition.

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2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
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From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]
Subject: RE: Routine AEFI report April 8
Date: Thursday, April 08, 2021 4:43:21 PM

Hi,

I don't think you need to send this anymore if we're going to be posting the other report.

Heather

From: Noftall, Kyle [BCCDC]
Sent: Thursday, April 08, 2021 10:49 AM
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Routine AEFI report April 8

Hi Heather,

Attached is today's daily AEFI report (non-public) with relevant details here:

	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)
Total AEFI	599	62.98
Serious AEFI	169	17.77
Anaphylaxis	106	11.15
Anaphylaxis Brighton levels 1/2/3	60	6.31
Other allergic	235	24.71

Just a note that I've updated the report so rates are now calculated per doses administered (rather than doses distributed) and those doses administered data will be updated daily.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Amos, Heather [BCCDC]
To: Naus, Monika [BCCDC]; Noftall, Kyle [BCCDC]
Subject: RE: April 8 Public COVID19 AEFI report
Date: Thursday, April 08, 2021 7:18:00 PM

Hi,
I'm so sorry – I've been meaning to write all evening to say this has been posted.
I added it to the Vaccine Monitoring Vaccine Safety page: http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/monitoring-vaccine-uptake-safety-and-effectiveness/#aefi
There is a also a link from the COVID-19 Data page: http://www.bccdc.ca/health-info/diseases-conditions/covid-19/data#vaccine
Heather

From: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Sent: Thursday, April 08, 2021 10:55 AM
To: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Subject: RE: April 8 Public COVID19 AEFI report

Here are the key messages; feel free to embellish Heather as you see fit from a 'comms' perspective:

- Vaccine safety surveillance is conducted for all vaccines including the COVID-19 vaccines under a regulatory framework in BC
- This surveillance system relies on reporting by health care providers to the regional, provincial and national reporting systems
- The reports received at BCCDC on the four COVID-19 vaccines used in the province to date indicate that these vaccines are very safe
- No unusual or concerning signals have been identified BC nor in Canada
- Serious allergic events called anaphylaxis and non-serious allergic events have been reported at higher rates than in other jurisdictions. This is likely due to symptoms of anxiety or faintness resembling an early anaphylactic reaction, with treatment initiated.
- All of the serious allergic events have been well managed and all recovered
- Because of the safety signal associated with use of AstraZeneca vaccine observed in Europe, the use of this vaccine in BC was limited starting Monday March 29th to those aged 55-65 years old
- BC will continue to conduct surveillance on these and additional COVID-19 vaccines as these are introduced into the program

Thank you,
Monika

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell 604.219.4524
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday)
mnds.assist@bccdc.ca Tel 604 707 2519
I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

From: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>
Sent: Thursday, April 08, 2021 10:34 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: April 8 Public COVID19 AEFI report

Hi Heather,

Attached is the final version of this week's (and first!) public COVID-19 AEFI report. I've included a Word and PDF, but only the PDF would be posted to the website. You were still deciding where on the website it would make sense to include this report, as the COVID-19 Data section was being reworked.

Monika was going to send you some key messages related to the report as well.

Thanks,

Kyle

Kyle Noftall, MPH

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Public AEFI report - April 15
Date: Thursday, April 15, 2021 11:23:23 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-04-15.docx
COVID19_AEFI_Weekly_Report_2021-04-15.pdf

Hi Heather,

Attached is this week's public COVID19 AEFI report (PDF for posting).

Thank you,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to April 10, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including April 10, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in the reports received in BC to date. These results are in keeping with observed events elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of the vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed and reported as anaphylaxis out of an abundance of caution. Serious events have not been reported at rates higher than expected compared to background rates.

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[5] When an AEFI report is received at a local public health unit, it is reviewed and recorded in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[6] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[7]

Definitions

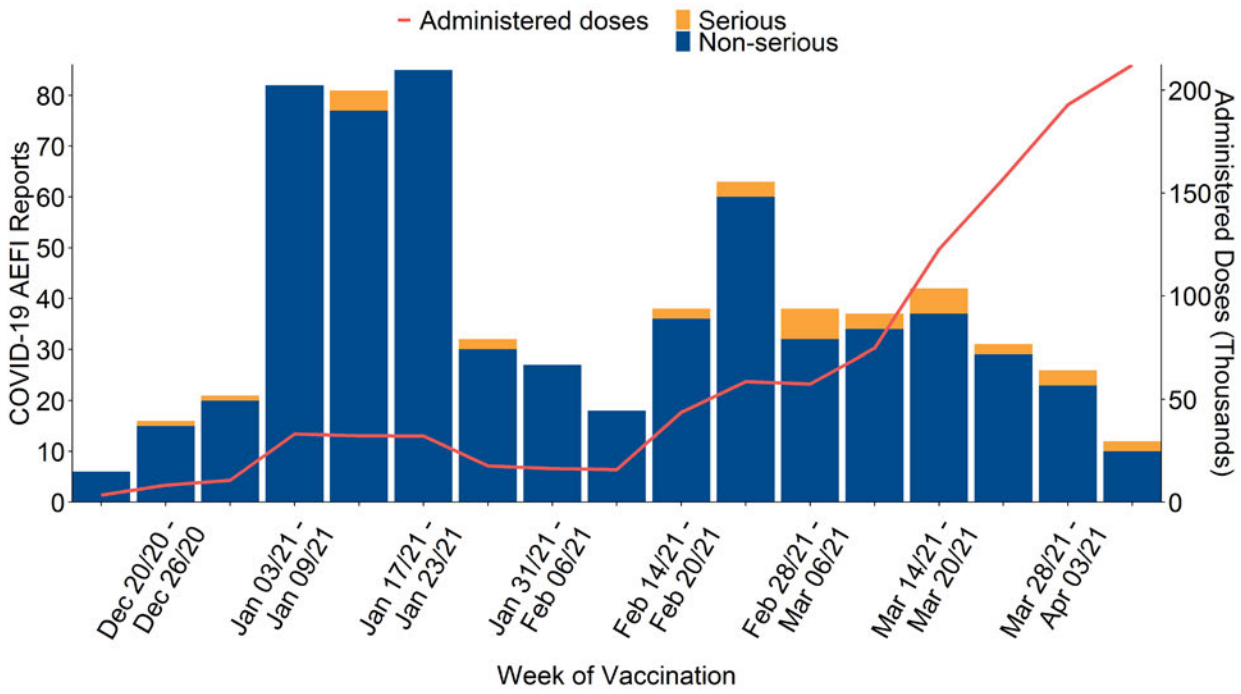
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[8]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of April 10, 2021, there have been 1,089,393 COVID-19 vaccine doses administered in BC and 655 COVID-19 AEFI reports (60.1 reports per 100,000 doses administered)
- 34 reports (5.2%) met the serious definition, for a rate of 3.1 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 - Apr.10, 2021 **(N=655)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including April 10, 2021, a total of 1,089,393 doses have been administered. During this period, there have been 655 AEFI reports following a COVID-19 vaccine, for a reporting rate of 60.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of

vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 - Apr.10, 2021 **(N=655)**

		COVID-19 Vaccine			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**655**	**0**	**17**	**253**	**385**
Non-serious reports	621	0	15	241	365
Serious reports	34	0	2	12	20
Proportion serious	5.2%	0.0%	11.8%	4.7%	5.2%
Dose 1 reports	566	0	17	227	322
Dose 2 reports	89	0	0	26	63
Total doses administered	**1,089,393**	**31,240**	**53,941**	**191,787**	**812,425**
Dose 1 administered	1,001,582	31,240	53,941	174,434	741,967
Dose 2 administered	87,811	0	0	17,353	70,458
Total reporting rate	**60.1**	**0.0**	**31.5**	**131.9**	**47.4**
Serious rate	3.1	0.0	3.7	6.3	2.5
Dose 1 rate	56.5	0.0	31.5	130.1	43.4
Dose 2 rate	101.4	--	--	149.8	89.4

Note: Rates calculated per 100,000 doses administered

Serious Reports

Thirty-four reports (5.2%) were considered serious (refer to serious AEFI definition above). Of these, 30 individuals were admitted to hospital. These included thirteen individuals hospitalized after anaphylaxis or other allergic event, eleven for neurological investigations/monitoring (including two for transverse myelitis, two for seizures, one stroke, one encephalitis/ hemorrhage, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), four for chest pain/cardiac events, one respiratory distress, and one for a pregnancy related complication.

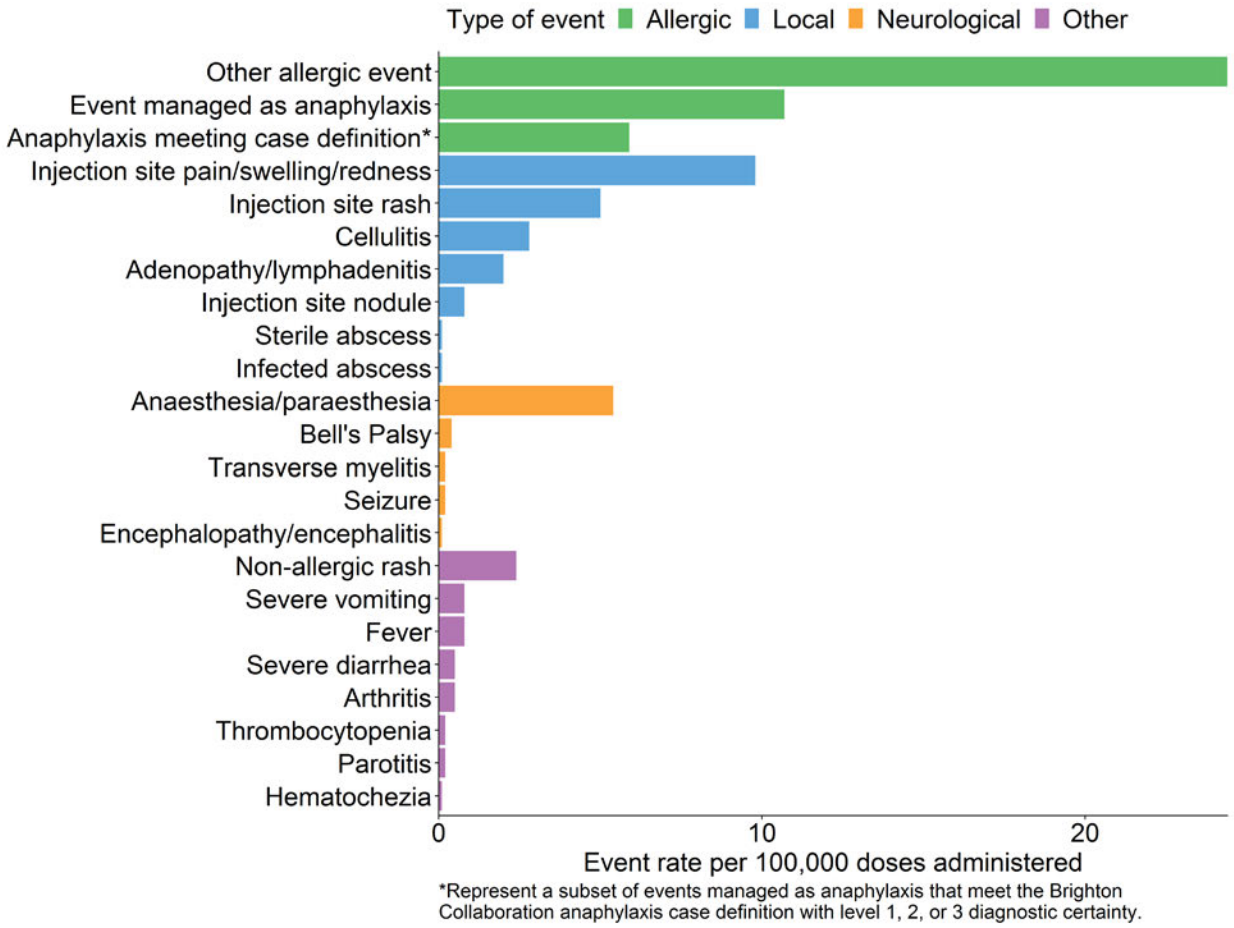
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[5] Death may also be recorded as the outcome of a specific reportable event. Four serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based off of the individuals' medical history. The third death was the outcome of a

cardiac event that occurred in an elderly individual with multiple underlying medical conditions. The fourth death also occurred in an elderly individual with underlying medical conditions but was still being investigated at the time of this report.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 655 AEFI reports received up to April 10, 2021 contained a total of 899 adverse events for a ratio of 1.4 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[9]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 - Apr.10, 2021 **(N=899)**



Event Descriptions

One hundred seventeen reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 64 (55%) met the

Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[9] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Thirty reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[10] None of these reports were confirmed by microbial testing.

Nine reports contained a diagnosed neurological event. Four individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. Two individuals were admitted to hospital for seizures, including one with a history of a seizure disorder. The other had an event that appeared to be a seizure but upon further investigation could have been related to a cardiac arrhythmia. Finally, one individual was admitted to hospital for an intracerebral hemorrhage and query encephalitis.

There were two reports of thrombocytopenia. Both were for individuals who had a prior episode of thrombocytopenia pre-vaccination and were found to have a low platelet count after vaccination when seen in the emergency department for signs of bleeding. Neither was associated with receipt of AstraZeneca/COVISHIELD vaccine.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on April 15, 2021. Only AEFIs reported and doses administered up to April 10, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

References

1. BC Centre for Disease Control. Adverse events following immunization [Internet]; 2021 [cited 2021 Mar 23]. Available from: http://www.bccdc.ca/health-professionals/clinical-resources/adverse-events-following-immunization
2. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
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British Columbia Report

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Background

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Key Findings

- As of April 10, 2021, there have been 1,089,393 COVID-19 vaccine doses administered in BC and 655 COVID-19 AEFI reports (60.1 reports per 100,000 doses administered)
- 34 reports (5.2%) met the serious definition, for a rate of 3.1 per 100,000 doses administered
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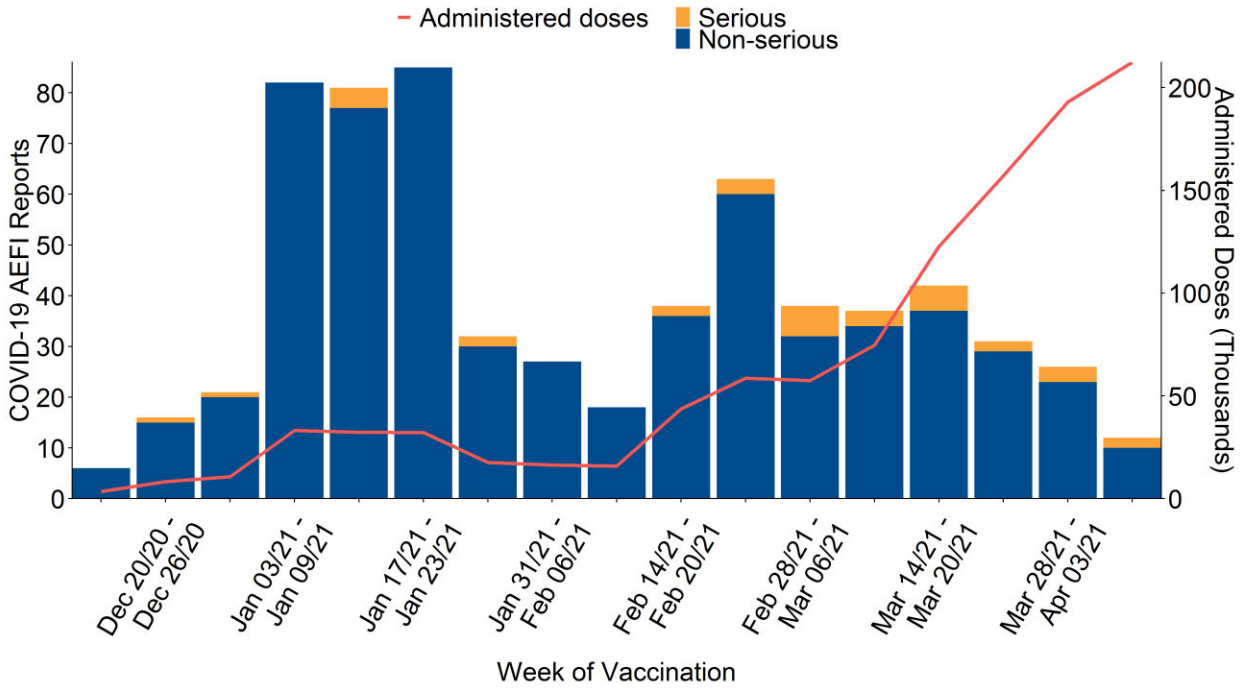
Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 - Apr.10, 2021 **(N=655)**



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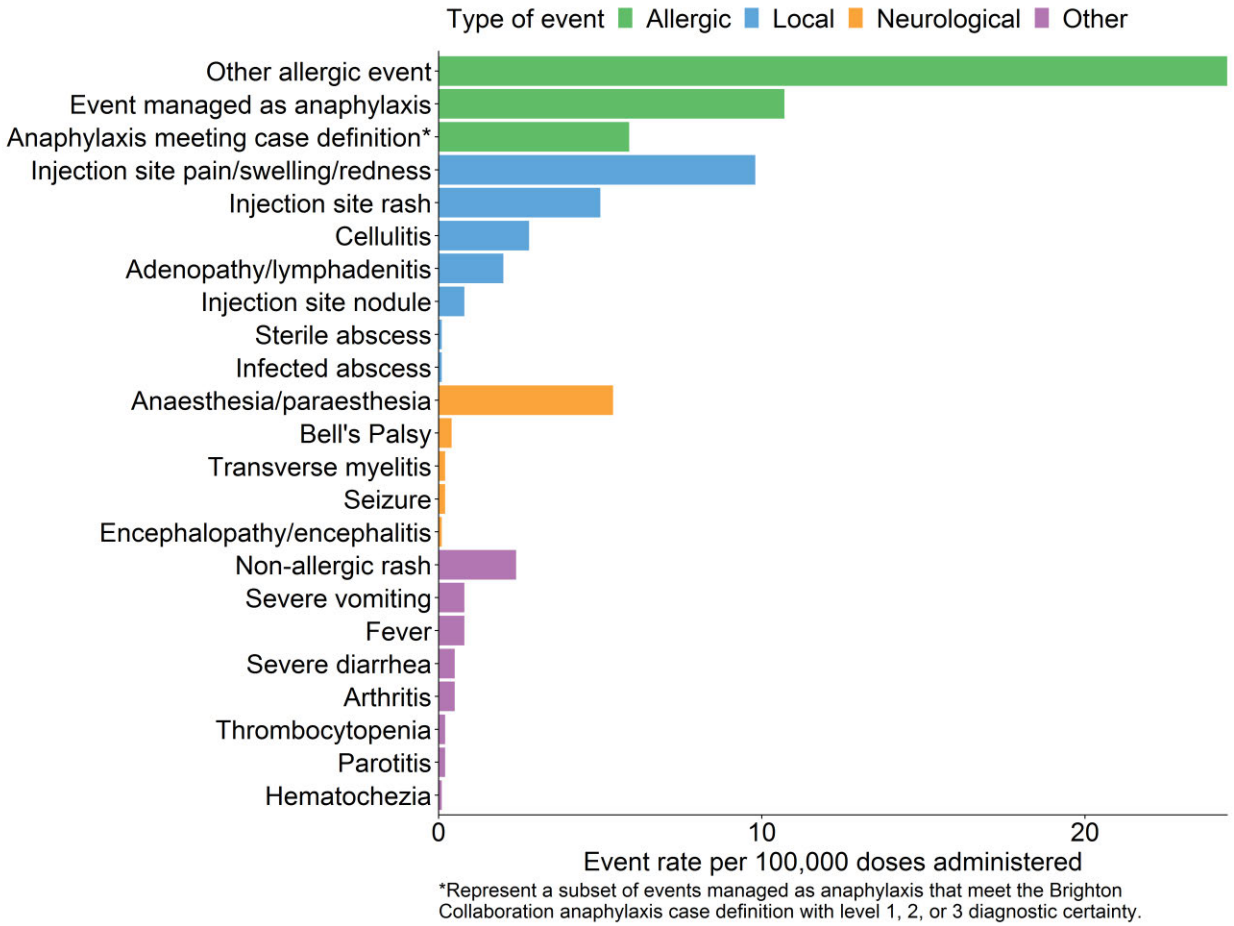

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References

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Public AEFI Report
Date: Thursday, April 22, 2021 1:31:09 PM
Attachments: COVID19_AEFI_Weekly_Report_2021-04-22.pdf

Hi Heather,

This week's public AEFI report is attached.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to April 17, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including April 17, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in the reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. There have been no reports of thrombocytopenia with thrombosis syndrome (TTS) reported in BC to date; this syndrome was identified in March in Europe in association with the ChAdOx1 (chimpanzee adenovirus vector AstraZeneca) COVID-19 vaccine, with very few cases reported in Canada to date.[5,6]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[7] When an AEFI report is received at a local public health unit, it is reviewed and recorded in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[8] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[9]

Definitions

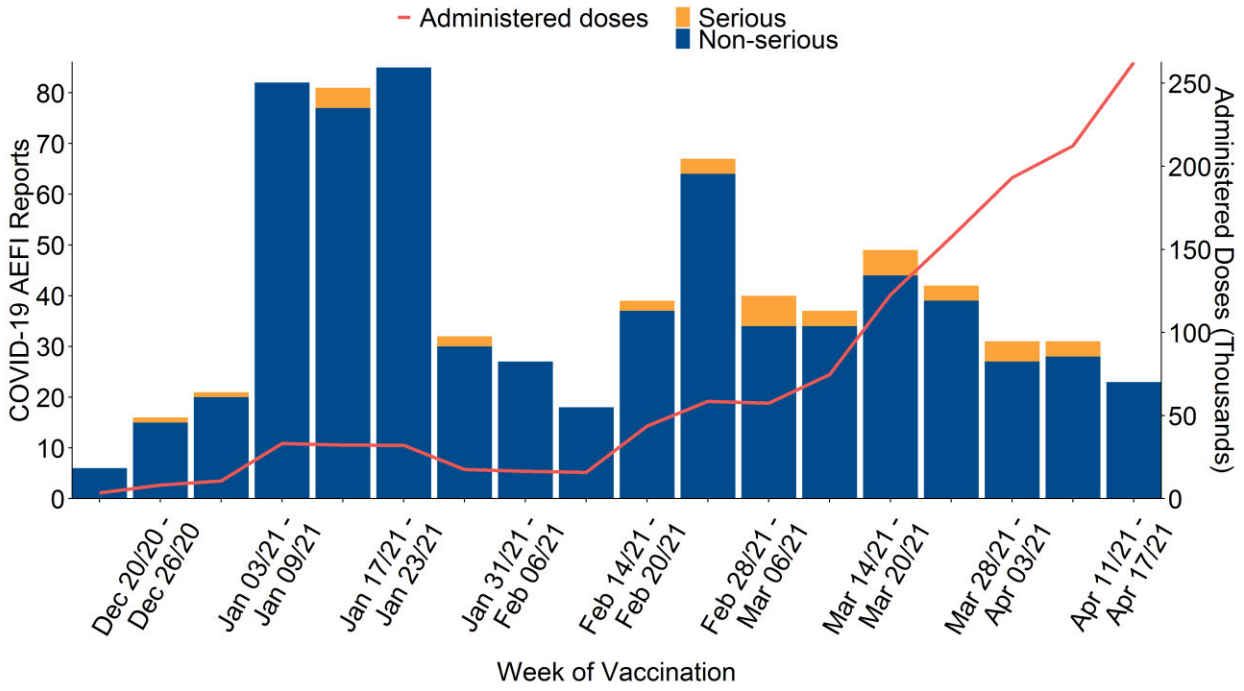
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[10]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of April 17, 2021, there have been 1,352,709 COVID-19 vaccine doses administered in BC and 727 COVID-19 AEFI reports (53.7 reports per 100,000 doses administered)
- 37 reports (5.1%) met the serious definition, for a rate of 2.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 - Apr.17, 2021 **(N=727)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including April 17, 2021, a total of 1,352,709 doses have been administered. During this period, there have been 727 AEFI reports following a COVID-19 vaccine, for a reporting rate of 53.7 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of

vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 - Apr.17, 2021 **(N=727)**

		COVID-19 Vaccine			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**727**	**4**	**24**	**274**	**425**
Non-serious reports	690	4	21	262	403
Serious reports	37	0	3	12	22
Proportion serious	5.1%	0%	12.5%	4.4%	5.2%
Dose 1 reports	638	4	24	248	362
Dose 2 reports	89	0	0	26	63
Total doses administered	**1,352,709**	**76,943**	**55,461**	**255,861**	**964,444**
Dose 1 administered	1,264,522	76,941	55,461	238,351	893,769
Dose 2 administered	88,187	2	0	17,510	70,675
Total reporting rate	**53.7**	**5.2**	**43.3**	**107.1**	**44.1**
Serious rate	2.7	0.0	5.4	4.7	2.3
Dose 1 rate	50.5	5.2	43.3	104.0	40.5
Dose 2 rate	100.9	0.0	--	148.5	89.1

Note: Rates calculated per 100,000 doses administered

Serious Reports

Thirty-seven reports (5.1%) were considered serious (refer to serious AEFI definition above). Of these, 33 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis or other allergic event, 13 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, two for stroke, one hemorrhage and associated encephalopathy, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), four for chest pain/cardiac events, one pulmonary embolism, one respiratory distress, and one for a pregnancy related complication.

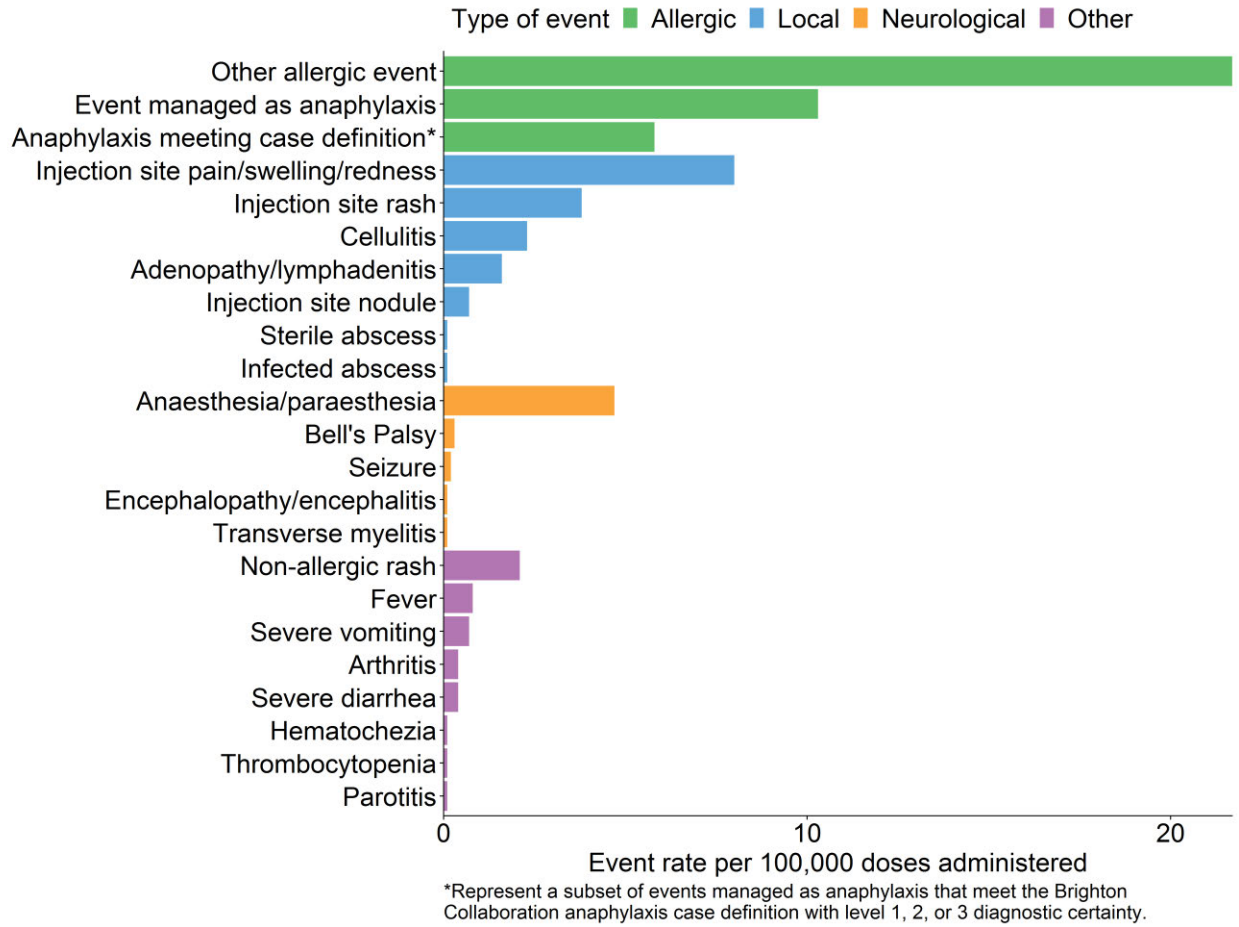
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[7] Death may also be recorded as the outcome of a specific reportable event. Four serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. The third death was the outcome of a

cardiac event that occurred in an elderly individual with multiple underlying medical conditions. The fourth death also occurred in an elderly individual with underlying medical conditions; the coroner deemed this death not unexpected and further investigation into the cause of death was not conducted.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 727 AEFI reports received up to April 17, 2021 contained a total of 979 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[11]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 - Apr.17, 2021 **(N=979)**



Event Descriptions

One hundred forty reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 79 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[11] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Thirty-one reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[12] None of these reports were confirmed by microbial testing.

Ten reports contained a diagnosed neurological event. Four individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. Three individuals were admitted to hospital for seizures, including one with a history of a seizure disorder and another that could have been related to a cardiac arrhythmia. Finally, one individual was admitted to hospital for an intracerebral hemorrhage and subsequent encephalopathy.

There were two reports of thrombocytopenia. Both were for individuals who had a prior episode of thrombocytopenia and were found to have a low platelet count after vaccination when seen in the emergency department for signs of bleeding. Neither was associated with receipt of AstraZeneca/COVISHIELD vaccine.

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, ten were for various thrombotic/thromboembolic conditions. These included two strokes, three myocardial infarctions, two pulmonary embolisms, two deep vein thromboses, and one peripheral vein thrombosis. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[5,6]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on April 21, 2021. Only AEFIs reported and doses administered up to April 17, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]
Subject: RE: Public AEFI Report
Date: Thursday, April 22, 2021 1:36:00 PM

Thanks!

From: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>
Sent: Thursday, April 22, 2021 1:31 PM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Public AEFI Report

Hi Heather,

This week's public AEFI report is attached.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Naus, Monika [BCCDC]
Subject: Weekly Public AEFI Report
Date: Thursday, April 29, 2021 11:35:33 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-04-29.docx
COVID19_AEFI_Weekly_Report_2021-04-29.pdf

Hi Heather,

This week's C-19 AEFI report attached.

Thanks!

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to April 24, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including April 24, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in the reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. There have been no reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date; this syndrome was identified in March in Europe in association with the ChAdOx1 (chimpanzee adenovirus vector AstraZeneca) COVID-19 vaccine, with very few cases reported in Canada to date.[5,6]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[7] When an AEFI report is received at a local public health unit, it is reviewed and recorded in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[8] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[9]

Definitions

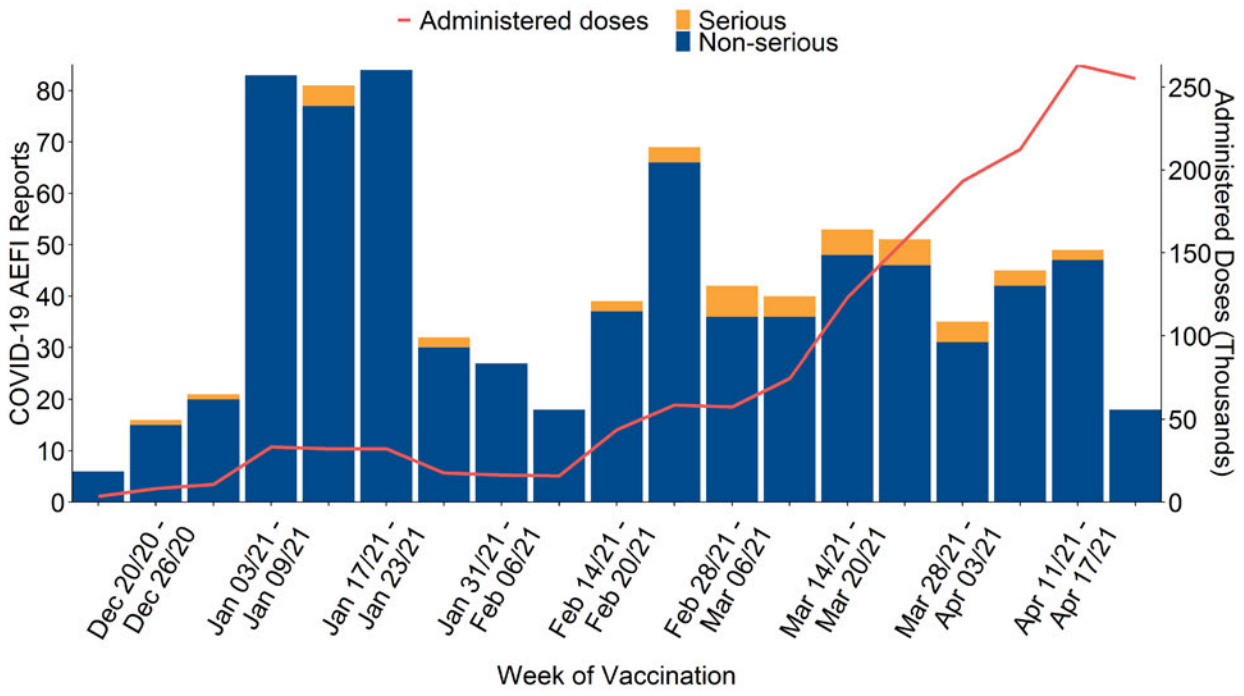
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[10]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of April 24, 2021, there have been 1,609,104 COVID-19 vaccine doses administered in BC and 809 COVID-19 AEFI reports (50.3 reports per 100,000 doses administered)
- 42 reports (5.2%) met the serious definition, for a rate of 2.6 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 - Apr.24, 2021 **(N=809)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including April 24, 2021, a total of 1,609,104 doses have been administered. During this period, there have been 809 AEFI reports following a COVID-19 vaccine, for a reporting rate of 50.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of

vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 - Apr.24, 2021 **(N=809)**

		COVID-19 Vaccine			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**809**	**18**	**30**	**295**	**466**
Non-serious reports	767	17	26	283	441
Serious reports	42	1	4	12	25
Proportion serious	5.2%	5.6%	13.3%	4.1%	5.4%
Dose 1 reports	719	18	30	268	403
Dose 2 reports	90	0	0	27	63
Total doses administered	**1,609,104**	**140,376**	**56,243**	**303,872**	**1,108,613**
Dose 1 administered	1,520,030	140,365	56,238	286,069	1,037,358
Dose 2 administered	89,074	11	5	17,803	71,255
Total reporting rate	**50.3**	**12.8**	**53.3**	**97.1**	**42.0**
Serious rate	2.6	0.7	7.1	3.9	2.3
Dose 1 rate	47.3	12.8	53.3	93.7	38.8
Dose 2 rate	101.0	0.0	0.0	151.7	88.4

Note: Rates calculated per 100,000 doses administered

Serious Reports

Forty-two reports (5.2%) were considered serious (refer to serious AEFI definition above). Of these, 38 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis or other allergic event, 13 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, two for stroke, one hemorrhage and associated encephalopathy, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), six for chest pain/cardiac events, three pulmonary embolism, one respiratory distress, and one for a pregnancy related complication.

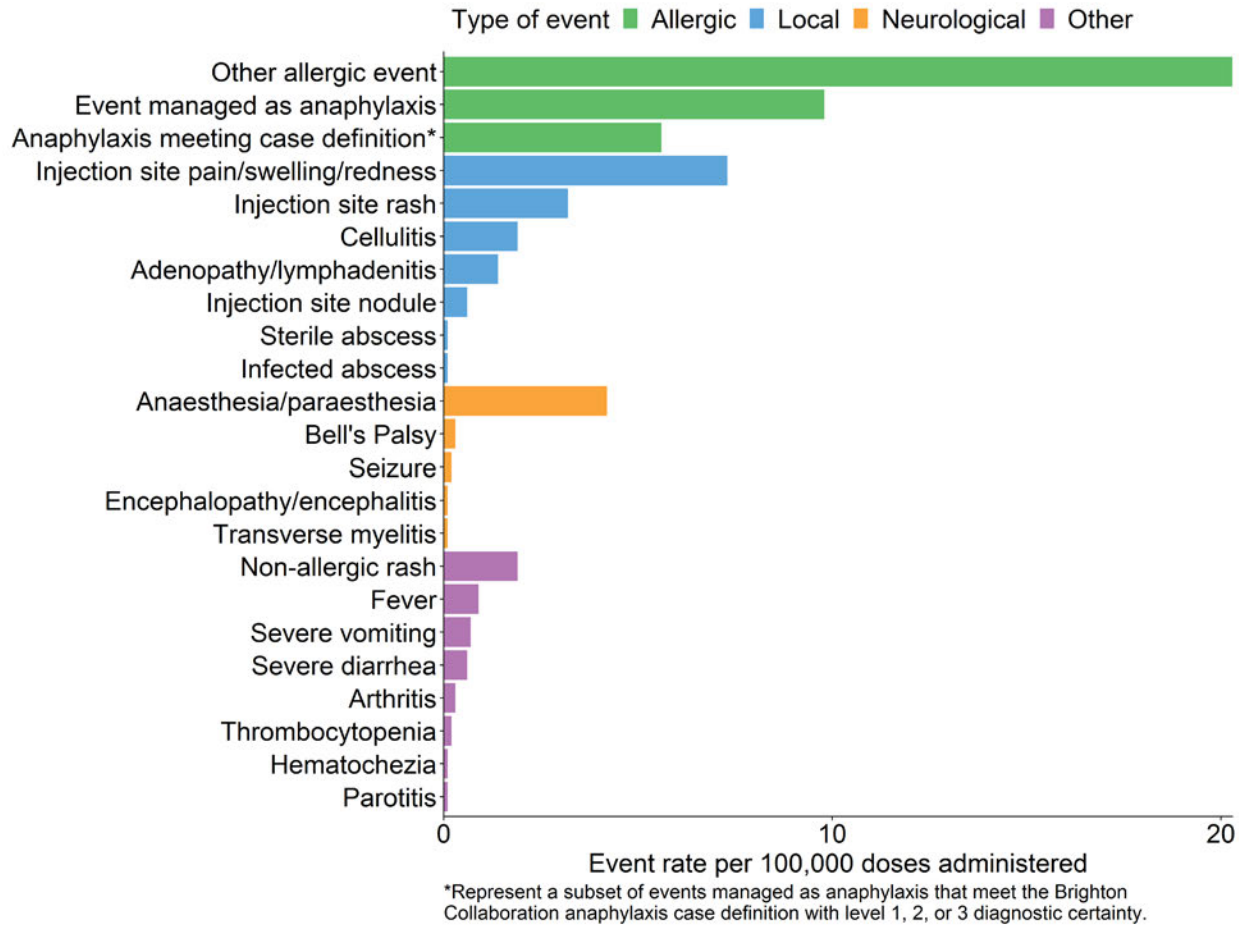
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[7] Death may also be recorded as the outcome of a specific reportable event. Four serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. The third death was the outcome of a

cardiac event that occurred in an elderly individual with multiple underlying medical conditions. The fourth death also occurred in an elderly individual with underlying medical conditions; the coroner deemed this death not unexpected and further investigation into the cause of death was not conducted.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 809 AEFI reports received up to April 24, 2021 contained a total of 1,080 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[11]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 - Apr.24, 2021 **(N=1080)**



Event Descriptions

One hundred fifty-eight reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 90 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[11] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Thirty reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[12] None of these reports were confirmed by microbial testing.

Eleven reports contained a diagnosed neurological event. Five individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. Three individuals were admitted to hospital for seizures, including one with a history of a seizure disorder and another that could have been related to a cardiac arrhythmia. Finally, one individual was admitted to hospital for an intracerebral hemorrhage and subsequent encephalopathy.

There were two reports of thrombocytopenia. Both were for individuals who had a prior episode of thrombocytopenia and were found to have a low platelet count after vaccination when seen in the emergency department for signs of bleeding. Neither was associated with receipt of AstraZeneca/COVISHIELD vaccine.

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, seventeen were for various thrombotic/thromboembolic conditions. These included two strokes, five myocardial infarctions, four pulmonary embolisms, five deep vein thromboses, and one peripheral vein thrombosis. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[5,6]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on April 28, 2021. Only AEFIs reported and doses administered up to April 24, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

References

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to April 24, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including April 24, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in the reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. There have been no reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date; this syndrome was identified in March in Europe in association with the ChAdOx1 (chimpanzee adenovirus vector AstraZeneca) COVID-19 vaccine, with very few cases reported in Canada to date.[5,6]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[7] When an AEFI report is received at a local public health unit, it is reviewed and recorded in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[8] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[9]

Definitions

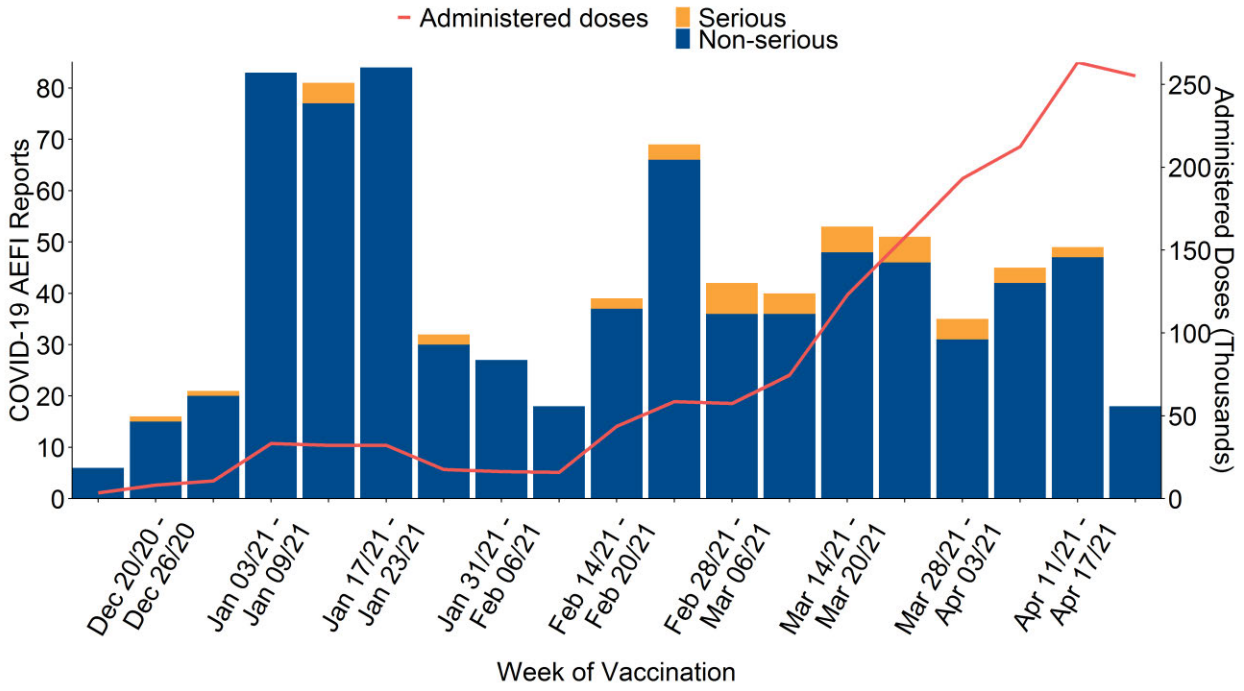
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[10]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of April 24, 2021, there have been 1,609,104 COVID-19 vaccine doses administered in BC and 809 COVID-19 AEFI reports (50.3 reports per 100,000 doses administered)
- 42 reports (5.2%) met the serious definition, for a rate of 2.6 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 - Apr.24, 2021 **(N=809)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including April 24, 2021, a total of 1,609,104 doses have been administered. During this period, there have been 809 AEFI reports following a COVID-19 vaccine, for a reporting rate of 50.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of

vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 - Apr.24, 2021 **(N=809)**

		COVID-19 Vaccine			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**809**	**18**	**30**	**295**	**466**
Non-serious reports	767	17	26	283	441
Serious reports	42	1	4	12	25
Proportion serious	5.2%	5.6%	13.3%	4.1%	5.4%
Dose 1 reports	719	18	30	268	403
Dose 2 reports	90	0	0	27	63
Total doses administered	**1,609,104**	**140,376**	**56,243**	**303,872**	**1,108,613**
Dose 1 administered	1,520,030	140,365	56,238	286,069	1,037,358
Dose 2 administered	89,074	11	5	17,803	71,255
Total reporting rate	**50.3**	**12.8**	**53.3**	**97.1**	**42.0**
Serious rate	2.6	0.7	7.1	3.9	2.3
Dose 1 rate	47.3	12.8	53.3	93.7	38.8
Dose 2 rate	101.0	0.0	0.0	151.7	88.4

Note: Rates calculated per 100,000 doses administered

Serious Reports

Forty-two reports (5.2%) were considered serious (refer to serious AEFI definition above). Of these, 38 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis or other allergic event, 13 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, two for stroke, one hemorrhage and associated encephalopathy, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), six for chest pain/cardiac events, three pulmonary embolism, one respiratory distress, and one for a pregnancy related complication.

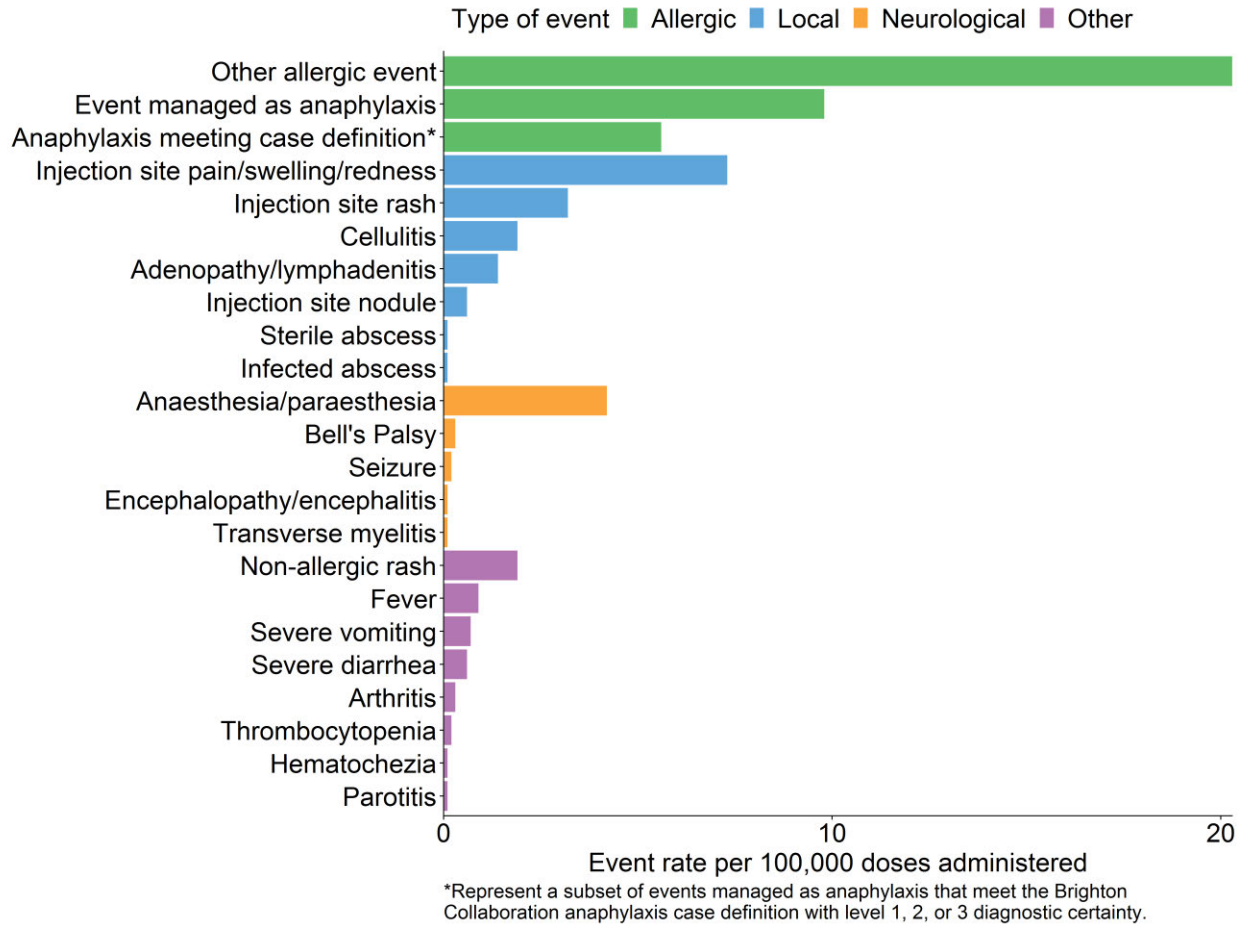
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[7] Death may also be recorded as the outcome of a specific reportable event. Four serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. The third death was the outcome of a

cardiac event that occurred in an elderly individual with multiple underlying medical conditions. The fourth death also occurred in an elderly individual with underlying medical conditions; the coroner deemed this death not unexpected and further investigation into the cause of death was not conducted.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 809 AEFI reports received up to April 24, 2021 contained a total of 1,080 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[11]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 - Apr.24, 2021 **(N=1080)**



Event Descriptions

One hundred fifty-eight reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 90 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[11] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Naus, Monika [BCCDC]
Cc: Minhas, Sableen
Subject: RE: Weekly Public AEFI Report
Date: Thursday, April 29, 2021 11:51:28 AM

Yes no problem ☺

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Sə́l̓ilwətaʔ/Selilwitulh Nations.

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From: Amos, Heather [BCCDC]
Sent: Thursday, April 29, 2021 11:51 AM
To: Noftall, Kyle [BCCDC]; Naus, Monika [BCCDC]
Cc: Minhas, Sableen
Subject: RE: Weekly Public AEFI Report

Thanks Kyle.

Do you mind adding my new colleague Sableen to your distribution list next Thursday?

I'll be showing her how to post these this afternoon.

Heather

From: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>

Sent: Thursday, April 29, 2021 11:36 AM

To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>

Subject: Weekly Public AEFI Report

Hi Heather,

This week's C-19 AEFI report attached.

Thanks!

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Public AEFI Report
Date: Thursday, May 06, 2021 10:10:03 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-05-06.docx
COVID19_AEFI_Weekly_Report_2021-05-06.pdf

Hi Heather,

This week's AEFI report is attached.

Thank you,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to May 01, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including May 01, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in the reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. There have been no reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date; this syndrome was identified in March in Europe in association with the ChAdOx1 (chimpanzee adenovirus vector AstraZeneca) COVID-19 vaccine, with very few cases reported in Canada to date.[5,6]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[7] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[8] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[9]

Definitions

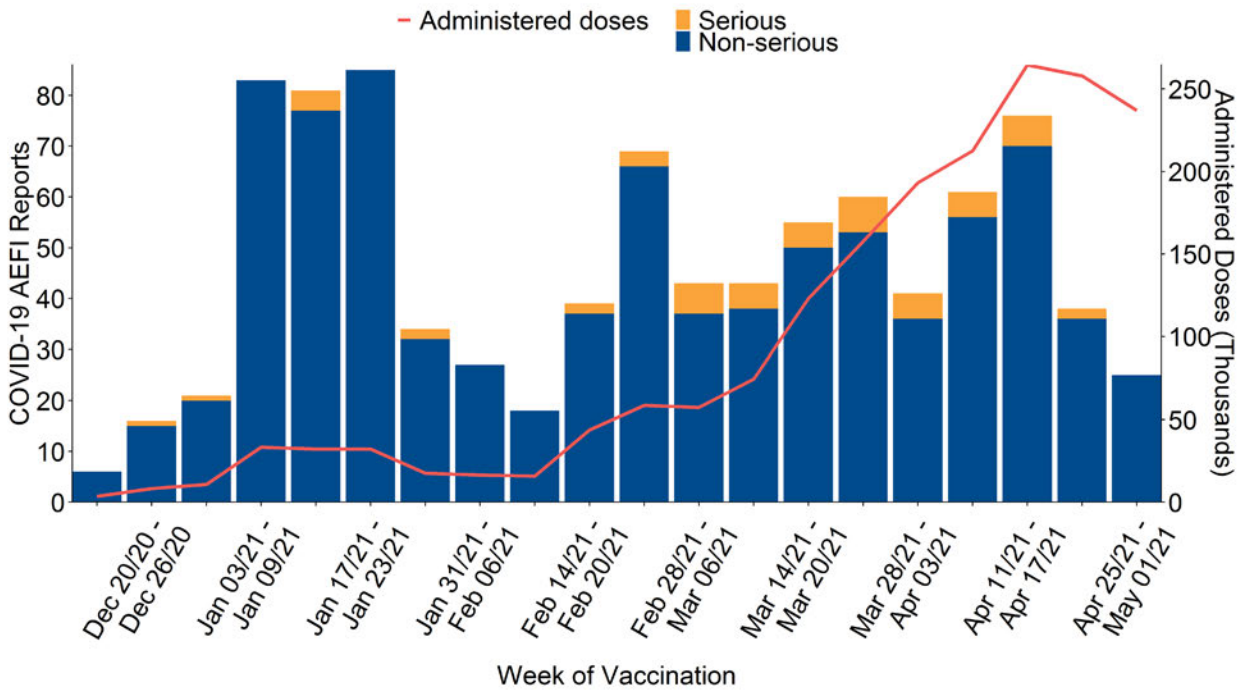
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[10]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of May 01, 2021, there have been 1,850,371 COVID-19 vaccine doses administered in BC and 921 COVID-19 AEFI reports (49.8 reports per 100,000 doses administered)
- 54 reports (5.9%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 - May.01, 2021 **(N=921)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including May 01, 2021, a total of 1,850,371 doses have been administered. During this period, there have been 921 AEFI reports following a COVID-19 vaccine, for a reporting rate of 49.8 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of

vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 - May.01, 2021 **(N=921)**

		COVID-19 Vaccine			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**921**	**36**	**34**	**325**	**526**
Non-serious reports	867	34	30	309	494
Serious reports	54	2	4	16	32
Proportion serious	5.9%	5.6%	11.8%	4.9%	6.1%
Dose 1 reports	831	36	34	298	463
Dose 2 reports	90	0	0	27	63
Total doses administered	**1,850,371**	**193,220**	**56,830**	**344,117**	**1,256,204**
Dose 1 administered	1,758,806	193,197	56,817	324,972	1,183,820
Dose 2 administered	91,565	23	13	19,145	72,384
Total reporting rate	**49.8**	**18.6**	**59.8**	**94.4**	**41.9**
Serious rate	2.9	1.0	7.0	4.6	2.5
Dose 1 rate	47.2	18.6	59.8	91.7	39.1
Dose 2 rate	98.3	0.0	0.0	141.0	87.0

Note: Rates calculated per 100,000 doses administered

Serious Reports

Fifty-four reports (5.9%) were considered serious (refer to serious AEFI definition above). Of these, 50 individuals were admitted to hospital. These included 16 individuals hospitalized after anaphylaxis or other allergic event, 18 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, six for stroke, one hemorrhage and associated encephalopathy, one meningitis, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), nine for chest pain/cardiac events, five pulmonary embolism, one respiratory distress, and one for a pregnancy related complication.

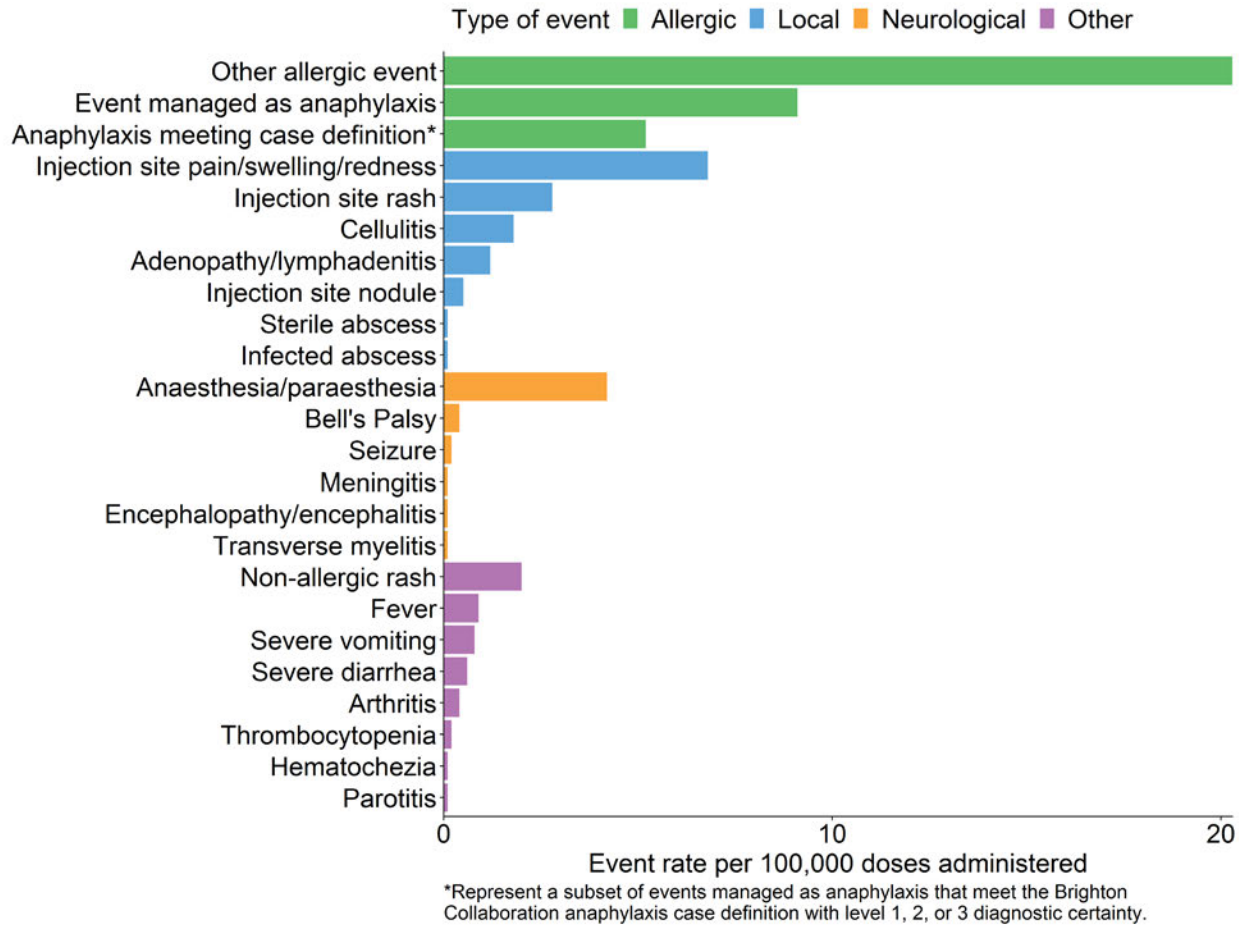
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[7] Death may also be recorded as the outcome of a specific reportable event. Four serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. The third death was the outcome of a

cardiac event that occurred in an elderly individual with multiple underlying medical conditions. The fourth death also occurred in an elderly individual with underlying medical conditions; the coroner deemed this death not unexpected and further investigation into the cause of death was not conducted.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 921 AEFI reports received up to May 01, 2021 contained a total of 1,222 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[11]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 - May.01, 2021 **(N=1,222)**



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Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 29 were for various thrombotic/thromboembolic conditions. These included seven strokes, seven myocardial infarctions, seven pulmonary embolisms, six deep vein thromboses, and two superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[5,6]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on May 05, 2021. Only AEFIs reported and doses administered up to May 01, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to May 01, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including May 01, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in the reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. There have been no reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date; this syndrome was identified in March in Europe in association with the ChAdOx1 (chimpanzee adenovirus vector AstraZeneca) COVID-19 vaccine, with very few cases reported in Canada to date.[5,6]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[7] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[8] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[9]

Definitions

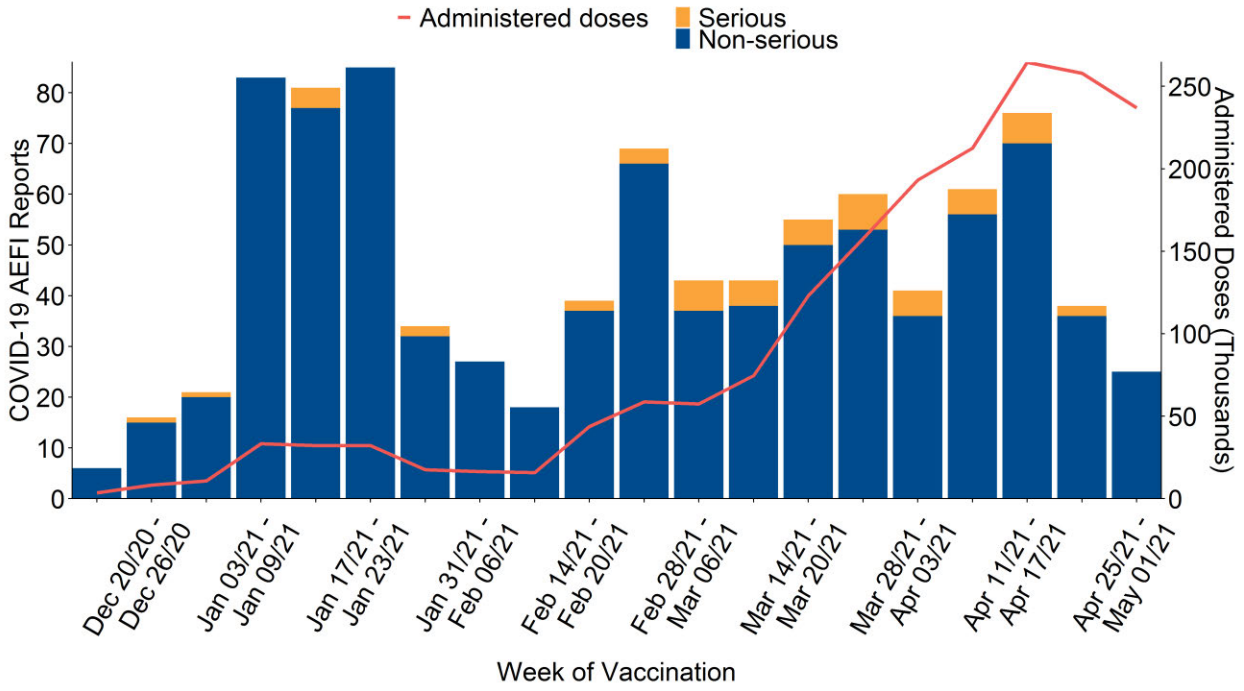
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[10]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of May 01, 2021, there have been 1,850,371 COVID-19 vaccine doses administered in BC and 921 COVID-19 AEFI reports (49.8 reports per 100,000 doses administered)
- 54 reports (5.9%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 - May.01, 2021 **(N=921)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including May 01, 2021, a total of 1,850,371 doses have been administered. During this period, there have been 921 AEFI reports following a COVID-19 vaccine, for a reporting rate of 49.8 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of

vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 - May.01, 2021 **(N=921)**

		COVID-19 Vaccine			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**921**	**36**	**34**	**325**	**526**
Non-serious reports	867	34	30	309	494
Serious reports	54	2	4	16	32
Proportion serious	5.9%	5.6%	11.8%	4.9%	6.1%
Dose 1 reports	831	36	34	298	463
Dose 2 reports	90	0	0	27	63
Total doses administered	**1,850,371**	**193,220**	**56,830**	**344,117**	**1,256,204**
Dose 1 administered	1,758,806	193,197	56,817	324,972	1,183,820
Dose 2 administered	91,565	23	13	19,145	72,384
Total reporting rate	**49.8**	**18.6**	**59.8**	**94.4**	**41.9**
Serious rate	2.9	1.0	7.0	4.6	2.5
Dose 1 rate	47.2	18.6	59.8	91.7	39.1
Dose 2 rate	98.3	0.0	0.0	141.0	87.0

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Serious Reports

Fifty-four reports (5.9%) were considered serious (refer to serious AEFI definition above). Of these, 50 individuals were admitted to hospital. These included 16 individuals hospitalized after anaphylaxis or other allergic event, 18 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, six for stroke, one hemorrhage and associated encephalopathy, one meningitis, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), nine for chest pain/cardiac events, five pulmonary embolism, one respiratory distress, and one for a pregnancy related complication.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[7] Death may also be recorded as the outcome of a specific reportable event. Four serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. The third death was the outcome of a

cardiac event that occurred in an elderly individual with multiple underlying medical conditions. The fourth death also occurred in an elderly individual with underlying medical conditions; the coroner deemed this death not unexpected and further investigation into the cause of death was not conducted.

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A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 921 AEFI reports received up to May 01, 2021 contained a total of 1,222 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[11]

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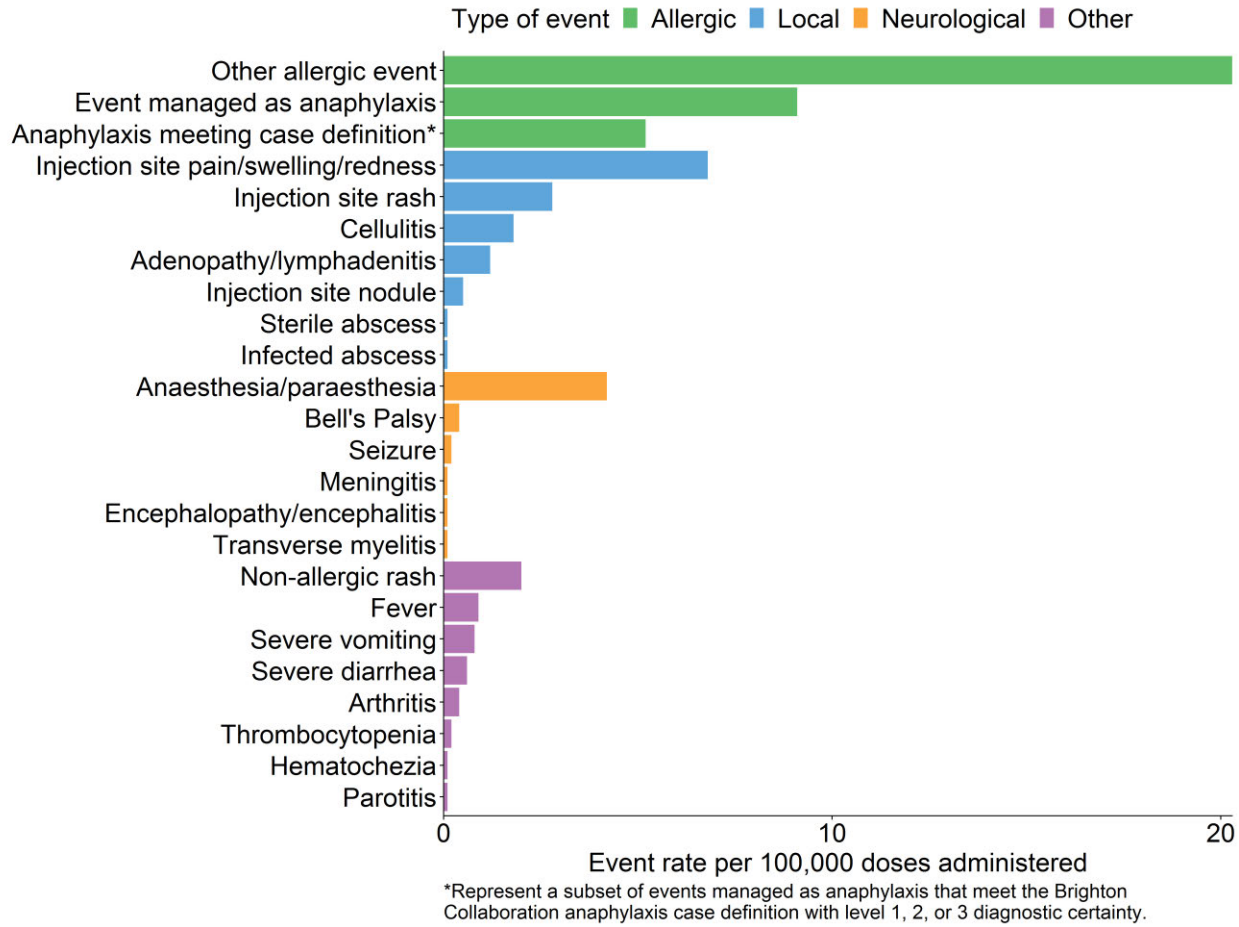

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From: Noftall, Kyle [BCCDC]
To: Minhas, Sableen
Cc: Amos, Heather [BCCDC]
Subject: FW: Public AEFI Report
Date: Thursday, May 06, 2021 10:48:38 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-05-06.docx
COVID19_AEFI_Weekly_Report_2021-05-06.pdf

Sorry Sableen,

Forgot to include you!

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
Sent: Thursday, May 06, 2021 10:10 AM
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Public AEFI Report

Hi Heather,

This week's AEFI report is attached.

Thank you,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

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Key Findings

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Summary of AEFI Reports

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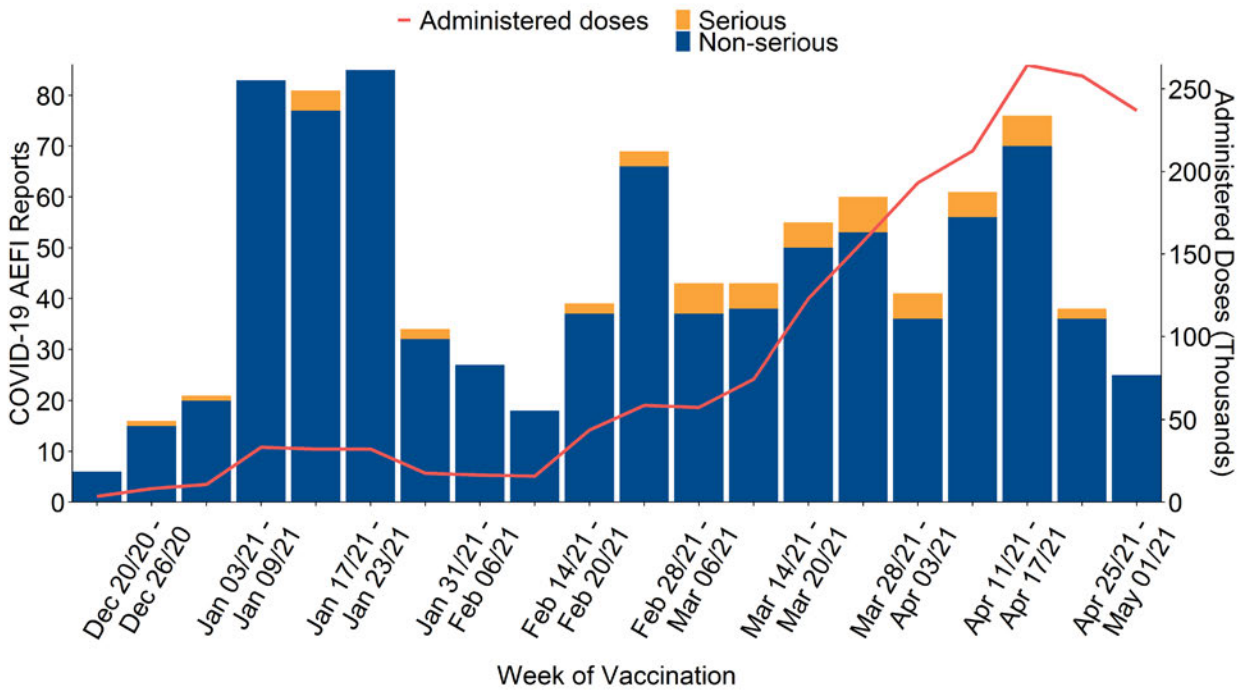

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Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 - May.01, 2021 **(N=921)**

		COVID-19 Vaccine			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**921**	**36**	**34**	**325**	**526**
Non-serious reports	867	34	30	309	494
Serious reports	54	2	4	16	32
Proportion serious	5.9%	5.6%	11.8%	4.9%	6.1%
Dose 1 reports	831	36	34	298	463
Dose 2 reports	90	0	0	27	63
Total doses administered	**1,850,371**	**193,220**	**56,830**	**344,117**	**1,256,204**
Dose 1 administered	1,758,806	193,197	56,817	324,972	1,183,820
Dose 2 administered	91,565	23	13	19,145	72,384
Total reporting rate	**49.8**	**18.6**	**59.8**	**94.4**	**41.9**
Serious rate	2.9	1.0	7.0	4.6	2.5
Dose 1 rate	47.2	18.6	59.8	91.7	39.1
Dose 2 rate	98.3	0.0	0.0	141.0	87.0

Note: Rates calculated per 100,000 doses administered

Serious Reports

Fifty-four reports (5.9%) were considered serious (refer to serious AEFI definition above). Of these, 50 individuals were admitted to hospital. These included 16 individuals hospitalized after anaphylaxis or other allergic event, 18 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, six for stroke, one hemorrhage and associated encephalopathy, one meningitis, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), nine for chest pain/cardiac events, five pulmonary embolism, one respiratory distress, and one for a pregnancy related complication.

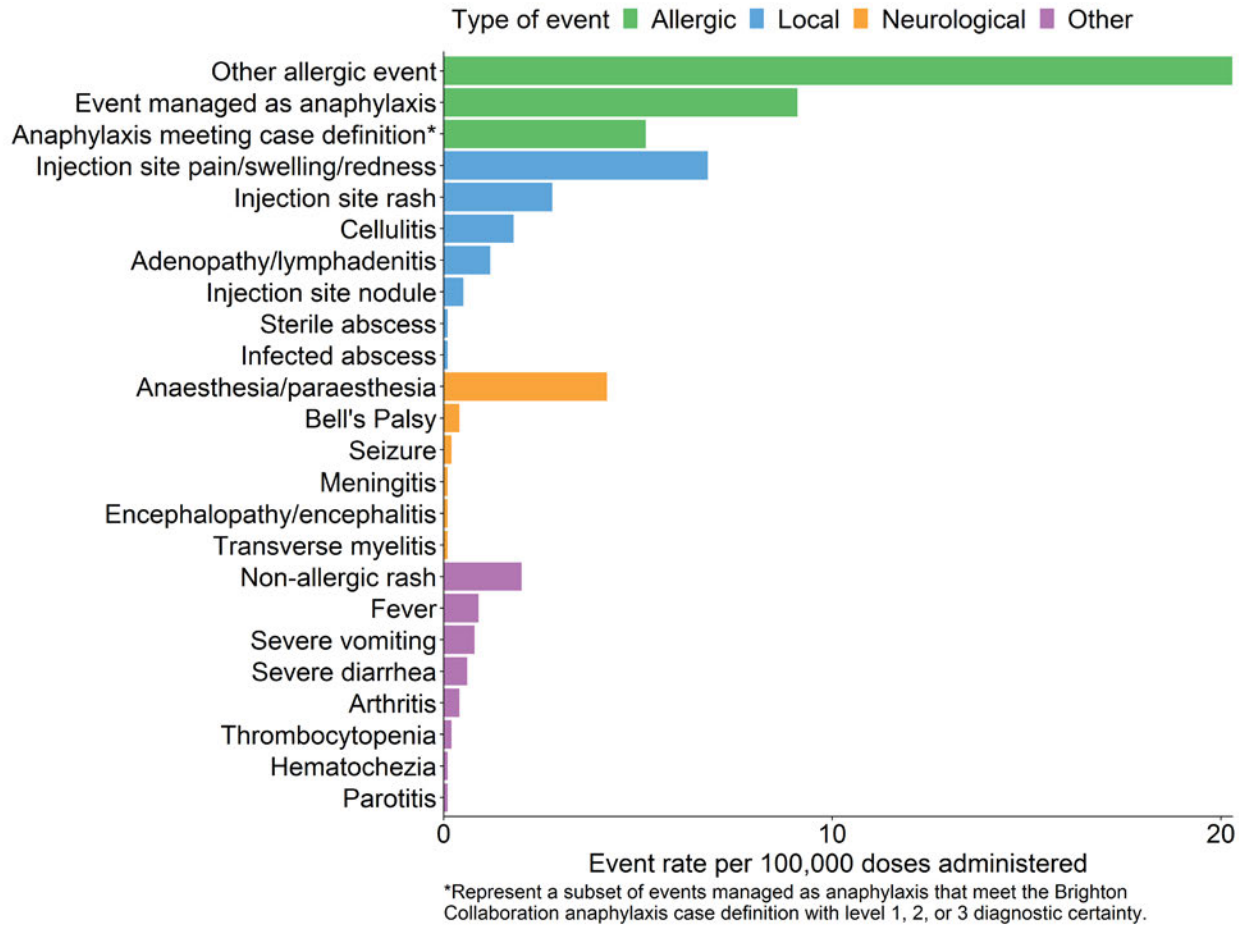
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[7] Death may also be recorded as the outcome of a specific reportable event. Four serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. The third death was the outcome of a

cardiac event that occurred in an elderly individual with multiple underlying medical conditions. The fourth death also occurred in an elderly individual with underlying medical conditions; the coroner deemed this death not unexpected and further investigation into the cause of death was not conducted.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 921 AEFI reports received up to May 01, 2021 contained a total of 1,222 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[11]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 - May.01, 2021 **(N=1,222)**



Event Descriptions

One hundred sixty-eight reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 96 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[11] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Thirty-three reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[12] None of these reports were confirmed by microbial testing.

Eleven reports contained a diagnosed neurological event. Seven individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. Four individuals reported seizures, including two with a history of a seizure disorder and another that could have been related to a cardiac arrhythmia. One individual was admitted to hospital for an intracerebral hemorrhage and subsequent encephalopathy. Finally, one individual was hospitalized for aseptic meningitis.

There were three reports of thrombocytopenia. Two were for individuals who had a prior episode of thrombocytopenia and were found to have a low platelet count after vaccination when seen in the emergency department for signs of bleeding. Neither was associated with receipt of AstraZeneca/COVISHIELD vaccine. The third was still being investigated and not yet confirmed at the time of this report.

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 29 were for various thrombotic/thromboembolic conditions. These included seven strokes, seven myocardial infarctions, seven pulmonary embolisms, six deep vein thromboses, and two superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[5,6]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on May 05, 2021. Only AEFIs reported and doses administered up to May 01, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

References

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to May 01, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including May 01, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in the reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. There have been no reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date; this syndrome was identified in March in Europe in association with the ChAdOx1 (chimpanzee adenovirus vector AstraZeneca) COVID-19 vaccine, with very few cases reported in Canada to date.[5,6]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[7] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[8] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[9]

Definitions

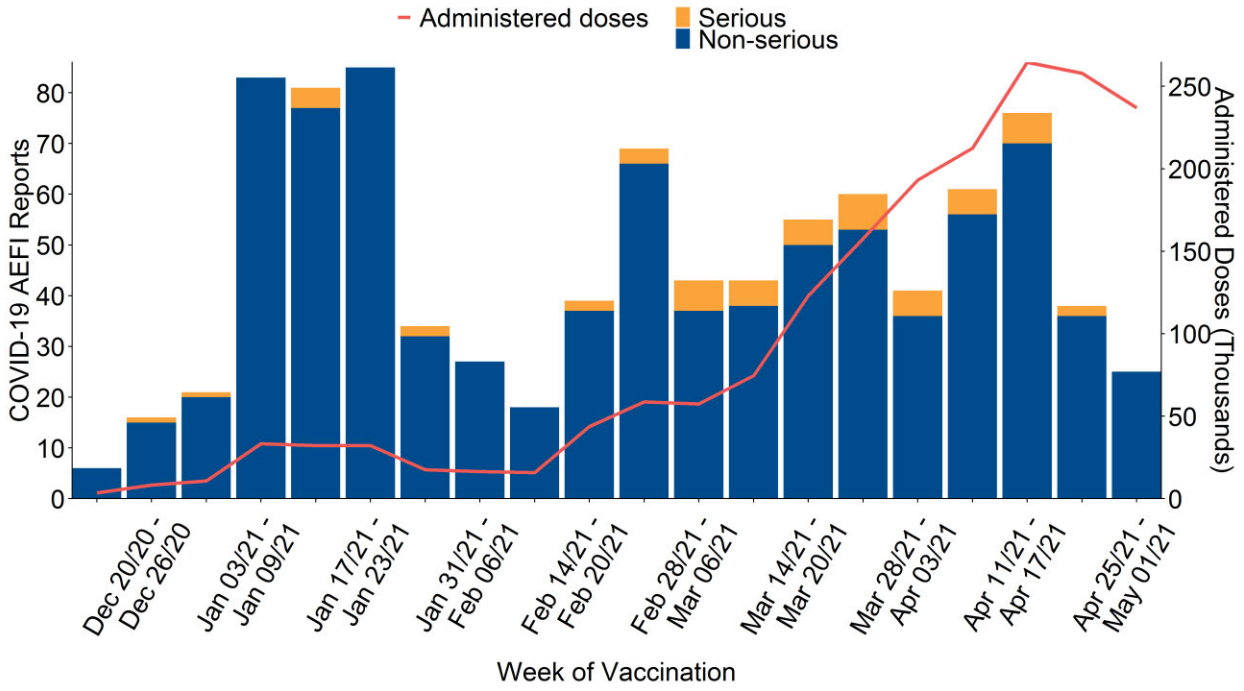
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[10]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of May 01, 2021, there have been 1,850,371 COVID-19 vaccine doses administered in BC and 921 COVID-19 AEFI reports (49.8 reports per 100,000 doses administered)
- 54 reports (5.9%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 - May.01, 2021 **(N=921)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including May 01, 2021, a total of 1,850,371 doses have been administered. During this period, there have been 921 AEFI reports following a COVID-19 vaccine, for a reporting rate of 49.8 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of

vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 - May.01, 2021 **(N=921)**

		COVID-19 Vaccine			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
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Serious Reports

Fifty-four reports (5.9%) were considered serious (refer to serious AEFI definition above). Of these, 50 individuals were admitted to hospital. These included 16 individuals hospitalized after anaphylaxis or other allergic event, 18 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, six for stroke, one hemorrhage and associated encephalopathy, one meningitis, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), nine for chest pain/cardiac events, five pulmonary embolism, one respiratory distress, and one for a pregnancy related complication.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[7] Death may also be recorded as the outcome of a specific reportable event. Four serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. The third death was the outcome of a

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Summary of Reported Events

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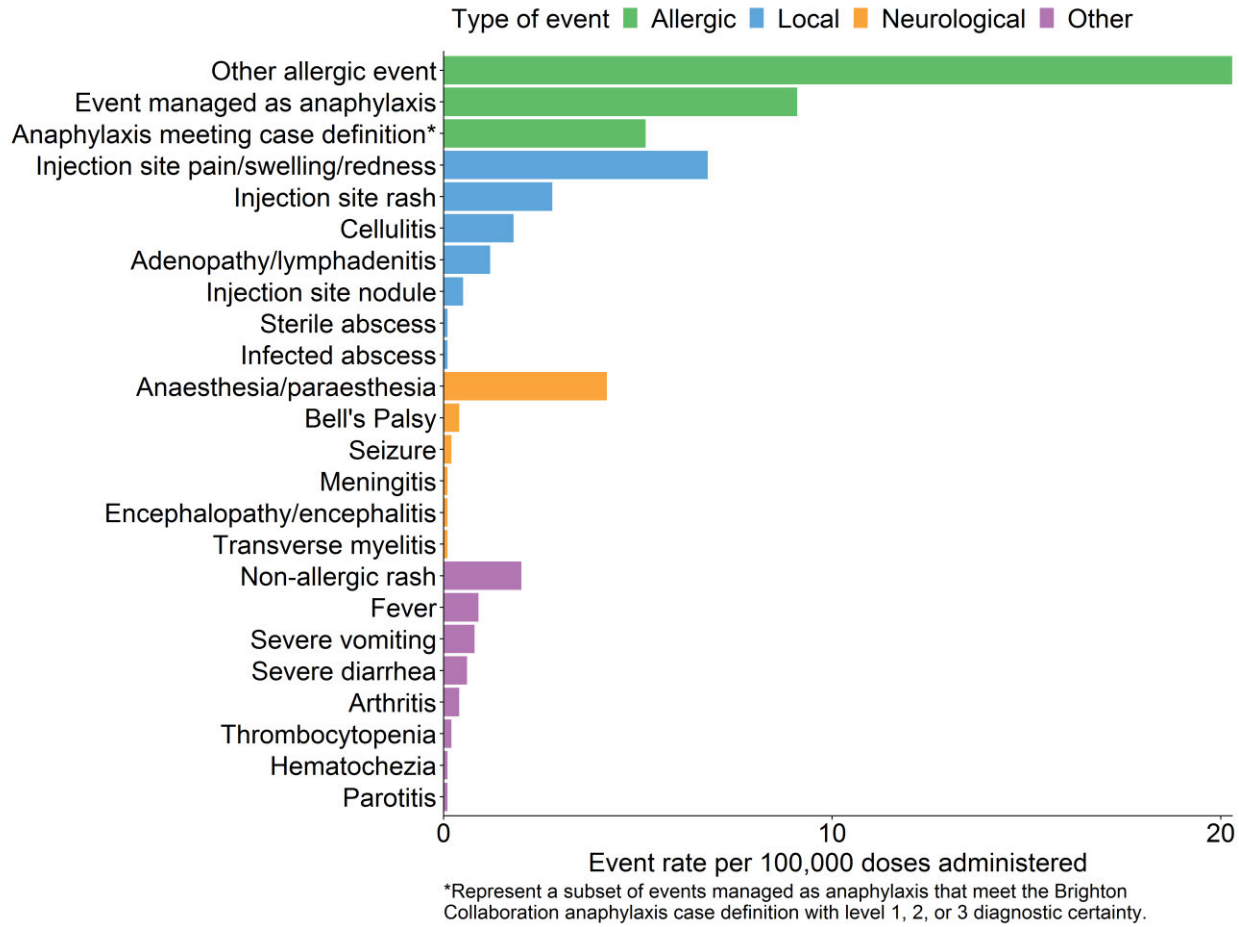

Event Descriptions

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From: Minhas, Sableen
To: Amos, Heather [BCCDC]
Subject: RE: Public AEFI Report
Date: Thursday, May 06, 2021 11:18:41 AM

Done!

From: Amos, Heather [BCCDC]
Sent: Thursday, May 06, 2021 11:16 AM
To: Minhas, Sableen
Subject: RE: Public AEFI Report

Oh yes please!

From: Minhas, Sableen <sableen.minhas@phsa.ca>

Sent: Thursday, May 06, 2021 11:14 AM

To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>

Subject: RE: Public AEFI Report

Thanks Heather! Should I also update the "Last Updated" date on the top of the page to today's?

From: Amos, Heather [BCCDC]
Sent: Thursday, May 06, 2021 10:51 AM
To: Noftall, Kyle [BCCDC]; Minhas, Sableen
Subject: RE: Public AEFI Report

Thanks Kyle.

Sableen – these reports are posted to this page: https://editbccdc.phsa.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/monitoring-vaccine-uptake-safety-and-effectiveness

In the accordion "B.C.'s weekly report on adverse events"

Heather

From: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>

Sent: Thursday, May 06, 2021 10:49 AM

To: Minhas, Sableen <sableen.minhas@phsa.ca>

Cc: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>

Subject: FW: Public AEFI Report

Sorry Sableen,

Forgot to include you!

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
Sent: Thursday, May 06, 2021 10:10 AM
To: Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Public AEFI Report

Hi Heather,
This week's AEFI report is attached.
Thank you,
Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly AEFI Report
Date: Thursday, May 13, 2021 10:46:58 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-05-13.docx
COVID19_AEFI_Weekly_Report_2021-05-13.pdf

Hello Heather and Sableen,

Attached is this week's AEFI report.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to May 8, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including May 8, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA vaccine reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. There has been one report of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 250,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[5,6]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[7] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and

analysis for potential safety signals is performed at the national level.[8] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[9]

Definitions

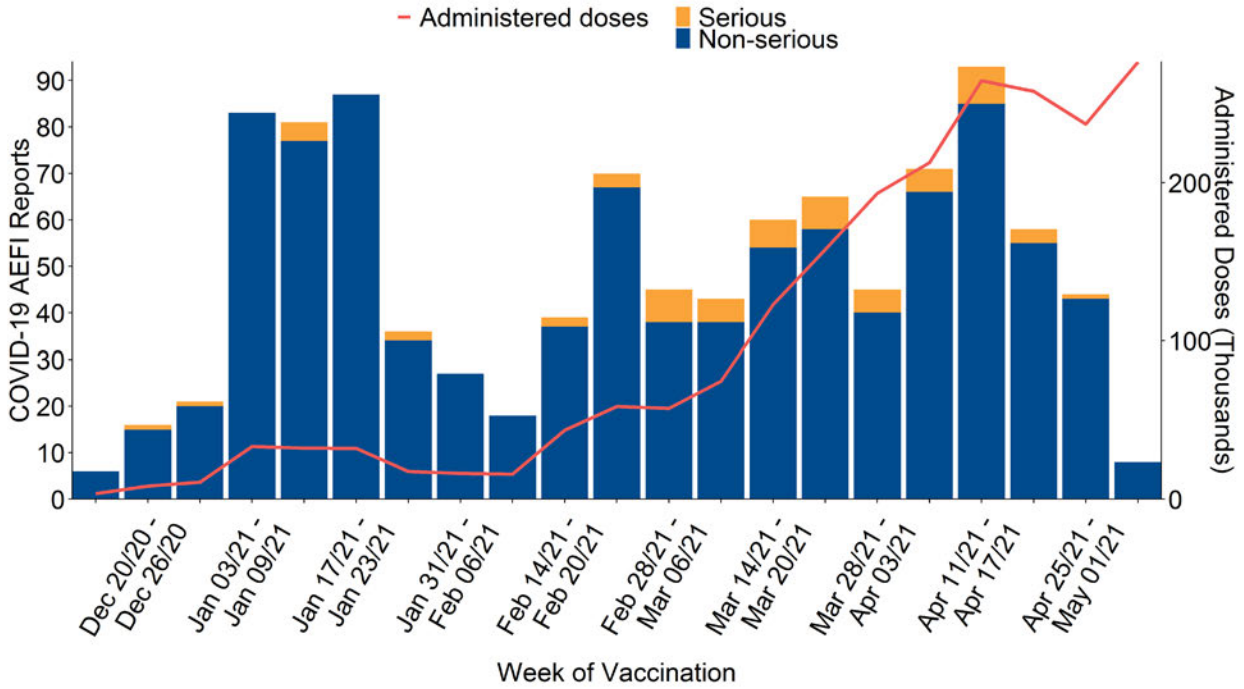
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[10]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of May 8, 2021, there have been 2,127,288 COVID-19 vaccine doses administered in BC and 1,016 COVID-19 AEFI reports (47.8 reports per 100,000 doses administered)
- 60 reports (5.9%) met the serious definition, for a rate of 2.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 – May 8, 2021 **(N=1,016)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including May 8, 2021, a total of 2,127,288 doses have been administered. During this

period, there have been 1,016 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.8 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 – May 8, 2021 **(N=1,016)**

		COVID-19 Vaccine*			
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Total reports	**1,016**	**58**	**37**	**353**	**566**
Non-serious reports	956	53	33	336	532
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Note: Rates calculated per 100,000 doses administered
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Serious Reports

Sixty reports (5.9%) were considered serious (refer to serious AEFI definition above). Of these, 55 individuals were admitted to hospital. These included 16 individuals hospitalized after anaphylaxis or other allergic event, 19 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, eight for stroke, one hemorrhage and associated encephalopathy, one meningitis, and four for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), 10 for chest pain/cardiac events, six pulmonary embolism, one respiratory distress, one for a pregnancy related complication, one for thrombocytopenia, and one for thrombosis with thrombocytopenia syndrome (described further below).

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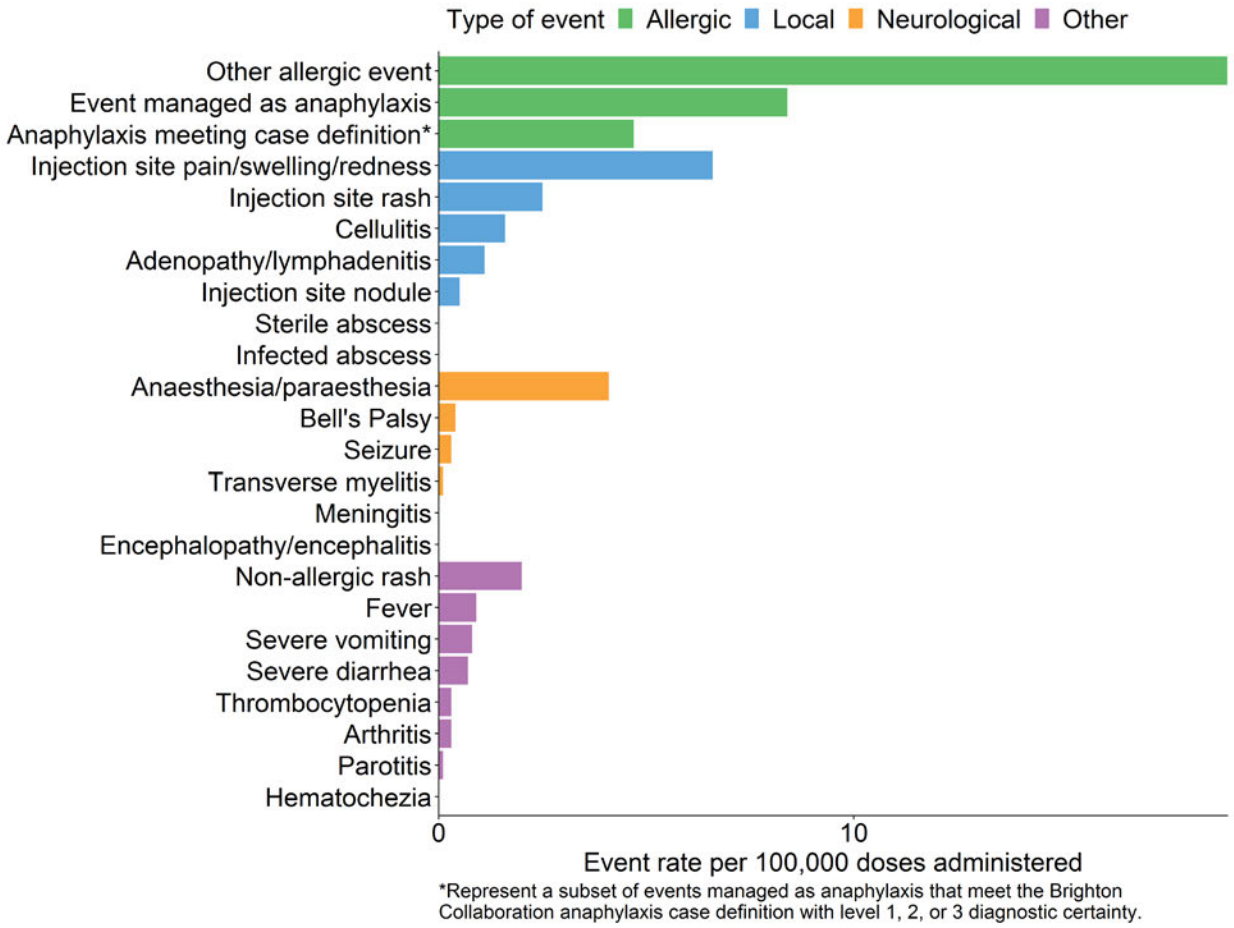
Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 – May 8, 2021 **(N=1,347)**



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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to May 8, 2021

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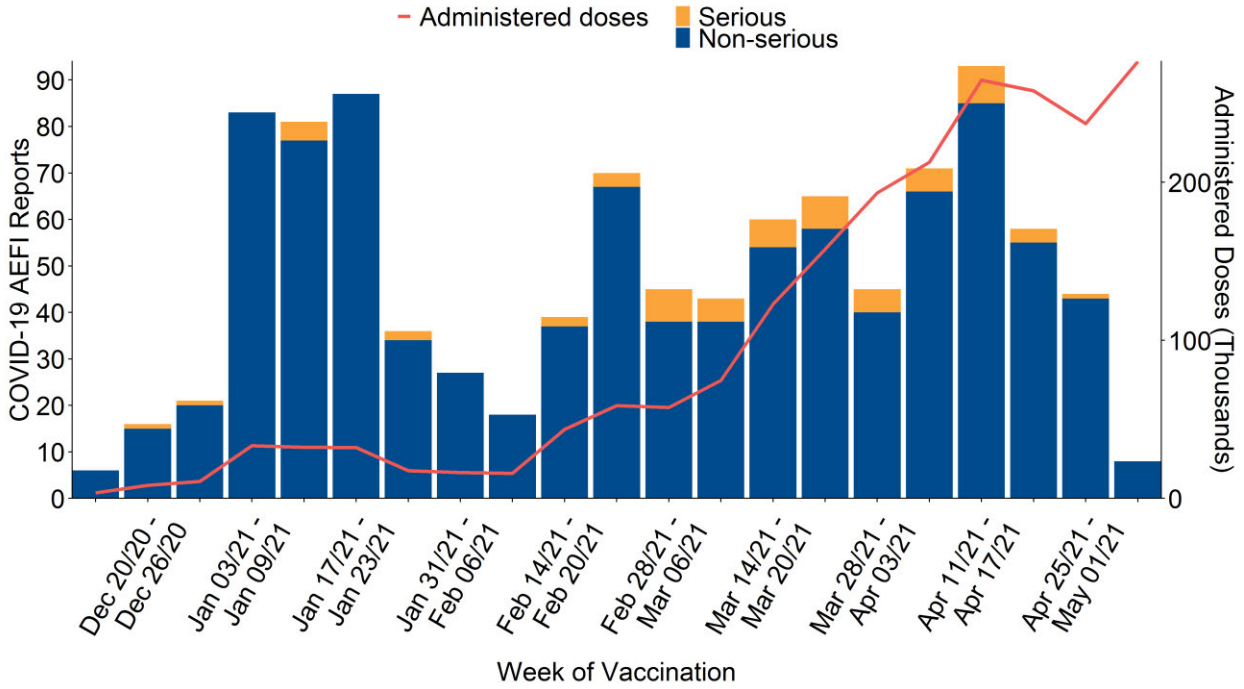

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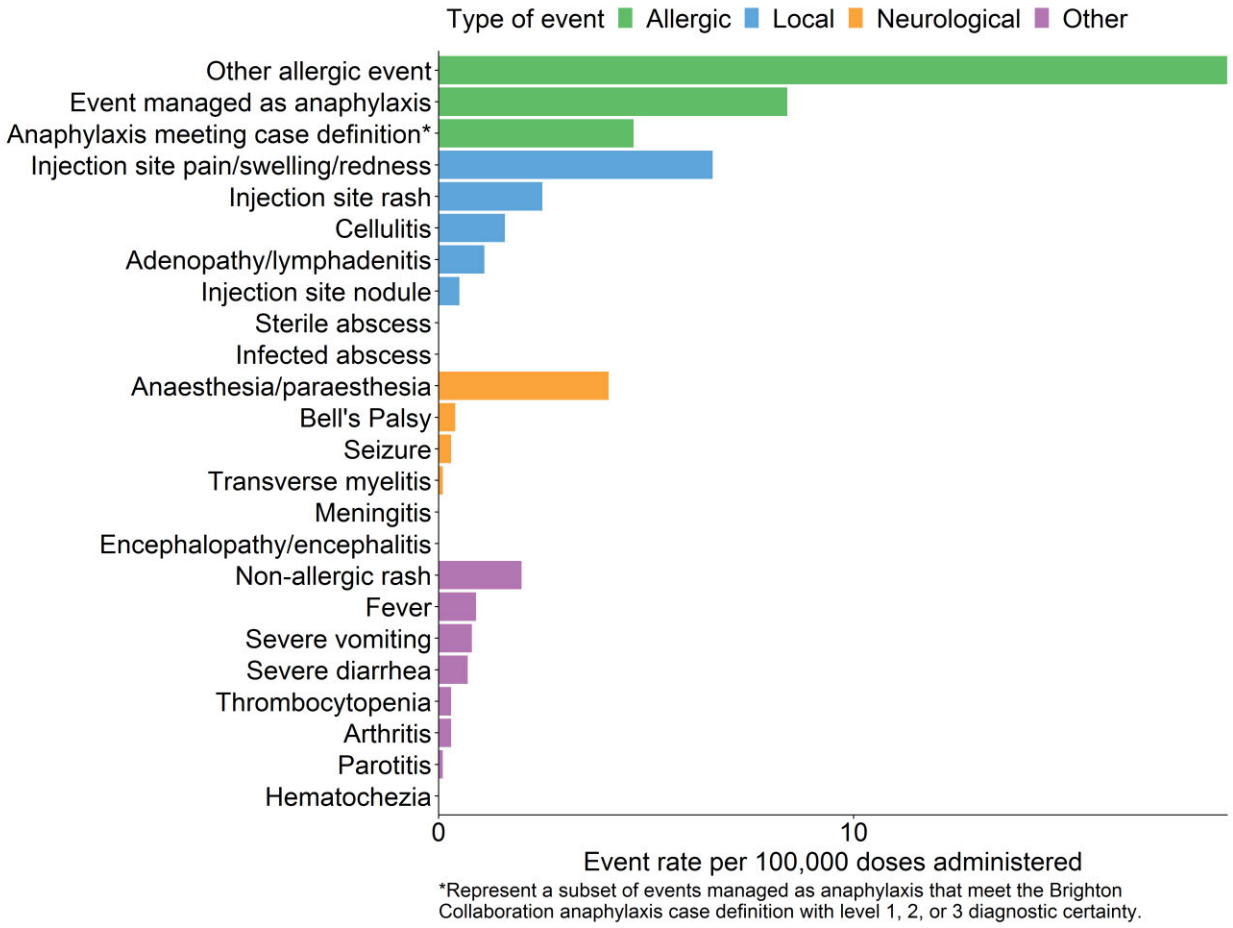

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From: Amos, Heather [BCCDC]
To: Minhas, Sableen
Subject: RE: Weekly AEFI Report
Date: Thursday, May 13, 2021 11:18:00 AM

You can do it now.
Thanks!

From: Minhas, Sableen <sableen.minhas@phsa.ca>
Sent: Thursday, May 13, 2021 11:05 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Subject: RE: Weekly AEFI Report

Heather, shall I add this to the safety and effectiveness page now or wait till eod?
Regards,
Sableen

From: Noftall, Kyle [BCCDC]
Sent: Thursday, May 13, 2021 10:47 AM
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly AEFI Report

Hello Heather and Sableen,

Attached is this week's AEFI report.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Sc̓ic̓ilwətaʔ/Selilwitulh Nations.

This e-mail message, including any attachments, is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged and/or confidential. If you are not the intended recipient or the employee or agent responsible for delivering the communication to the intended recipient, please notify us immediately by replying to this message and then delete this message from your system. You are hereby notified that any use, dissemination, distribution and/or reproduction of this message and/or any attachments by unintended recipients is unauthorized and may be unlawful.

From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: May 20 Public AEFI Report
Date: Thursday, May 20, 2021 10:15:33 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-05-20.docx
COVID19_AEFI_Weekly_Report_2021-05-20.pdf

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Thanks,

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Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to May 15, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including May 15, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. There have been two reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 250,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[5,6]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[7] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and

analysis for potential safety signals is performed at the national level.[8] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[9]

Definitions

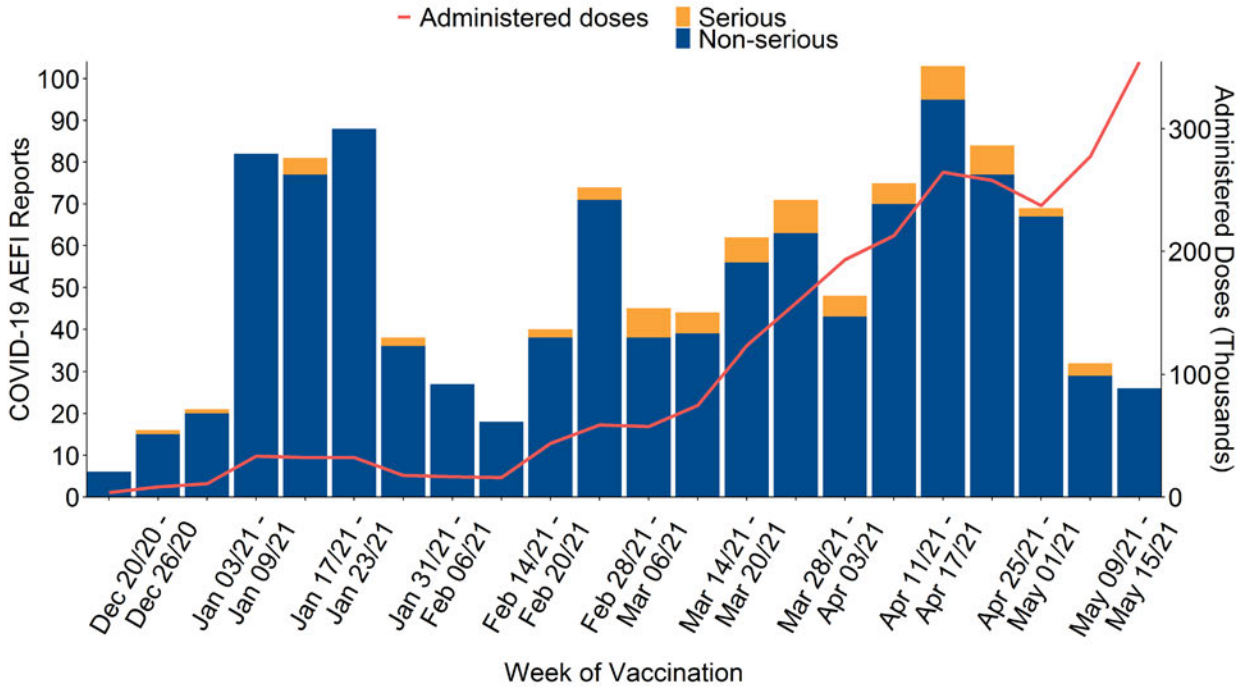
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[10]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of May 15, 2021, there have been 2,483,293 COVID-19 vaccine doses administered in BC and 1,150 COVID-19 AEFI reports (46.3 reports per 100,000 doses administered)
- 69 reports (6%) met the serious definition, for a rate of 2.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - May 15, 2021 **(N=1,150)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including May 15, 2021, a total of 2,483,293 doses have been administered. During this

period, there have been 1,150 AEFI reports following a COVID-19 vaccine, for a reporting rate of 46.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

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Proportion serious	6%	7.6%	9.5%	5.1%	6.1%
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Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=2). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

Sixty-nine reports (6%) were considered serious (refer to serious AEFI definition above). Of these, 63 individuals were admitted to hospital. These included 16 individuals hospitalized after anaphylaxis or other allergic event, 23 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, nine for stroke, two hemorrhage with one associated encephalopathy, one meningitis, and six for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), 10 for chest pain/cardiac events, eight pulmonary embolism, one respiratory distress, one for a pregnancy related complication, two for thrombocytopenia, and two for thrombosis with thrombocytopenia syndrome (described further below).

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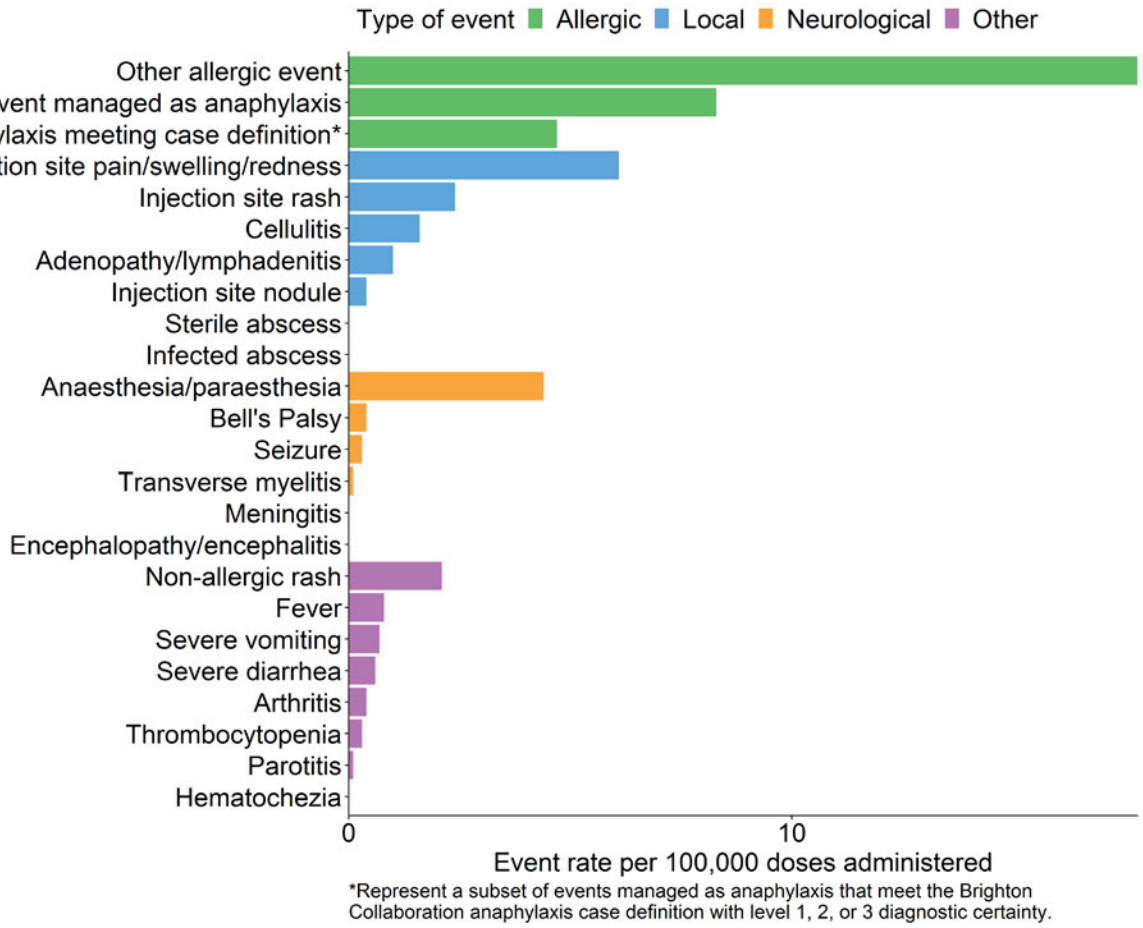
Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - May 15, 2021 **(N=1,515)**



Event Descriptions

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Twenty four reports contained a diagnosed neurological event. Eleven individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. Eight individuals reported seizures, including five with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, and one had a subsequent encephalopathy. Finally, one individual

was hospitalized for aseptic meningitis.

There were five reports of thrombocytopenia without concurrent thrombosis. One occurred in an individual with a single low platelet result followed subsequently by normal results in the days after. The one low result was deemed indicative of a laboratory error as it was not seen in subsequent testing. Two were in individuals who had a prior episode of thrombocytopenia and were found to have a low platelet count after vaccination when seen in the emergency department for signs of bleeding. None of these three were associated with receipt of AstraZeneca/COVISHIELD vaccine. The fourth report was for an individual with a low platelet count admitted to hospital eight days after the AstraZeneca vaccine for abdominal pain and bruising. This individual was treated with full recovery. The final report was for an individual with a concurrent blood condition that could have contributed to development of thrombocytopenia. Investigation was still ongoing for this report.

Some events may be reported as an “other serious” event when not its own discrete event on the provincial AEFI report form. Amongst these events, 45 were for various thrombotic/thromboembolic conditions. These included nine strokes, eight myocardial infarctions, 15 pulmonary embolisms, 11 deep vein thromboses, and two superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[5,6]

There have been two non-fatal confirmed cases of TTS reported in BC to date, both in adults in their 40s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on May 19, 2021. Only AEFIs reported and doses administered up to May 15, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

References

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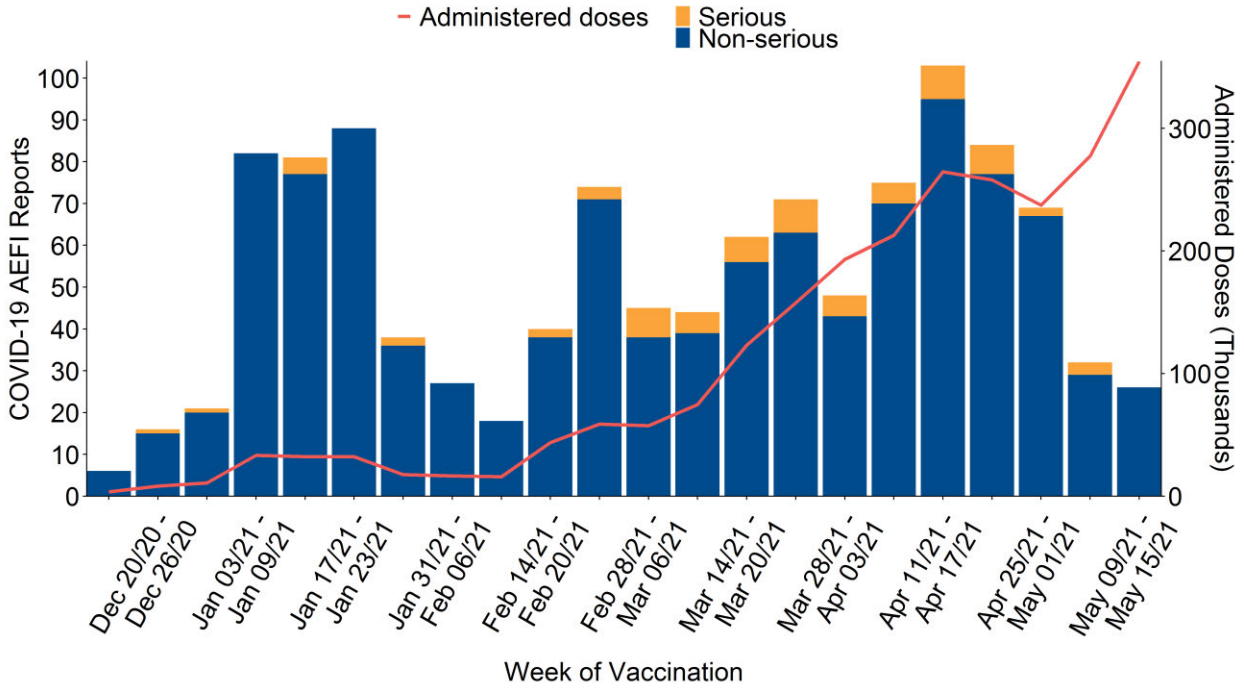

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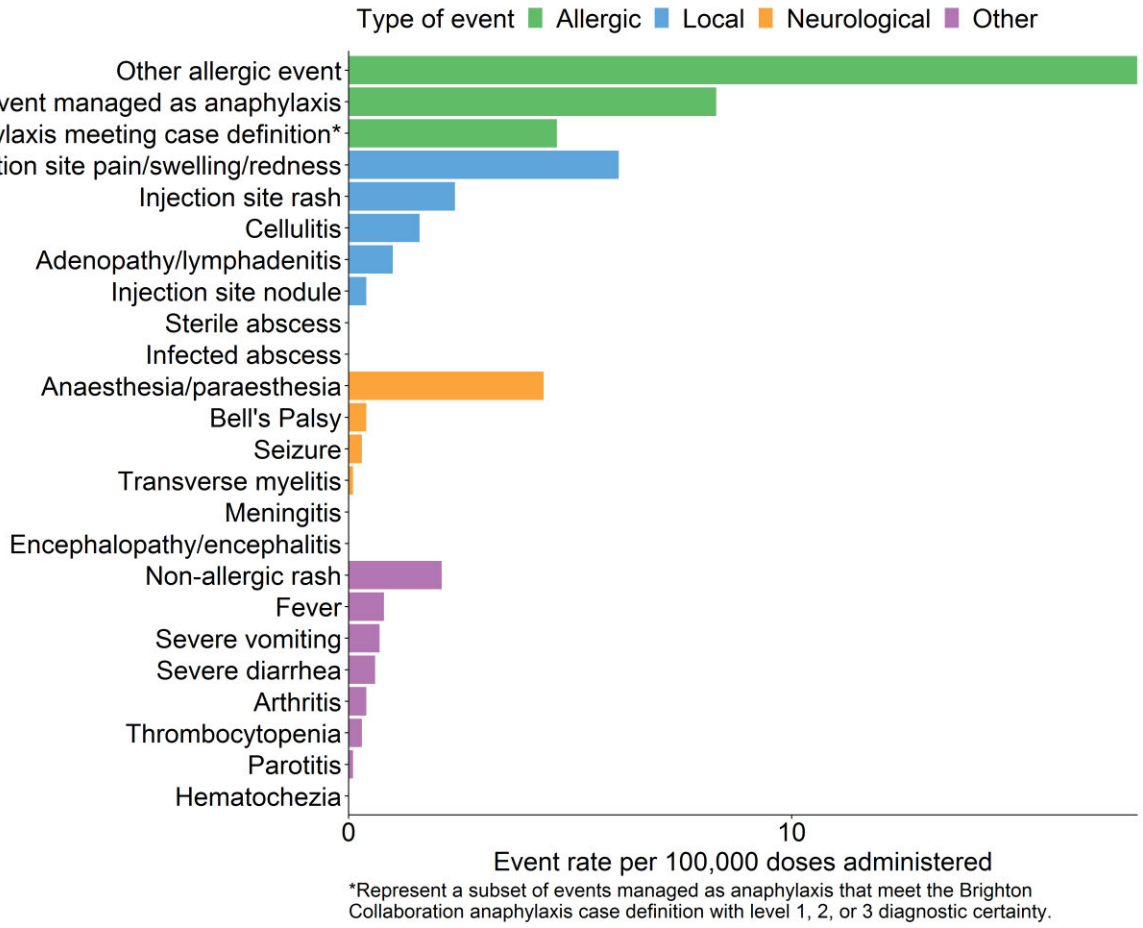

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There were five reports of thrombocytopenia without concurrent thrombosis. One occurred in an individual with a single low platelet result followed subsequently by normal results in the days after. The one low result was deemed indicative of a laboratory error as it was not seen in subsequent testing. Two were in individuals who had a prior episode of thrombocytopenia and were found to have a low platelet count after vaccination when seen in the emergency department for signs of bleeding. None of these three were associated with receipt of AstraZeneca/COVISHIELD vaccine. The fourth report was for an individual with a low platelet count admitted to hospital eight days after the AstraZeneca vaccine for abdominal pain and bruising. This individual was treated with full recovery. The final report was for an individual with a concurrent blood condition that could have contributed to development of thrombocytopenia. Investigation was still ongoing for this report.

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 45 were for various thrombotic/thromboembolic conditions. These included nine strokes, eight myocardial infarctions, 15 pulmonary embolisms, 11 deep vein thromboses, and two superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[5,6]

There have been two non-fatal confirmed cases of TTS reported in BC to date, both in adults in their 40s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia.

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From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: RE: May 20 Public AEFI Report
Date: Thursday, May 20, 2021 1:50:01 PM

Thanks Kyle!

Sableen – FYI – I will l post this with my update to the safety page regarding the 12-17 vaccination announcement.

From: Noftall, Kyle [BCCDC]
Sent: Thursday, May 20, 2021 10:16 AM
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: May 20 Public AEFI Report

Hi Heather and Sableen,

Here is this week's AEFI report.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly AEFI Report
Date: Thursday, May 27, 2021 9:32:56 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-05-27.docx
COVID19_AEFI_Weekly_Report_2021-05-27.pdf

Hi Heather and Sableen,

Here's this week's AEFI report for posting.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to May 22, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including May 22, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates.

There have been two reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 250,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[5,6]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[7] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously

unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[8] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[9]

Definitions

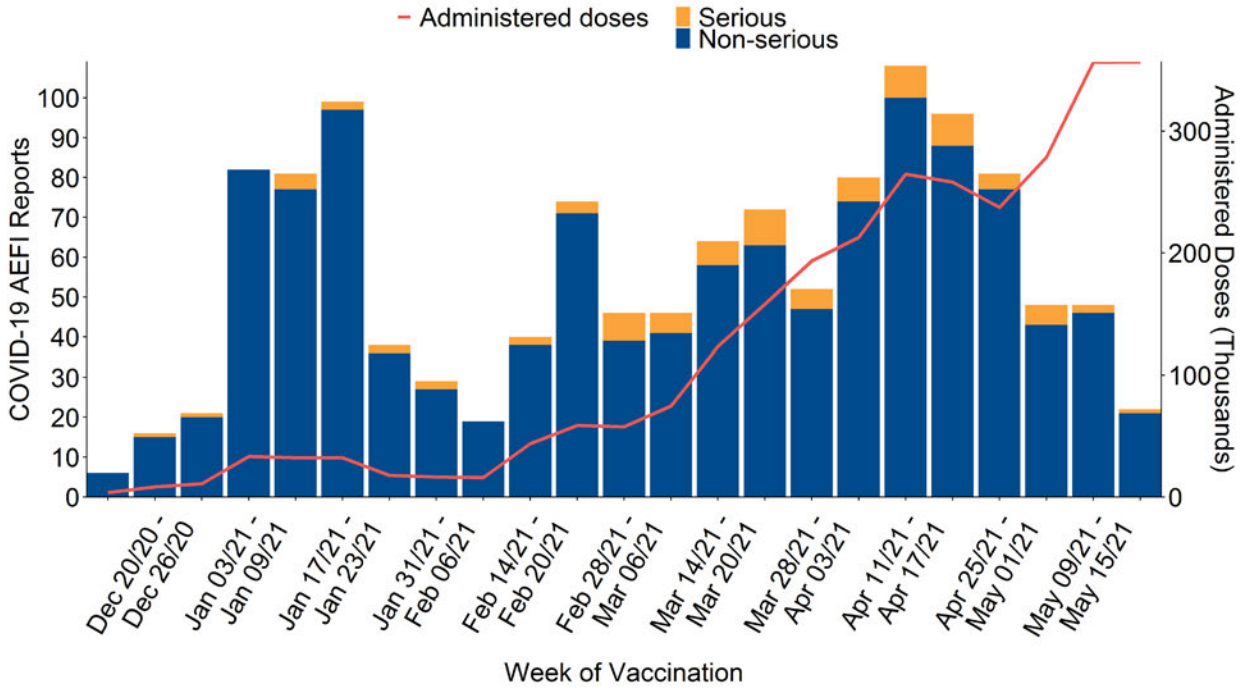
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[10]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of May 22, 2021, there have been 2,843,530 COVID-19 vaccine doses administered in BC and 1,268 COVID-19 AEFI reports (44.6 reports per 100,000 doses administered)
- 83 reports (6.5%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - May 22, 2021 **(N=1,268)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including May 22, 2021, a total of 2,843,530 doses have been administered. During this period, there have been 1,268 AEFI reports following a COVID-19 vaccine, for a reporting rate of 44.6 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - May 22, 2021 **(N=1,268)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**1268**	**106**	**44**	**409**	**707**
Non-serious reports	1185	99	40	384	661
Serious reports	83	7	4	25	46
Proportion serious	6.5%	6.6%	9.1%	6.1%	6.5%
Dose 1 reports	1167	106	44	377	638
Dose 2 reports	101	0	0	32	69
Total doses administered	**2,843,530**	**214,699**	**59,578**	**538,441**	**2,030,810**
Dose 1 administered	2,697,001	214,543	58,822	497,282	1,926,352
Dose 2 administered	146,529	156	756	41,159	104,458
Total reporting rate	**44.6**	**49.4**	**73.9**	**76.0**	**34.8**
Serious rate	2.9	3.3	6.7	4.6	2.3
Dose 1 rate	43.3	49.4	74.8	75.8	33.1
Dose 2 rate	68.9	0.0	0.0	77.7	66.1

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=2). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

Eighty-three reports (6.5%) were considered serious (refer to serious AEFI definition above). Of these, 73 individuals were admitted to hospital. These included 17 individuals hospitalized after anaphylaxis or other allergic event, 26 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, 10 for stroke, two hemorrhage with one associated encephalopathy, one meningitis, and eight for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), 12 for chest pain/cardiac events, 10 pulmonary embolism, one respiratory distress, one for a pregnancy related complication, one sepsis with myocarditis, three for thrombocytopenia, and two for thrombosis with thrombocytopenia

syndrome (described further below).

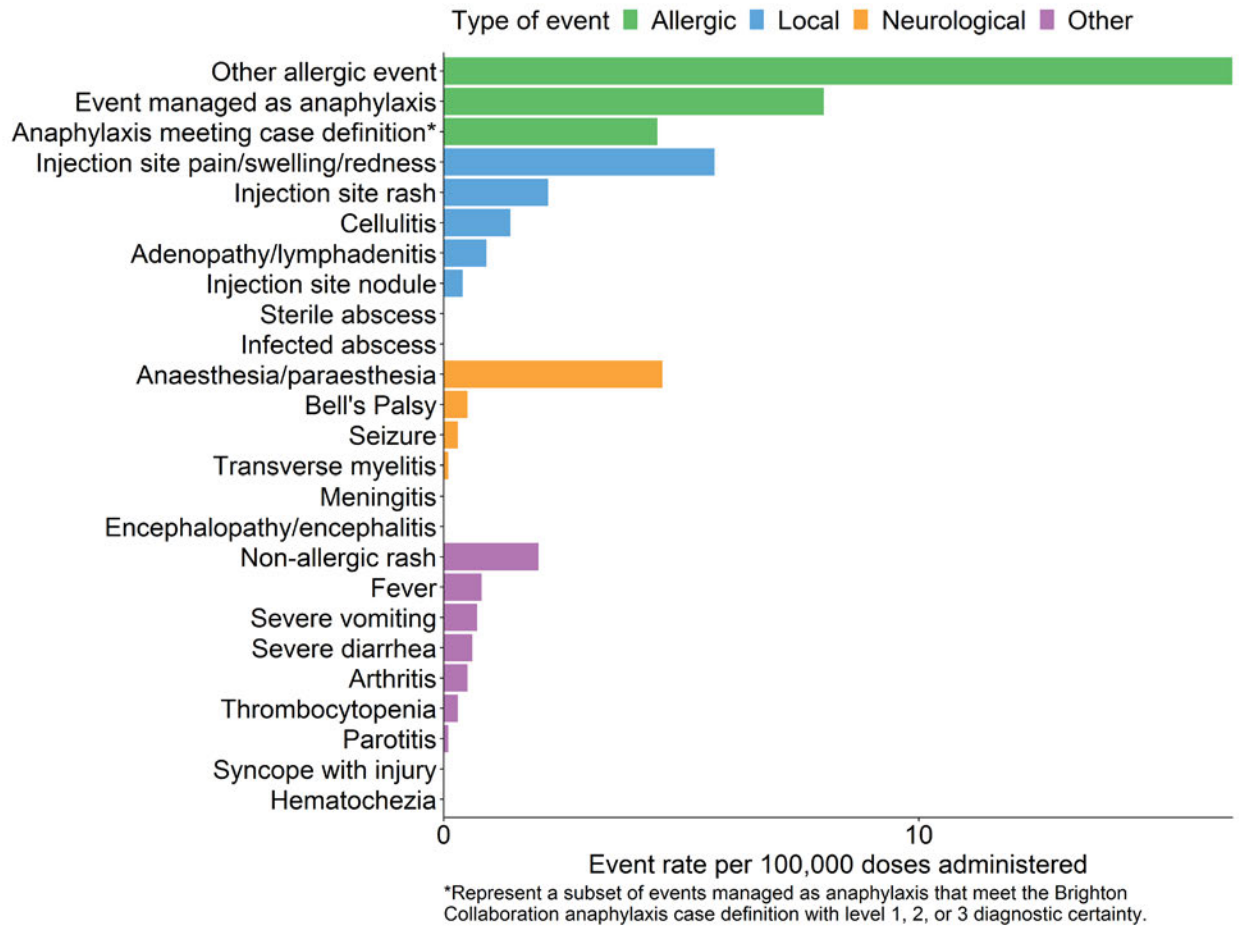
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[7] Death may also be recorded as the outcome of a specific reportable event. Eight serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. One death occurred in an elderly individual with underlying medical conditions; the coroner deemed this death not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified. Finally, one death occurred in an individual with an underlying lung condition who passed away 24 days after vaccination. Investigation into the cause of death was still underway.

For two individuals, death was the outcome of cardiac arrest. Both were elderly individuals with multiple underlying medical conditions. A third death occurred in an elderly individual following a stroke and hospital admission (included in hospitalized count above). This individual had previous history of stroke along with other medical conditions.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 1,268 AEFI reports received up to May 22, 2021 contained a total of 1,664 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[11]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - May 22, 2021 **(N=1,664)**



Event Descriptions

Two hundred twenty-eight reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 127 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[11] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Forty reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[12] None of these reports were confirmed by microbial testing.

Twenty six reports contained a diagnosed neurological event. Thirteen individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. Eight individuals reported seizures, including five with a history of a seizure disorder. Two individuals were admitted to hospital for an

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Key Findings

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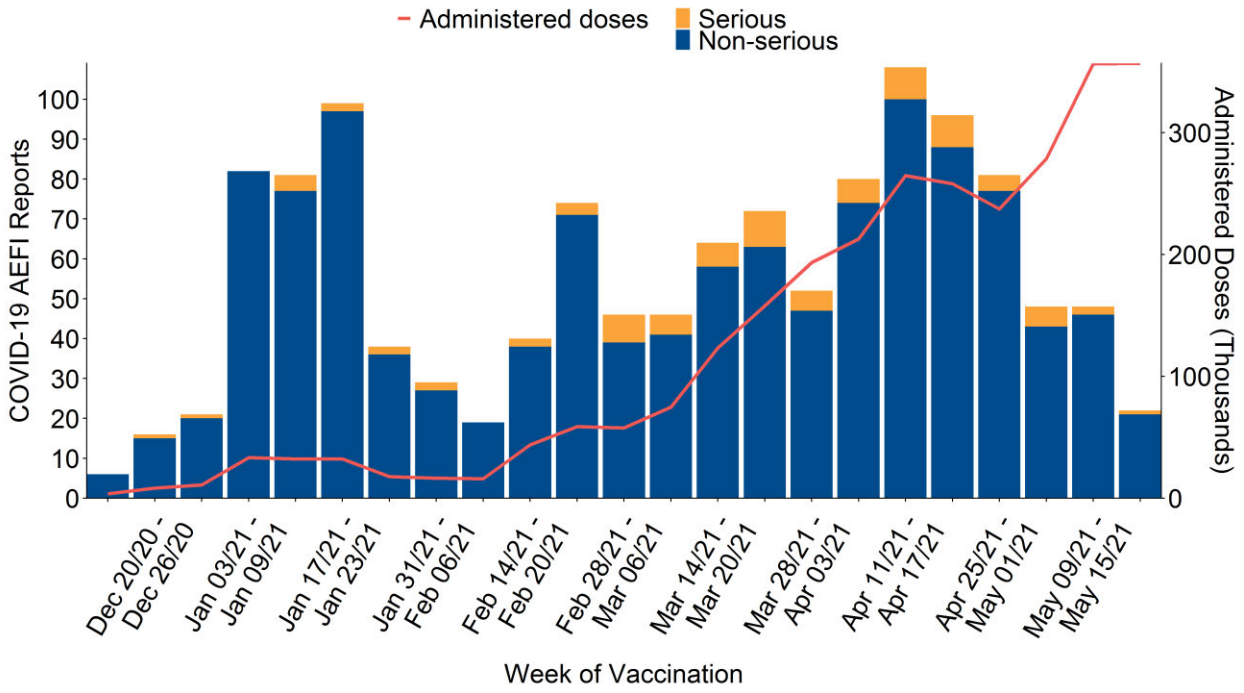

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Dose 1 reports	1167	106	44	377	638
Dose 2 reports	101	0	0	32	69
Total doses administered	**2,843,530**	**214,699**	**59,578**	**538,441**	**2,030,810**
Dose 1 administered	2,697,001	214,543	58,822	497,282	1,926,352
Dose 2 administered	146,529	156	756	41,159	104,458
Total reporting rate	**44.6**	**49.4**	**73.9**	**76.0**	**34.8**
Serious rate	2.9	3.3	6.7	4.6	2.3
Dose 1 rate	43.3	49.4	74.8	75.8	33.1
Dose 2 rate	68.9	0.0	0.0	77.7	66.1

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=2). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

Eighty-three reports (6.5%) were considered serious (refer to serious AEFI definition above). Of these, 73 individuals were admitted to hospital. These included 17 individuals hospitalized after anaphylaxis or other allergic event, 26 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, 10 for stroke, two hemorrhage with one associated encephalopathy, one meningitis, and eight for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), 12 for chest pain/cardiac events, 10 pulmonary embolism, one respiratory distress, one for a pregnancy related complication, one sepsis with myocarditis, three for thrombocytopenia, and two for thrombosis with thrombocytopenia

syndrome (described further below).

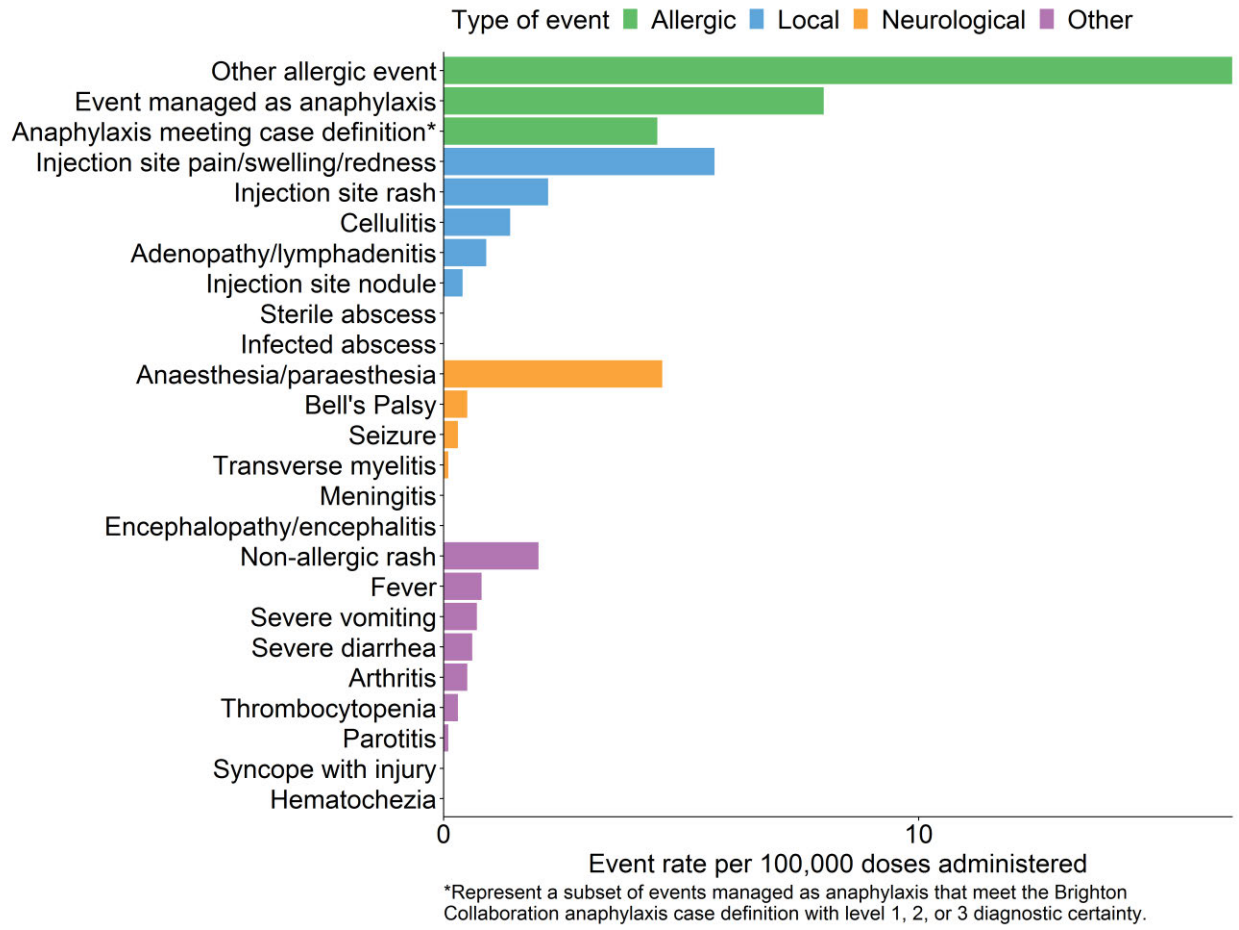
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[7] Death may also be recorded as the outcome of a specific reportable event. Eight serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. One death occurred in an elderly individual with underlying medical conditions; the coroner deemed this death not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified. Finally, one death occurred in an individual with an underlying lung condition who passed away 24 days after vaccination. Investigation into the cause of death was still underway.

For two individuals, death was the outcome of cardiac arrest. Both were elderly individuals with multiple underlying medical conditions. A third death occurred in an elderly individual following a stroke and hospital admission (included in hospitalized count above). This individual had previous history of stroke along with other medical conditions.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 1,268 AEFI reports received up to May 22, 2021 contained a total of 1,664 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[11]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - May 22, 2021 **(N=1,664)**



Event Descriptions

Two hundred twenty-eight reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 127 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[11] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Forty reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[12] None of these reports were confirmed by microbial testing.

Twenty six reports contained a diagnosed neurological event. Thirteen individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. Eight individuals reported seizures, including five with a history of a seizure disorder. Two individuals were admitted to hospital for an

intracerebral hemorrhage, and one had a subsequent encephalopathy. Finally, one individual was hospitalized for aseptic meningitis.

There were seven reports of thrombocytopenia without concurrent thrombosis. One occurred in an individual with a single low platelet result followed subsequently by normal results in the days after. The one low result was deemed indicative of a laboratory error as it was not seen in subsequent testing. Two were in individuals who had a prior episode of thrombocytopenia and were found to have a low platelet count after vaccination when seen in the emergency department for signs of bleeding. Three reports were for individuals who had a concurrent medical condition (one blood disorder and two with sepsis) that could contribute to development of thrombocytopenia. None of these reports were associated with receipt of AstraZeneca/COVISHIELD vaccine. The last report was for an individual with a low platelet count admitted to hospital eight days after the AstraZeneca vaccine for abdominal pain and bruising. This individual was treated with full recovery.

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 48 were for various thrombotic/thromboembolic conditions. These included 10 strokes, eight myocardial infarctions, 13 pulmonary embolisms, 15 deep vein thromboses, and two superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[5,6]

There have been two non-fatal confirmed cases of TTS reported in BC to date, both in adults in their 40s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on May 26, 2021. Only AEFIs reported and doses administered up to May 22, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly AEFI report
Date: Thursday, June 03, 2021 12:19:24 PM
Attachments: COVID19_AEFI_Weekly_Report_2021-06-03.docx
COVID19_AEFI_Weekly_Report_2021-06-03.pdf

Hi Heather and Sableen,

Attached is this week's AEFI report for posting.

Thanks,

Kyle

Kyle Noftall, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to May 29, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including May 29, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. BC is monitoring for reports of myocarditis following mRNA vaccines, which has been identified as an adverse event of interest based on reports from Israel and is being monitored in several countries.[5,6]

There have been three reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with roughly 275,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[7,8]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[9] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and

detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[10] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[11]

Definitions

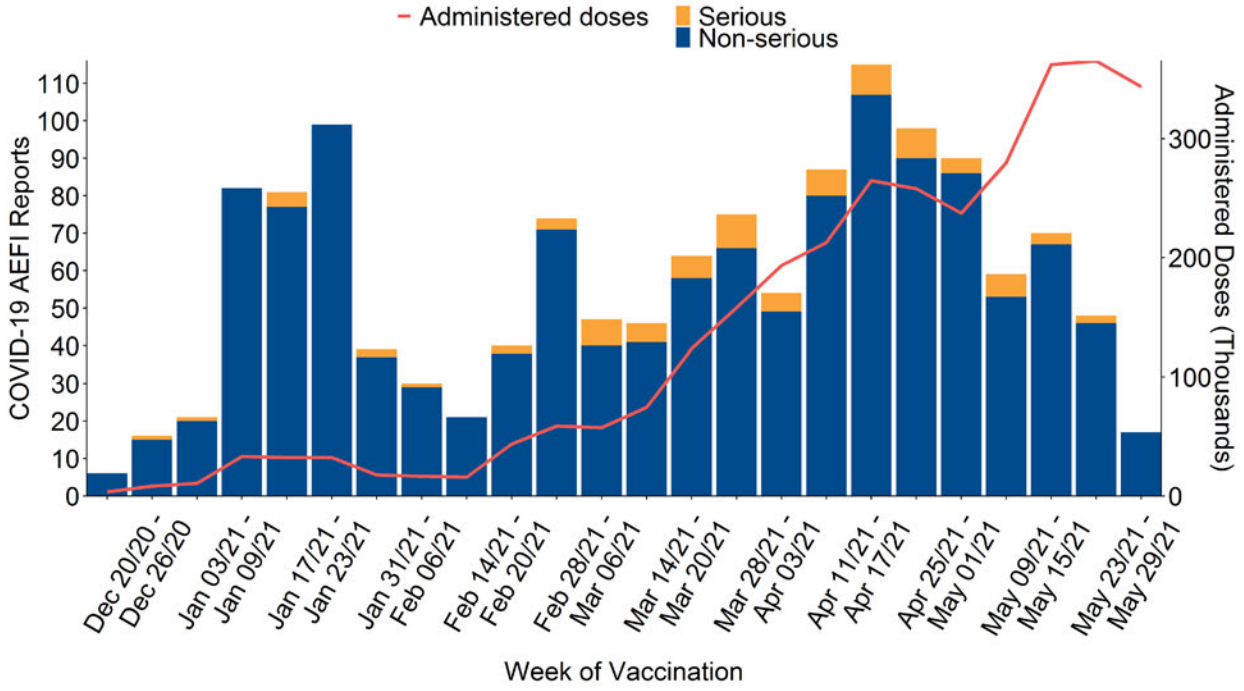
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[12]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of May 29, 2021, there have been 3,203,628 COVID-19 vaccine doses administered in BC and 1,379 COVID-19 AEFI reports (43.0 reports per 100,000 doses administered)
- 84 reports (6.1%) met the serious definition, for a rate of 2.6 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - May 29, 2021 **(N=1,379)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including May 29, 2021, a total of 3,203,628 doses have been administered. During this period, there have been 1,379 AEFI reports following a COVID-19 vaccine, for a reporting rate of 43.0 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - May 29, 2021 **(N=1,379)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**1,379**	**122**	**46**	**436**	**773**
Non-serious reports	1,295	114	42	414	724
Serious reports	84	8	4	22	49
Proportion serious	6.1%	6.6%	8.7%	5%	6.3%
Dose 1 reports	1,272	122	46	403	699

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 2 reports	107	0	0	33	74
Total doses administered	**3,203,628**	**215,210**	**60,452**	**618,367**	**2,309,596**
Dose 1 administered	3,029,224	214,669	59,103	572,630	2,182,819
Dose 2 administered	174,404	541	1,349	45,737	126,777
Total reporting rate	**43.0**	**56.7**	**76.1**	**70.5**	**33.5**
Serious rate	2.6	3.7	6.6	3.6	2.1
Dose 1 rate	42.0	56.8	77.8	70.4	32.0
Dose 2 rate	61.4	0.0	0.0	72.2	58.4

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=2). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

Eighty-four reports (6.1%) were considered serious (refer to serious AEFI definition above). Of these, 77 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis, 19 for a neurological diagnosis (including two for transverse myelitis, three for seizure, 10 for stroke, two cerebral hemorrhage with one associated encephalopathy, one meningitis, and one Guillain-Barre Syndrome), 11 for cardiac events (including eight for myocardial infarction and three for perimyocarditis), 10 pulmonary embolism, one respiratory distress, one for a pregnancy related complication, four for thrombocytopenia, and three for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[9] Death may also be recorded as the outcome of a specific reportable event. Eight serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. One death occurred in an elderly individual with underlying medical conditions; the coroner deemed this death not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified. Finally, one death occurred in an individual with an underlying lung condition who passed away 24 days after vaccination. Investigation into the cause of death was still underway.

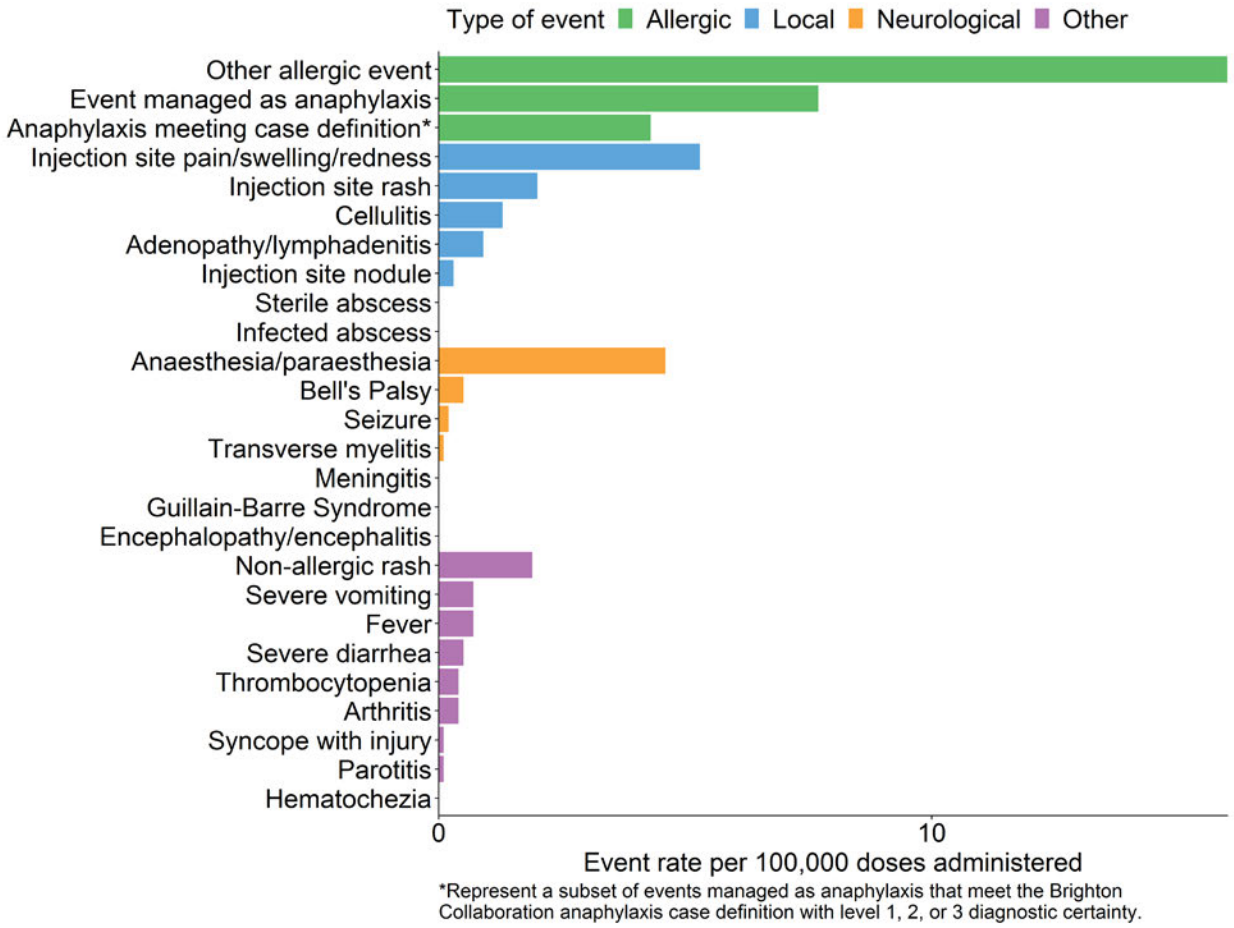
For two individuals, death was the outcome of cardiac arrest. Both were elderly individuals with multiple underlying medical conditions. The third death occurred in an elderly individual

following a stroke and hospital admission (included in hospitalized count above). This individual had previous history of stroke along with other medical conditions.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 1,379 AEFI reports received up to May 29, 2021 contained a total of 1,794 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[13]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - May 29, 2021 **(N=1,794)**



Event Descriptions

Two hundred forty-eight reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 138 (56%) met the

Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[13] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Forty-one reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[14] None of these reports were confirmed by microbial testing.

Twenty-nine reports contained a diagnosed neurological event. Fifteen individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. Eight individuals reported seizures, including five with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, and one had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis. Finally, there was one report for an individual hospitalized with Guillain-Barre Syndrome (GBS) who has since been discharged and is recovering with rehabilitation therapy. A possible infectious cause of GBS was not identified. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[11,15,16]

There were nine reports of thrombocytopenia without concurrent thrombosis. One occurred in an individual with a single low platelet result followed subsequently by normal results in the days after. The one low result was deemed indicative of a laboratory error as it was not seen in subsequent testing. Two were in individuals who had a prior episode of thrombocytopenia and were found to have a low platelet count after vaccination when seen in the emergency department for signs of bleeding. Five reports were for individuals who had a concurrent medical condition or who were taking medications that could contribute to development of thrombocytopenia. None of these reports were associated with receipt of AstraZeneca/COVISHIELD vaccine. The last report was for an individual with a low platelet count admitted to hospital eight days after the AstraZeneca vaccine for abdominal pain and bruising. This individual was treated with full recovery.

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 52 were for various thrombotic/thromboembolic conditions. These included 10 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), eight myocardial infarctions, 14 pulmonary embolisms, 17 deep vein thromboses, and two superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[7,8]

There have been three non-fatal confirmed cases of TTS reported in BC to date, all in adults in their 30s or 40s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the

AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital.

There have been seven reports of pericarditis/myocarditis. Three individuals had a diagnosis of pericarditis alone, two had myocarditis, and two had perimyocarditis. Ages ranged from 29 to 95, and five were male. Four had received Moderna vaccine and three had Pfizer vaccine; two of the events occurred after second dose of Pfizer. Many had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. One met the diagnostic criteria to be considered a definite case according to the draft Brighton Collaboration myocarditis case definition.[17] This individual also presented with signs of sepsis but no infective agent was identified. Myocarditis is being investigated as a possible safety signal after mRNA vaccines in Canada and internationally, but at this time a confirmed association has not been made and event rates reported in Canada have been well within the expected background rates for these conditions.[5,6,11]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on June 2, 2021. Only AEFIs reported and doses administered up to May 29, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to May 29, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including May 29, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. BC is monitoring for reports of myocarditis following mRNA vaccines, which has been identified as an adverse event of interest based on reports from Israel and is being monitored in several countries.[5,6]

There have been three reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with roughly 275,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[7,8]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[9] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and

detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[10] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[11]

Definitions

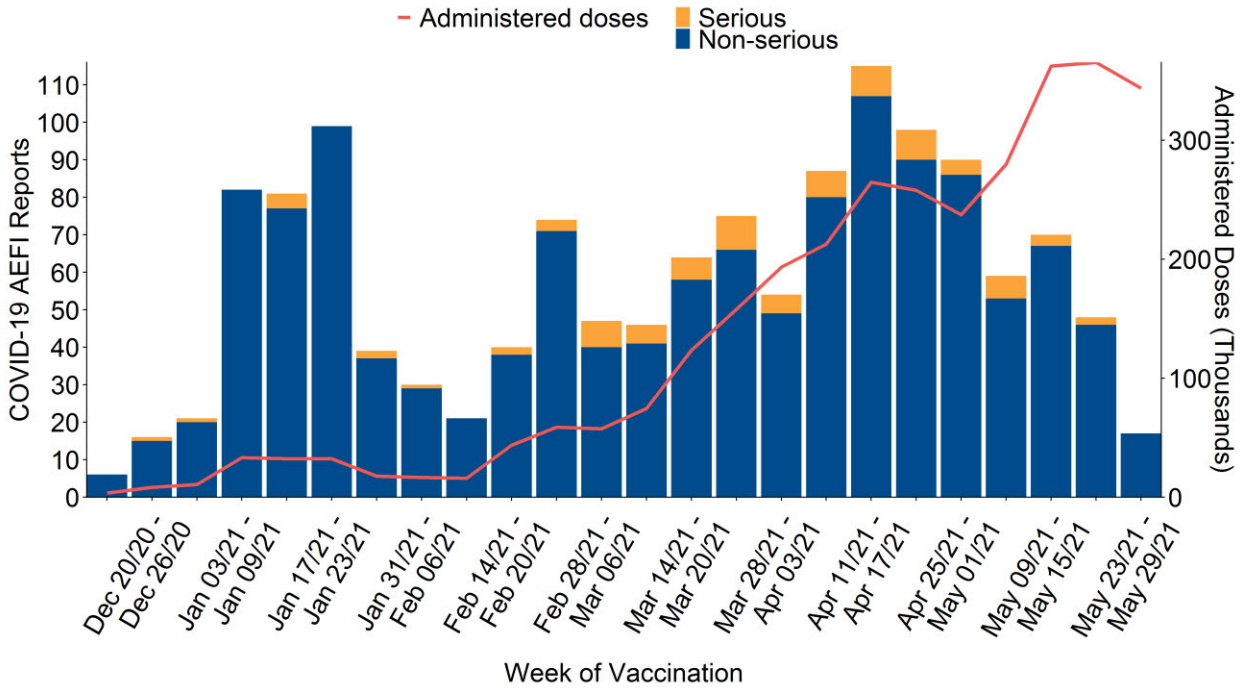
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[12]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of May 29, 2021, there have been 3,203,628 COVID-19 vaccine doses administered in BC and 1,379 COVID-19 AEFI reports (43.0 reports per 100,000 doses administered)
- 84 reports (6.1%) met the serious definition, for a rate of 2.6 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - May 29, 2021 **(N=1,379)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including May 29, 2021, a total of 3,203,628 doses have been administered. During this period, there have been 1,379 AEFI reports following a COVID-19 vaccine, for a reporting rate of 43.0 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - May 29, 2021 **(N=1,379)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**1,379**	**122**	**46**	**436**	**773**
Non-serious reports	1,295	114	42	414	724
Serious reports	84	8	4	22	49
Proportion serious	6.1%	6.6%	8.7%	5%	6.3%
Dose 1 reports	1,272	122	46	403	699

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 2 reports	107	0	0	33	74
Total doses administered	**3,203,628**	**215,210**	**60,452**	**618,367**	**2,309,596**
Dose 1 administered	3,029,224	214,669	59,103	572,630	2,182,819
Dose 2 administered	174,404	541	1,349	45,737	126,777
Total reporting rate	**43.0**	**56.7**	**76.1**	**70.5**	**33.5**
Serious rate	2.6	3.7	6.6	3.6	2.1
Dose 1 rate	42.0	56.8	77.8	70.4	32.0
Dose 2 rate	61.4	0.0	0.0	72.2	58.4

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=2). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

Eighty-four reports (6.1%) were considered serious (refer to serious AEFI definition above). Of these, 77 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis, 19 for a neurological diagnosis (including two for transverse myelitis, three for seizure, 10 for stroke, two cerebral hemorrhage with one associated encephalopathy, one meningitis, and one Guillain-Barre Syndrome), 11 for cardiac events (including eight for myocardial infarction and three for perimyocarditis), 10 pulmonary embolism, one respiratory distress, one for a pregnancy related complication, four for thrombocytopenia, and three for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[9] Death may also be recorded as the outcome of a specific reportable event. Eight serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. One death occurred in an elderly individual with underlying medical conditions; the coroner deemed this death not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified. Finally, one death occurred in an individual with an underlying lung condition who passed away 24 days after vaccination. Investigation into the cause of death was still underway.

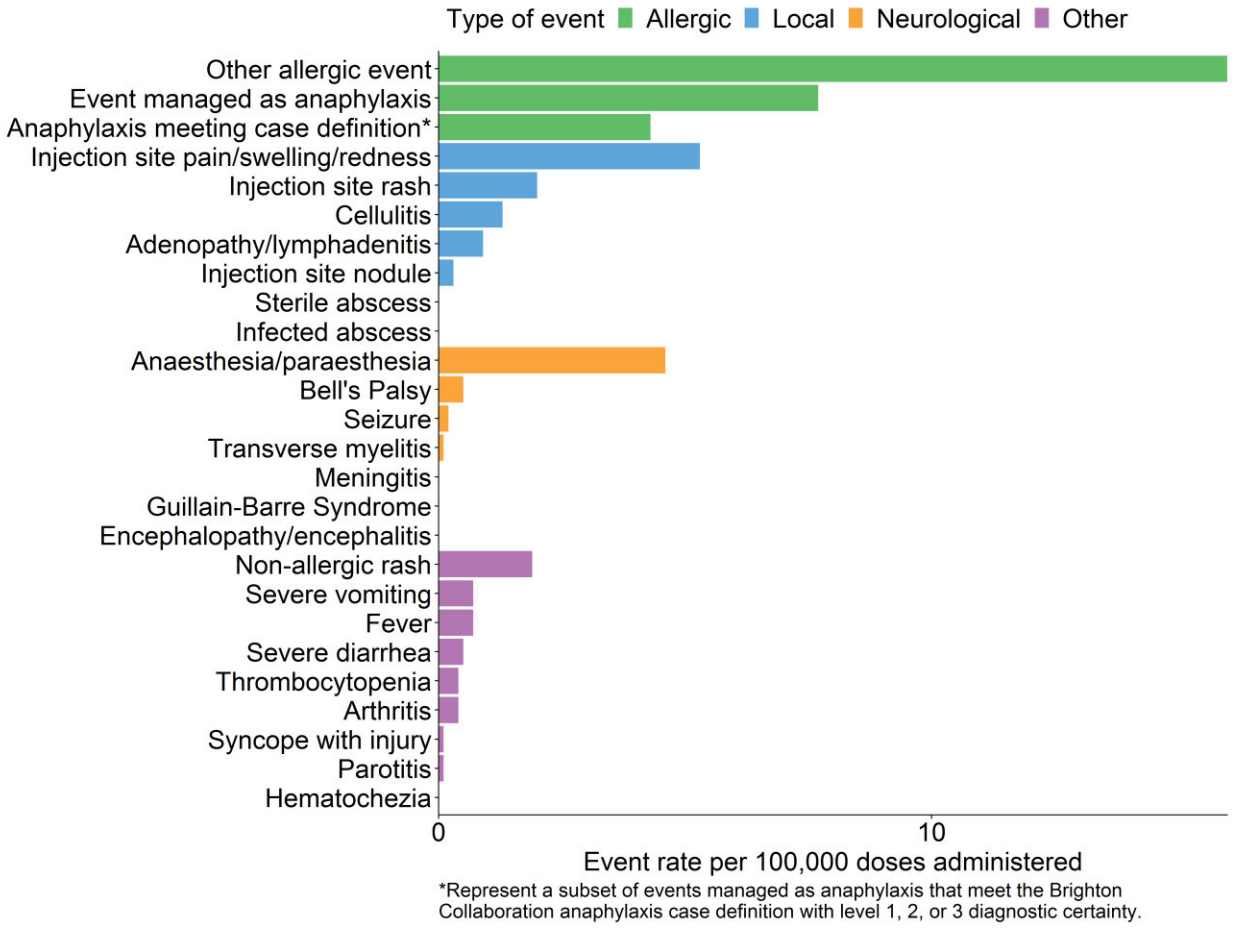
For two individuals, death was the outcome of cardiac arrest. Both were elderly individuals with multiple underlying medical conditions. The third death occurred in an elderly individual

following a stroke and hospital admission (included in hospitalized count above). This individual had previous history of stroke along with other medical conditions.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 1,379 AEFI reports received up to May 29, 2021 contained a total of 1,794 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.[13]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - May 29, 2021 **(N=1,794)**



Event Descriptions

Two hundred forty-eight reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 138 (56%) met the

Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[13] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Forty-one reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[14] None of these reports were confirmed by microbial testing.

Twenty-nine reports contained a diagnosed neurological event. Fifteen individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. Eight individuals reported seizures, including five with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, and one had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis. Finally, there was one report for an individual hospitalized with Guillain-Barre Syndrome (GBS) who has since been discharged and is recovering with rehabilitation therapy. A possible infectious cause of GBS was not identified. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[11,15,16]

There were nine reports of thrombocytopenia without concurrent thrombosis. One occurred in an individual with a single low platelet result followed subsequently by normal results in the days after. The one low result was deemed indicative of a laboratory error as it was not seen in subsequent testing. Two were in individuals who had a prior episode of thrombocytopenia and were found to have a low platelet count after vaccination when seen in the emergency department for signs of bleeding. Five reports were for individuals who had a concurrent medical condition or who were taking medications that could contribute to development of thrombocytopenia. None of these reports were associated with receipt of AstraZeneca/COVISHIELD vaccine. The last report was for an individual with a low platelet count admitted to hospital eight days after the AstraZeneca vaccine for abdominal pain and bruising. This individual was treated with full recovery.

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 52 were for various thrombotic/thromboembolic conditions. These included 10 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), eight myocardial infarctions, 14 pulmonary embolisms, 17 deep vein thromboses, and two superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[7,8]

There have been three non-fatal confirmed cases of TTS reported in BC to date, all in adults in their 30s or 40s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the

AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital.

There have been seven reports of pericarditis/myocarditis. Three individuals had a diagnosis of pericarditis alone, two had myocarditis, and two had perimyocarditis. Ages ranged from 29 to 95, and five were male. Four had received Moderna vaccine and three had Pfizer vaccine; two of the events occurred after second dose of Pfizer. Many had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. One met the diagnostic criteria to be considered a definite case according to the draft Brighton Collaboration myocarditis case definition.[17] This individual also presented with signs of sepsis but no infective agent was identified. Myocarditis is being investigated as a possible safety signal after mRNA vaccines in Canada and internationally, but at this time a confirmed association has not been made and event rates reported in Canada have been well within the expected background rates for these conditions.[5,6,11]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on June 2, 2021. Only AEFIs reported and doses administered up to May 29, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly COVID19 AEFI Report
Date: Thursday, June 17, 2021 9:30:36 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-06-17.docx
COVID19_AEFI_Weekly_Report_2021-06-17.pdf

Hi Heather and Sableen,

Attached is this week's COVID-19 AEFI report.

Thank you,

Kyle

Kyle Noftall, RN, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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British Columbia Report

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There have been three reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 300,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[7,8]

Background

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AEFI reports are further investigated provincially with particular focus on serious AEFI and

detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[10] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[11]

Definitions

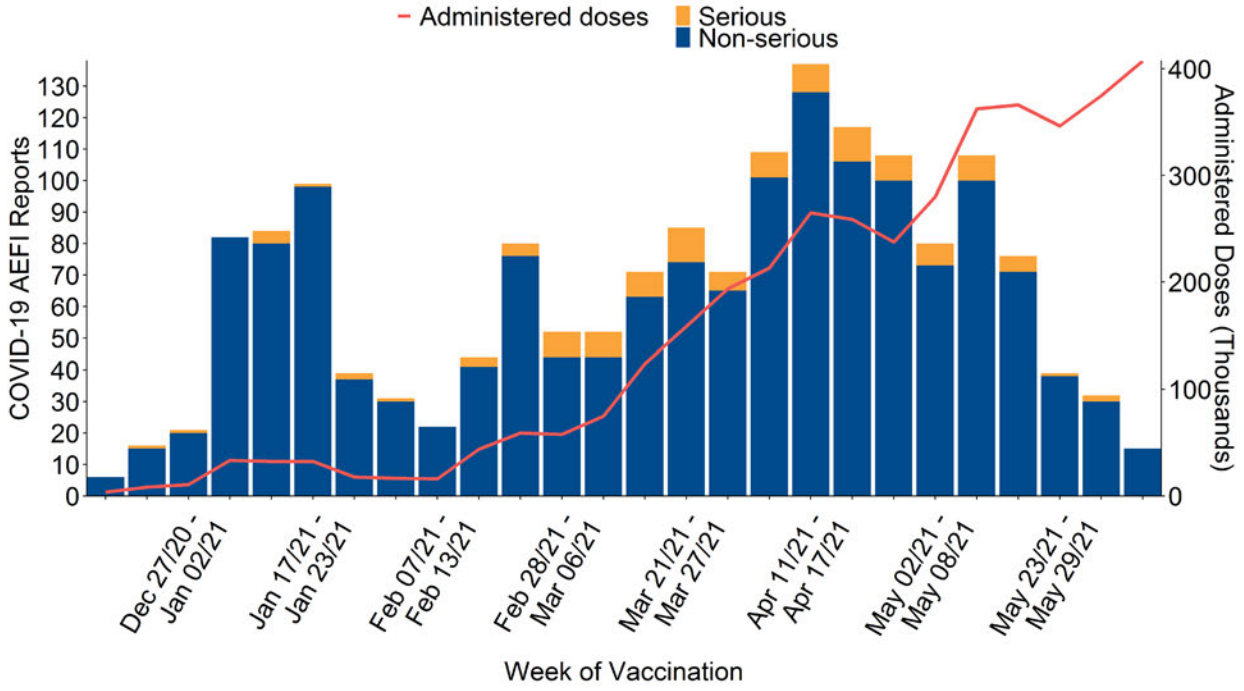
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[12]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of June 12, 2021, there have been 3,993,717 COVID-19 vaccine doses administered in BC and 1,676 COVID-19 AEFI reports (42.0 reports per 100,000 doses administered)
- 117 reports (7%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and anaesthesia/paraesthesia

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jun. 12, 2021 **(N=1,676)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including June 12, 2021, a total of 3,993,717 doses have been administered. During this period, there have been 1,676 AEFI reports following a COVID-19 vaccine, for a reporting rate of 42.0 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jun. 12, 2021 **(N=1,676)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**1,676**	**159**	**50**	**498**	**968**
Non-serious reports	1,559	147	46	470	895
Serious reports	117	12	4	28	73
Proportion serious	7%	7.5%	8%	5.6%	7.5%
Dose 1 reports	1,546	159	50	458	878

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 2 reports	130	0	0	40	90
Total doses administered	**3,993,717**	**255,169**	**63,758**	**717,628**	**2,957,132**
Dose 1 administered	3,415,209	215,279	59,497	606,985	2,533,418
Dose 2 administered	578,508	39,890	4,261	110,643	423,714
Total reporting rate	**42.0**	**62.3**	**78.4**	**69.4**	**32.7**
Serious rate	2.9	4.7	6.3	3.9	2.5
Dose 1 rate	45.3	73.9	84.0	75.5	34.7
Dose 2 rate	22.5	0.0	0.0	36.2	21.2

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred seventeen reports (7%) were considered serious (refer to serious AEFI definition above). Of these, 107 individuals were admitted to hospital. These included 12 individuals hospitalized after anaphylaxis, 25 for a neurological diagnosis (including three for transverse myelitis, four for seizure, 14 for stroke, two intracerebral hemorrhage with one associated encephalopathy, one meningitis, and one Guillain-Barre Syndrome), 20 for cardiac events (including 11 for myocardial infarction, seven for myopericarditis, and two for an arrhythmia), 12 pulmonary embolism, one respiratory distress, one for exacerbation of idiopathic pulmonary fibrosis, one for a pregnancy related complication, seven for thrombocytopenia alone or associated with a concurrent condition, and three for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[9] Death may also be recorded as the outcome of a specific reportable event. Thirteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified. Two additional deaths occurred in long term care residents and were still being reviewed at the time of this report.

For four individuals, death was the outcome of cardiac arrest. Three of these were elderly

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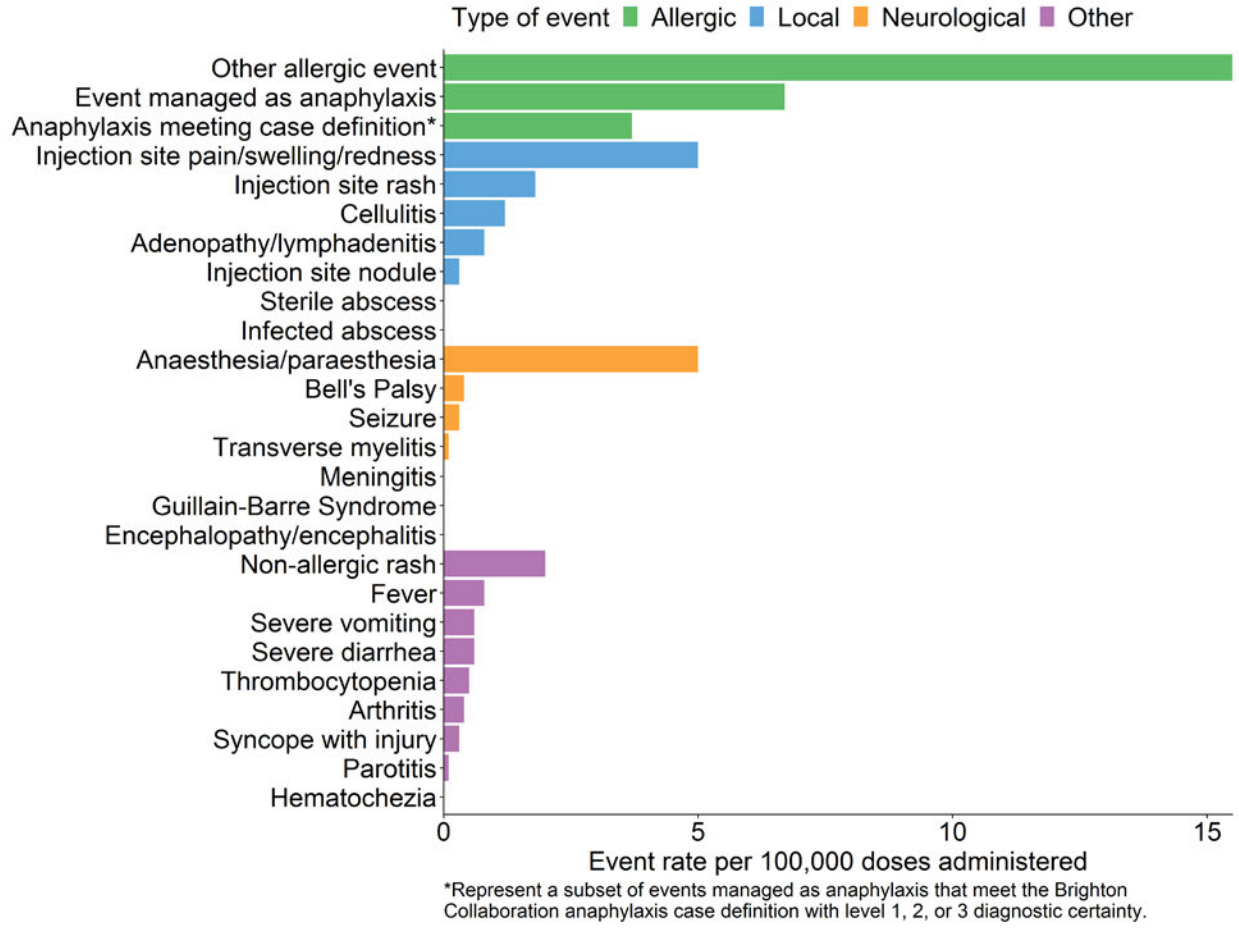

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Two hundred sixty-seven reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 147 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[13] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

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Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 66 were for various thrombotic/ thromboembolic conditions. These included 14 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 11 myocardial infarctions, 16 pulmonary embolisms, 21 deep vein thromboses, and three superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[7,8]

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to June 12, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including June 12, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. BC is monitoring for reports of myocarditis following mRNA vaccines, which has been identified as an adverse event of interest based on reports from Israel and is being monitored in several countries.[5,6]

There have been three reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 300,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[7,8]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[9] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and

detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[10] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[11]

Definitions

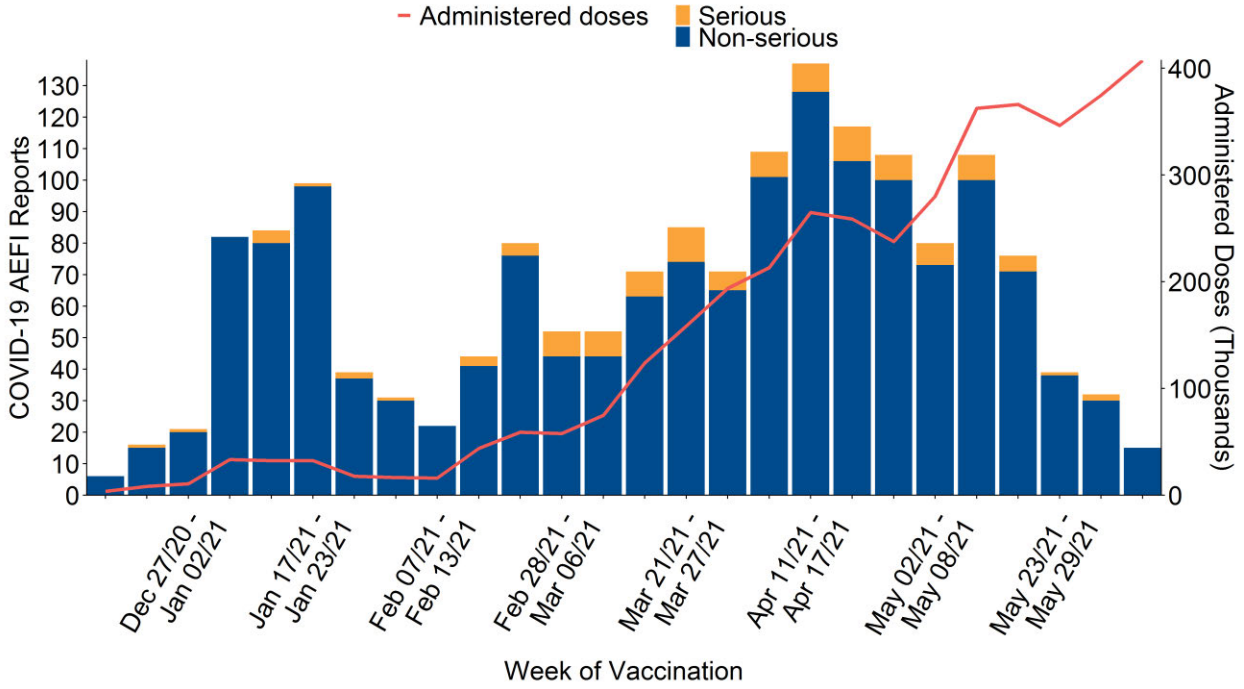
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[12]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of June 12, 2021, there have been 3,993,717 COVID-19 vaccine doses administered in BC and 1,676 COVID-19 AEFI reports (42.0 reports per 100,000 doses administered)
- 117 reports (7%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and anaesthesia/paraesthesia

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jun. 12, 2021 **(N=1,676)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including June 12, 2021, a total of 3,993,717 doses have been administered. During this period, there have been 1,676 AEFI reports following a COVID-19 vaccine, for a reporting rate of 42.0 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jun. 12, 2021 **(N=1,676)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**1,676**	**159**	**50**	**498**	**968**
Non-serious reports	1,559	147	46	470	895
Serious reports	117	12	4	28	73
Proportion serious	7%	7.5%	8%	5.6%	7.5%
Dose 1 reports	1,546	159	50	458	878

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 2 reports	130	0	0	40	90
Total doses administered	**3,993,717**	**255,169**	**63,758**	**717,628**	**2,957,132**
Dose 1 administered	3,415,209	215,279	59,497	606,985	2,533,418
Dose 2 administered	578,508	39,890	4,261	110,643	423,714
Total reporting rate	**42.0**	**62.3**	**78.4**	**69.4**	**32.7**
Serious rate	2.9	4.7	6.3	3.9	2.5
Dose 1 rate	45.3	73.9	84.0	75.5	34.7
Dose 2 rate	22.5	0.0	0.0	36.2	21.2

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred seventeen reports (7%) were considered serious (refer to serious AEFI definition above). Of these, 107 individuals were admitted to hospital. These included 12 individuals hospitalized after anaphylaxis, 25 for a neurological diagnosis (including three for transverse myelitis, four for seizure, 14 for stroke, two intracerebral hemorrhage with one associated encephalopathy, one meningitis, and one Guillain-Barre Syndrome), 20 for cardiac events (including 11 for myocardial infarction, seven for myopericarditis, and two for an arrhythmia), 12 pulmonary embolism, one respiratory distress, one for exacerbation of idiopathic pulmonary fibrosis, one for a pregnancy related complication, seven for thrombocytopenia alone or associated with a concurrent condition, and three for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[9] Death may also be recorded as the outcome of a specific reportable event. Thirteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified. Two additional deaths occurred in long term care residents and were still being reviewed at the time of this report.

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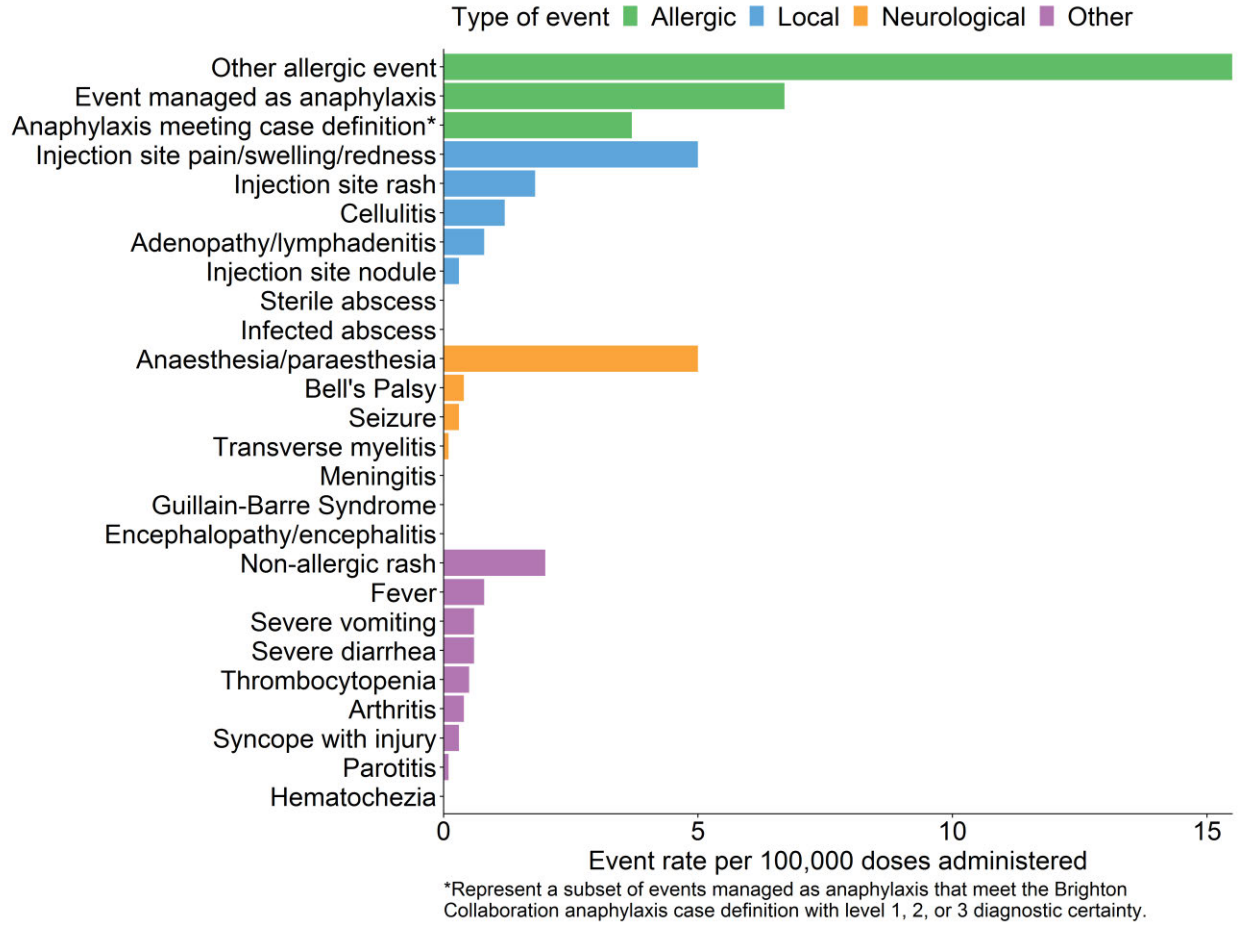

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly AEFI Report for posting
Date: Thursday, June 24, 2021 9:43:23 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-06-24.docx
COVID19_AEFI_Weekly_Report_2021-06-24.pdf

Hi Heather and Sableen,

Attached is this week's public AEFI report for posting to the website. Thanks!

Kyle

Kyle Noftall, RN, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to June 19, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including June 19, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These results are in keeping with observed safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these vaccines in clinical trials prior to authorization for use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. BC is monitoring for reports of myocarditis following mRNA vaccines, which has been identified as an adverse event of interest based on reports from Israel and is being monitored in several countries.[5,6]

There have been three reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[7,8]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[9] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and

detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[10] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[11]

Definitions

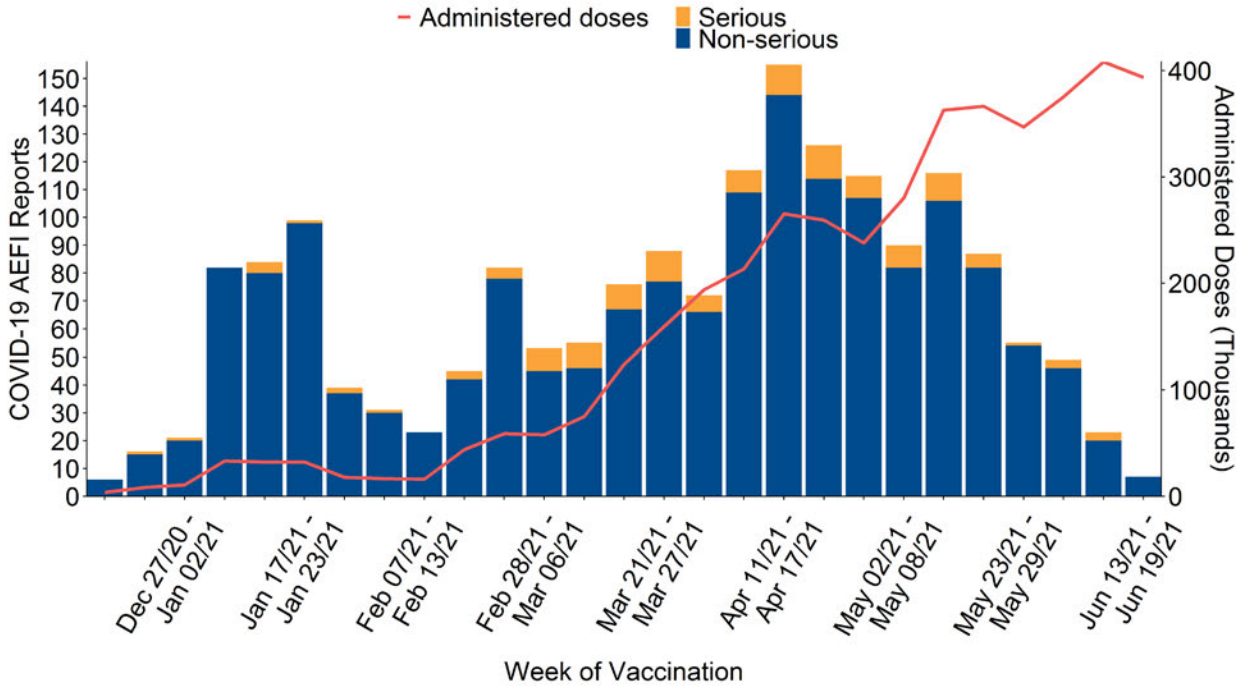
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[12]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of June 19, 2021, there have been 4,392,252 COVID-19 vaccine doses administered in BC and 1,812 COVID-19 AEFI reports (41.3 reports per 100,000 doses administered)
- 129 reports (7.1%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and anaesthesia/paraesthesia

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jun. 19, 2021 **(N=1,812)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including June 19, 2021, a total of 4,392,252 doses have been administered. During this period, there have been 1,812 AEFI reports following a COVID-19 vaccine, for a reporting rate of 41.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jun. 19, 2021 **(N=1,812)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**1,812**	**170**	**51**	**535**	**1,055**
Non-serious reports	1,683	156	47	502	977
Serious reports	129	14	4	33	78
Proportion serious	7.1%	8.2%	7.8%	6.2%	7.4%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	1,665	169	51	488	956
Dose 2 reports	147	1	0	47	99
Total doses administered	**4,392,252**	**284,865**	**66,460**	**773,155**	**3,267,702**
Dose 1 administered	3,496,666	215,694	59,845	617,498	2,603,560
Dose 2 administered	895,586	69,171	6,615	155,657	664,142
Total reporting rate	**41.3**	**59.7**	**76.7**	**69.2**	**32.3**
Serious rate	2.9	4.9	6.0	4.3	2.4
Dose 1 rate	47.6	78.4	85.2	79.0	36.7
Dose 2 rate	16.4	1.4	0.0	30.2	14.9

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred twenty-nine reports (7.1%) were considered serious (refer to serious AEFI definition above). Of these, 119 individuals were admitted to hospital. These included 12 individuals hospitalized after anaphylaxis, 29 for a neurological diagnosis (including three for transverse myelitis, five for seizure, 16 for stroke, two intracerebral hemorrhage with one associated encephalopathy, one meningitis, and two Guillain-Barre Syndrome), 22 for cardiac events (including 11 for myocardial infarction, nine for myopericarditis, and two for an arrhythmia), 13 pulmonary embolism, one respiratory distress, one for exacerbation of idiopathic pulmonary fibrosis, one for a pregnancy related complication, one for capillary leak syndrome, eight for thrombocytopenia alone or associated with a concurrent condition, and three for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

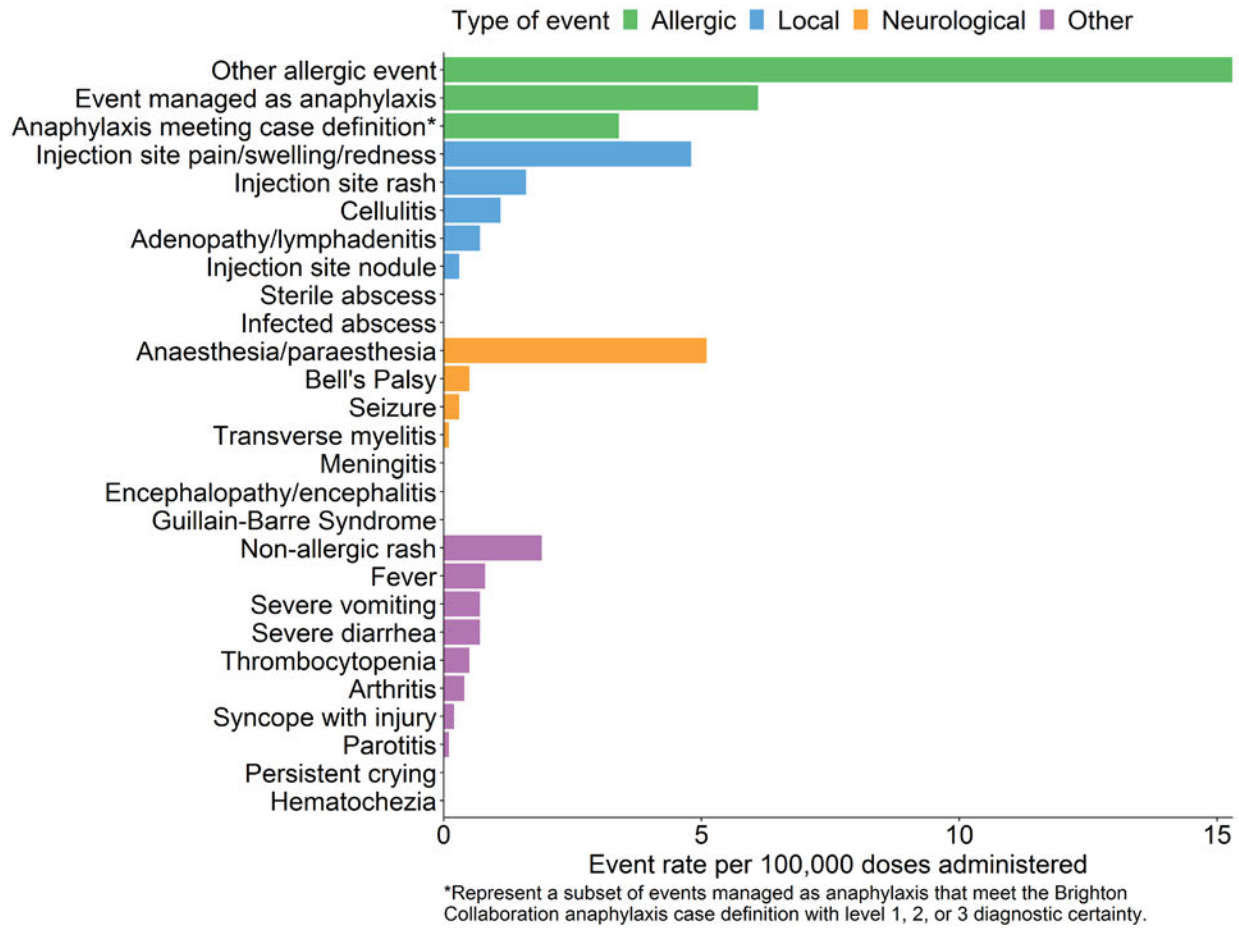
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[9] Death may also be recorded as the outcome of a specific reportable event. Fourteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified. Two additional deaths occurred in long term care residents and were still being reviewed at the time of this report.

For five individuals, death was the outcome of cardiac arrest. Four of these were elderly individuals with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. A death occurred in an elderly individual following a stroke and hospital admission. This individual had previous history of stroke along with other medical conditions. Finally, one death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 1,812 AEFI reports received up to June 19, 2021 contained a total of 2,341 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and anaesthesia/paraesthesia (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jun. 19, 2021 **(N=2,341)**



Event Descriptions

Two hundred sixty-nine reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 150 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[13] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Forty-seven reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[14] None of these reports were confirmed by microbial testing.

Forty-three reports contained a diagnosed neurological event. Twenty individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Fourteen individuals reported seizures, including ten with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, and one had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis. Finally, there were two reports for individuals hospitalized with Guillain-Barre Syndrome (GBS) who have since been discharged. A possible infectious cause of GBS was not identified in one case, and the other followed a recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[11,15,16]

There were seventeen reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were six reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Four of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 72 were for various thrombotic/ thromboembolic conditions. These included 17 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 11 myocardial infarctions, 16 pulmonary embolisms, 24 deep vein thromboses, and three superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[7,8]

One “other serious” report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. The individual has since been discharged after being treated in hospital. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[17]

There have been three non-fatal confirmed cases of TTS reported in BC to date, all in adults in their 30s or 40s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital.

There have been 18 reports of pericarditis/myocarditis. Eight individuals had a diagnosis of pericarditis alone, four had myocarditis, and six had myopericarditis. Ages ranged from 16 to 95, and 12 were male. Six had received Moderna vaccine, 10 had Pfizer vaccine, and two had AstraZeneca; two of the events occurred after a second dose (one Pfizer and one Moderna). Some had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. One met the diagnostic criteria to be considered a definite case according to the draft Brighton Collaboration myocarditis case definition.[18] This individual also presented with signs of sepsis but no infective agent was identified. Myocarditis is being investigated as a possible safety signal after mRNA vaccines in Canada and internationally, but at this time event rates reported in Canada have been within the expected background rates for these conditions.[5,6,11]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on June 23, 2021. Only AEFIs reported and doses administered up to June 19, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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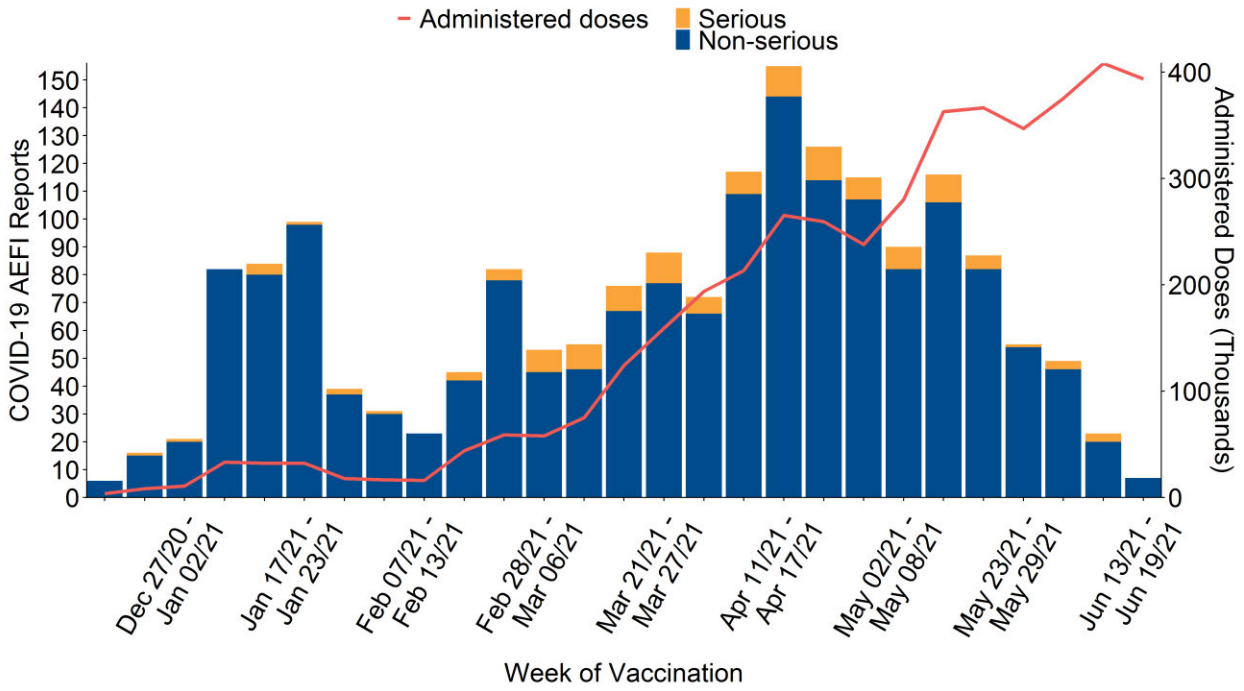

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* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred twenty-nine reports (7.1%) were considered serious (refer to serious AEFI definition above). Of these, 119 individuals were admitted to hospital. These included 12 individuals hospitalized after anaphylaxis, 29 for a neurological diagnosis (including three for transverse myelitis, five for seizure, 16 for stroke, two intracerebral hemorrhage with one associated encephalopathy, one meningitis, and two Guillain-Barre Syndrome), 22 for cardiac events (including 11 for myocardial infarction, nine for myopericarditis, and two for an arrhythmia), 13 pulmonary embolism, one respiratory distress, one for exacerbation of idiopathic pulmonary fibrosis, one for a pregnancy related complication, one for capillary leak syndrome, eight for thrombocytopenia alone or associated with a concurrent condition, and three for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

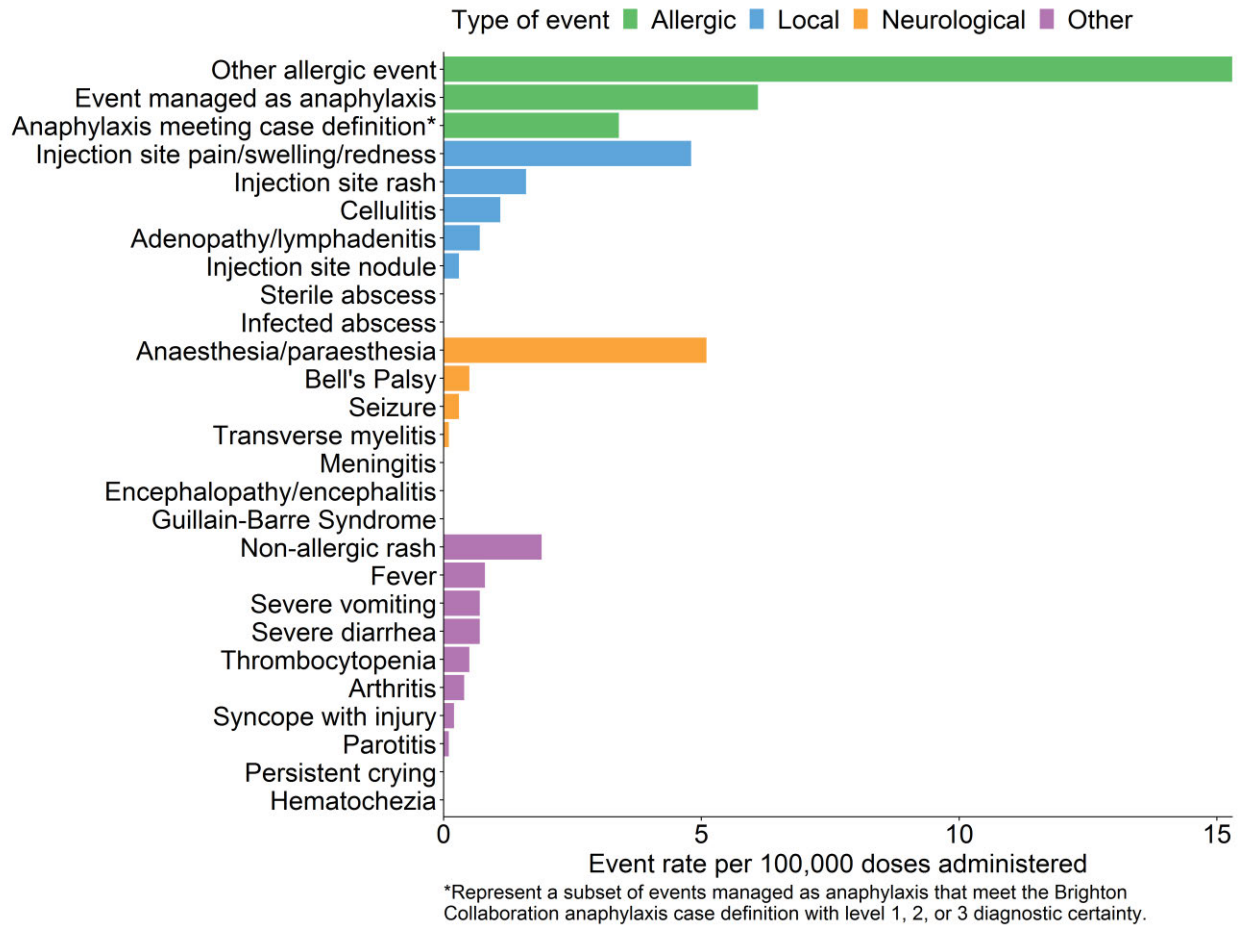
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[9] Death may also be recorded as the outcome of a specific reportable event. Fourteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified. Two additional deaths occurred in long term care residents and were still being reviewed at the time of this report.

For five individuals, death was the outcome of cardiac arrest. Four of these were elderly individuals with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. A death occurred in an elderly individual following a stroke and hospital admission. This individual had previous history of stroke along with other medical conditions. Finally, one death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 1,812 AEFI reports received up to June 19, 2021 contained a total of 2,341 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and anaesthesia/paraesthesia (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jun. 19, 2021 **(N=2,341)**



Event Descriptions

Two hundred sixty-nine reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 150 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[13] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Forty-seven reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[14] None of these reports were confirmed by microbial testing.

Forty-three reports contained a diagnosed neurological event. Twenty individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Fourteen individuals reported seizures, including ten with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, and one had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis. Finally, there were two reports for individuals hospitalized with Guillain-Barre Syndrome (GBS) who have since been discharged. A possible infectious cause of GBS was not identified in one case, and the other followed a recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[11,15,16]

There were seventeen reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were six reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Four of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 72 were for various thrombotic/ thromboembolic conditions. These included 17 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 11 myocardial infarctions, 16 pulmonary embolisms, 24 deep vein thromboses, and three superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[7,8]

One “other serious” report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. The individual has since been discharged after being treated in hospital. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[17]

There have been three non-fatal confirmed cases of TTS reported in BC to date, all in adults in their 30s or 40s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital.

There have been 18 reports of pericarditis/myocarditis. Eight individuals had a diagnosis of pericarditis alone, four had myocarditis, and six had myopericarditis. Ages ranged from 16 to 95, and 12 were male. Six had received Moderna vaccine, 10 had Pfizer vaccine, and two had AstraZeneca; two of the events occurred after a second dose (one Pfizer and one Moderna). Some had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. One met the diagnostic criteria to be considered a definite case according to the draft Brighton Collaboration myocarditis case definition.[18] This individual also presented with signs of sepsis but no infective agent was identified. Myocarditis is being investigated as a possible safety signal after mRNA vaccines in Canada and internationally, but at this time event rates reported in Canada have been within the expected background rates for these conditions.[5,6,11]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on June 23, 2021. Only AEFIs reported and doses administered up to June 19, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly AEFI report
Date: Friday, July 02, 2021 12:50:00 PM
Attachments: COVID19_AEFI_Weekly_Report_2021-07-02.docx
COVID19_AEFI_Weekly_Report_2021-07-02.pdf

Hi Heather and Sableen,

Hope you had a nice day off yesterday.

Here's this week's COVID19 AEFI report for posting to the website.

Thank you,

Kyle

Kyle Noftall, RN, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to June 26, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including June 26, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been three reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[8,9]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously

unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

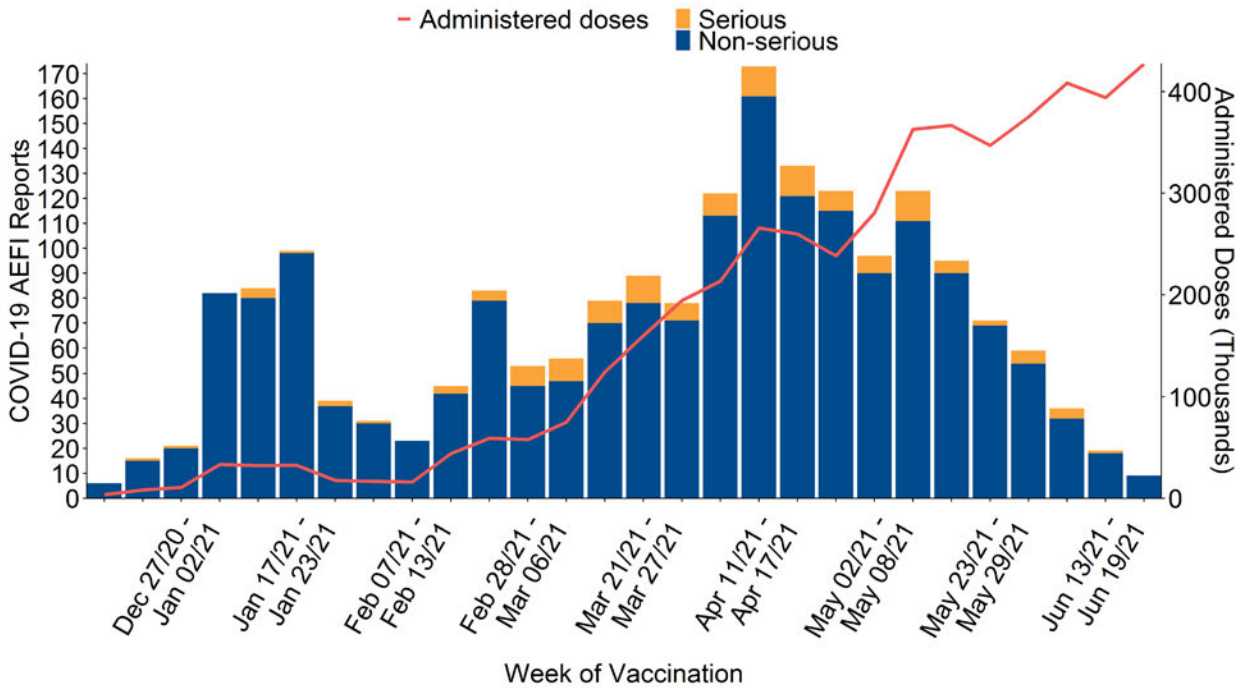
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of June 26, 2021, there have been 4,824,845 COVID-19 vaccine doses administered in BC and 1,944 COVID-19 AEFI reports (40.3 reports per 100,000 doses administered)
- 138 reports (7.1%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and anaesthesia/paraesthesia

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jun. 26, 2021 **(N=1,944)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including June 26, 2021, a total of 4,824,845 doses have been administered. During this period, there have been 1,944 AEFI reports following a COVID-19 vaccine, for a reporting rate of 40.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jun. 26, 2021 **(N=1,944)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**1,944**	**183**	**54**	**565**	**1,141**
Non-serious reports	1,806	167	50	529	1,059
Serious reports	138	16	4	36	82
Proportion serious	7.1%	8.7%	7.4%	6.4%	7.2%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	1,772	180	54	508	1,029
Dose 2 reports	172	3	0	57	112
Total doses administered	**4,824,845**	**305,246**	**67,309**	**1,022,184**	**3,430,009**
Dose 1 administered	3,602,165	216,413	59,791	691,663	2,634,202
Dose 2 administered	1,222,680	88,833	7,518	330,521	795,807
Total reporting rate	**40.3**	**60.0**	**80.2**	**55.3**	**33.3**
Serious rate	2.9	5.2	5.9	3.5	2.4
Dose 1 rate	49.2	83.2	90.3	73.4	39.1
Dose 2 rate	14.1	3.4	0.0	17.2	14.1

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred thirty-eight reports (7.1%) were considered serious (refer to serious AEFI definition above). Of these, 129 individuals were admitted to hospital. These included 12 individuals hospitalized after anaphylaxis, 29 for a neurological diagnosis (including three for transverse myelitis, five for seizure, 16 for stroke, two intracerebral hemorrhage with one associated encephalopathy, one meningitis, and two Guillain-Barre Syndrome), 25 for cardiac events (including 11 for myocardial infarction, 11 for myopericarditis, and three for an arrhythmia), and 15 for a respiratory condition (13 pulmonary embolism, one respiratory distress, and one for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Nine hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, and three were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

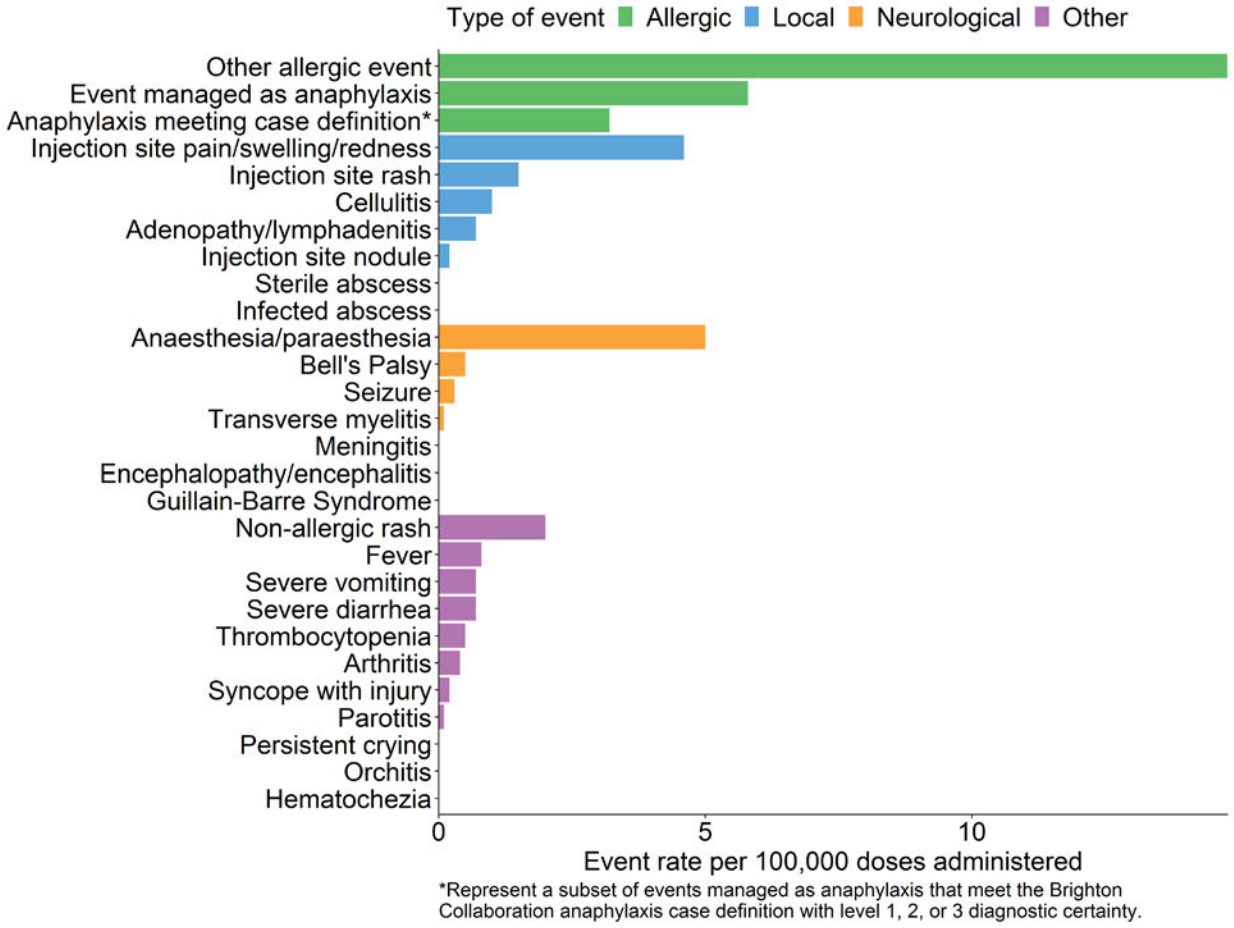
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Thirteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified. One additional death occurred in a long term care resident and was still being reviewed at the time of this report.

For five individuals, death was the outcome of cardiac arrest. Four of these were elderly individuals with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. A death occurred in an elderly individual following a stroke and hospital admission. This individual had previous history of stroke along with other medical conditions. Finally, one death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 1,944 AEFI reports received up to June 26, 2021 contained a total of 2,502 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and anaesthesia/paraesthesia (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jun. 26, 2021 **(N=2,502)**



Event Descriptions

Two hundred eighty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 155 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15] None of these reports were confirmed by microbial testing.

Forty-five reports contained a diagnosed neurological event. Twenty-two individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Fourteen individuals reported seizures, including ten with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, and one had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis. Finally, there were two reports for individuals hospitalized with Guillain-Barre Syndrome (GBS) who have since been discharged. A possible infectious cause of GBS was not identified in one case, and the other followed a recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17]

There were twenty-one reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were eight reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Six of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 73 were for various thrombotic/ thromboembolic conditions. These included 17 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 11 myocardial infarctions, 16 pulmonary embolisms, 24 deep vein thromboses, and four superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One “other serious” report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. The individual has since been discharged after being treated in hospital. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[18] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[19]

There have been three non-fatal confirmed cases of TTS reported in BC to date, all in adults in their 30s or 40s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital.

There have been 24 reports of pericarditis/myocarditis. Eleven individuals had a diagnosis of pericarditis alone, four had myocarditis, and nine had myopericarditis. Ages ranged from 16 to 95 with a median of 39.5 years, and 16 were male. Seven had received Moderna vaccine, 15 had Pfizer vaccine, and two had AstraZeneca; four of the events occurred after a second dose (two Pfizer and two Moderna). Some had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. One met the diagnostic criteria to be considered a definite case according to the draft Brighton Collaboration myocarditis case definition.[20] This individual also presented with signs of sepsis but no infective agent was identified. Myocarditis is being investigated as a possible safety signal after mRNA vaccines. An association between mRNA vaccines and myopericarditis was observed in adolescents and young adults in the United States, but at this time event rates reported in Canada have been within the expected background rates for these conditions.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on June 30, 2021. Only AEFIs reported and doses administered up to June 26, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to June 26, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including June 26, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been three reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[8,9]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously

unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

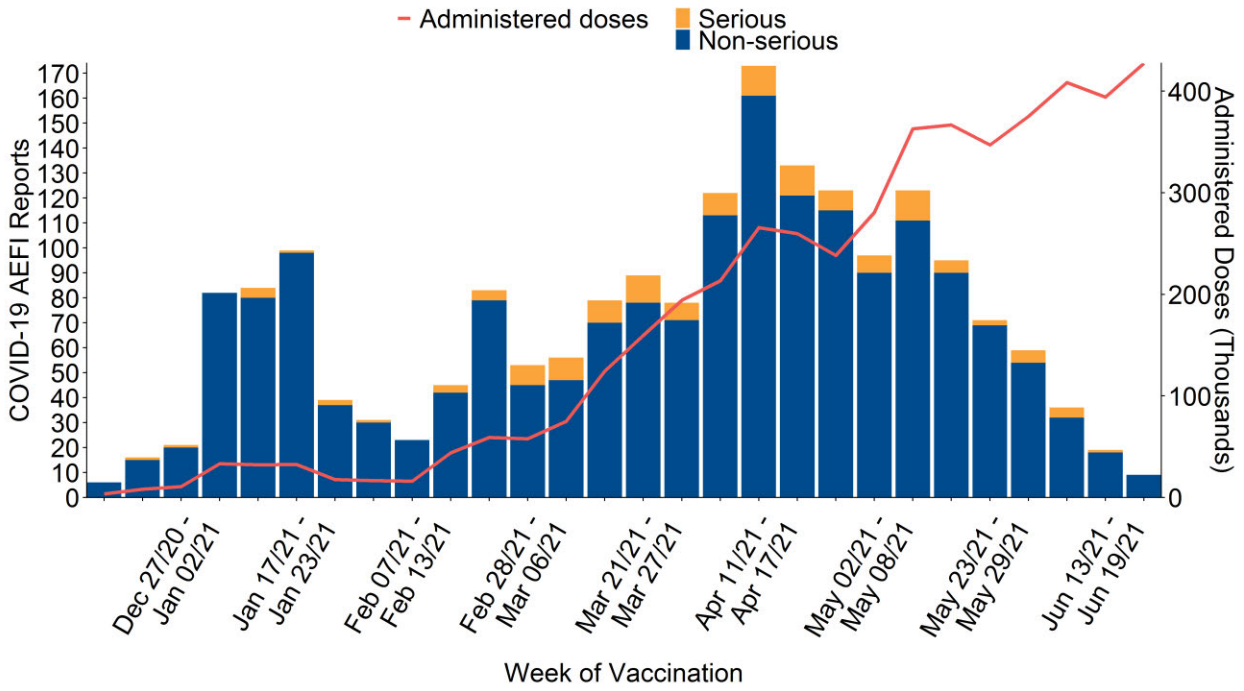
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of June 26, 2021, there have been 4,824,845 COVID-19 vaccine doses administered in BC and 1,944 COVID-19 AEFI reports (40.3 reports per 100,000 doses administered)
- 138 reports (7.1%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and anaesthesia/paraesthesia

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jun. 26, 2021 **(N=1,944)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including June 26, 2021, a total of 4,824,845 doses have been administered. During this period, there have been 1,944 AEFI reports following a COVID-19 vaccine, for a reporting rate of 40.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jun. 26, 2021 **(N=1,944)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**1,944**	**183**	**54**	**565**	**1,141**
Non-serious reports	1,806	167	50	529	1,059
Serious reports	138	16	4	36	82
Proportion serious	7.1%	8.7%	7.4%	6.4%	7.2%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	1,772	180	54	508	1,029
Dose 2 reports	172	3	0	57	112
Total doses administered	**4,824,845**	**305,246**	**67,309**	**1,022,184**	**3,430,009**
Dose 1 administered	3,602,165	216,413	59,791	691,663	2,634,202
Dose 2 administered	1,222,680	88,833	7,518	330,521	795,807
Total reporting rate	**40.3**	**60.0**	**80.2**	**55.3**	**33.3**
Serious rate	2.9	5.2	5.9	3.5	2.4
Dose 1 rate	49.2	83.2	90.3	73.4	39.1
Dose 2 rate	14.1	3.4	0.0	17.2	14.1

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred thirty-eight reports (7.1%) were considered serious (refer to serious AEFI definition above). Of these, 129 individuals were admitted to hospital. These included 12 individuals hospitalized after anaphylaxis, 29 for a neurological diagnosis (including three for transverse myelitis, five for seizure, 16 for stroke, two intracerebral hemorrhage with one associated encephalopathy, one meningitis, and two Guillain-Barre Syndrome), 25 for cardiac events (including 11 for myocardial infarction, 11 for myopericarditis, and three for an arrhythmia), and 15 for a respiratory condition (13 pulmonary embolism, one respiratory distress, and one for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Nine hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, and three were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

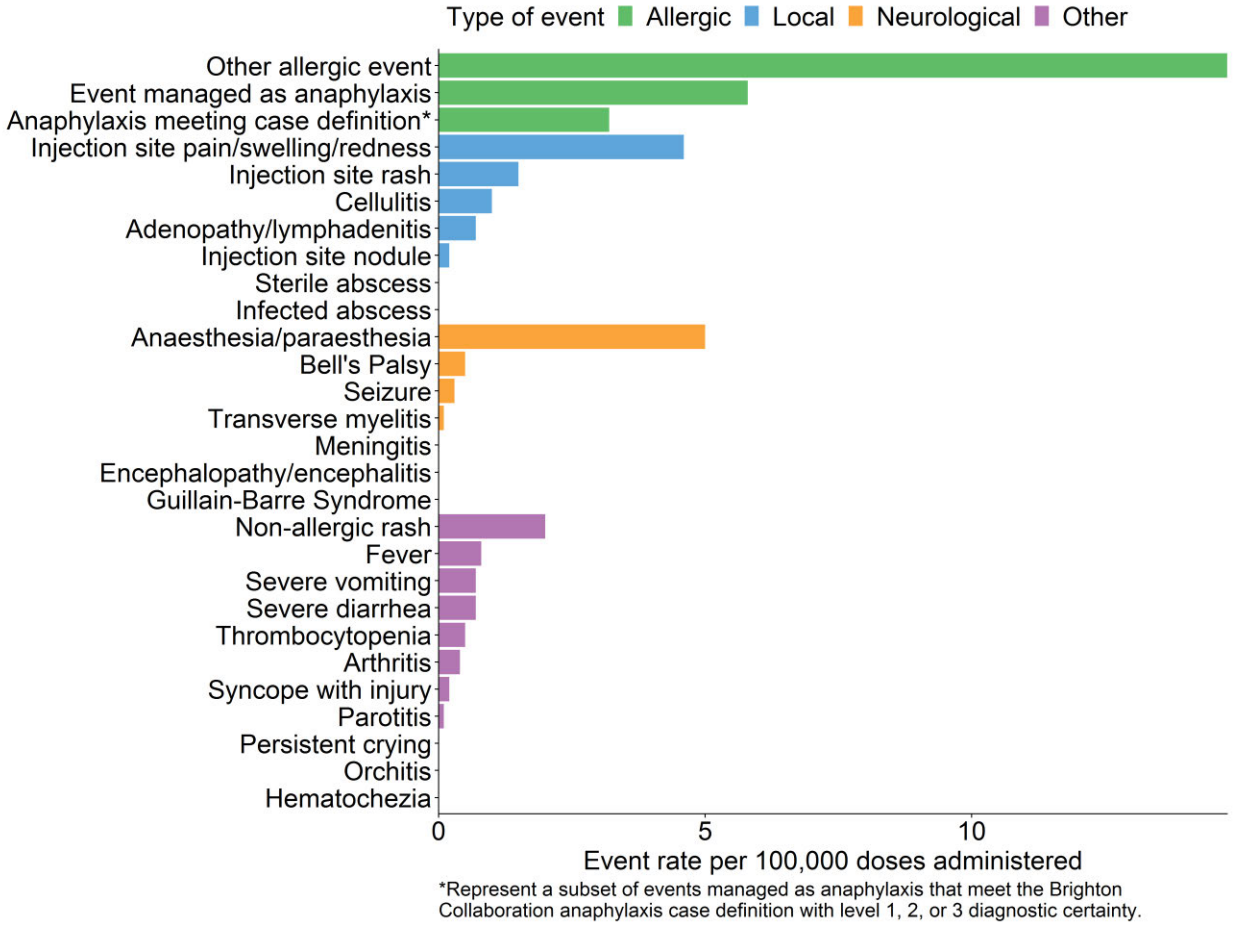
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Thirteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified. One additional death occurred in a long term care resident and was still being reviewed at the time of this report.

For five individuals, death was the outcome of cardiac arrest. Four of these were elderly individuals with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. A death occurred in an elderly individual following a stroke and hospital admission. This individual had previous history of stroke along with other medical conditions. Finally, one death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 1,944 AEFI reports received up to June 26, 2021 contained a total of 2,502 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and anaesthesia/paraesthesia (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jun. 26, 2021 **(N=2,502)**



Event Descriptions

Two hundred eighty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 155 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15] None of these reports were confirmed by microbial testing.

Forty-five reports contained a diagnosed neurological event. Twenty-two individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Fourteen individuals reported seizures, including ten with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, and one had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis. Finally, there were two reports for individuals hospitalized with Guillain-Barre Syndrome (GBS) who have since been discharged. A possible infectious cause of GBS was not identified in one case, and the other followed a recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17]

There were twenty-one reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were eight reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Six of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 73 were for various thrombotic/ thromboembolic conditions. These included 17 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 11 myocardial infarctions, 16 pulmonary embolisms, 24 deep vein thromboses, and four superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One “other serious” report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. The individual has since been discharged after being treated in hospital. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[18] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[19]

There have been three non-fatal confirmed cases of TTS reported in BC to date, all in adults in their 30s or 40s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital.

There have been 24 reports of pericarditis/myocarditis. Eleven individuals had a diagnosis of pericarditis alone, four had myocarditis, and nine had myopericarditis. Ages ranged from 16 to 95 with a median of 39.5 years, and 16 were male. Seven had received Moderna vaccine, 15 had Pfizer vaccine, and two had AstraZeneca; four of the events occurred after a second dose (two Pfizer and two Moderna). Some had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. One met the diagnostic criteria to be considered a definite case according to the draft Brighton Collaboration myocarditis case definition.[20] This individual also presented with signs of sepsis but no infective agent was identified. Myocarditis is being investigated as a possible safety signal after mRNA vaccines. An association between mRNA vaccines and myopericarditis was observed in adolescents and young adults in the United States, but at this time event rates reported in Canada have been within the expected background rates for these conditions.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on June 30, 2021. Only AEFIs reported and doses administered up to June 26, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Amos, Heather [BCCDC]
To: Noftall, Kyle [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: RE: Weekly AEFI report
Date: Friday, July 02, 2021 12:50:21 PM

Thanks. I will get it posted.

From: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>
Sent: Friday, July 02, 2021 12:50 PM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Weekly AEFI report

Hi Heather and Sableen,

Hope you had a nice day off yesterday.

Here's this week's COVID19 AEFI report for posting to the website.

Thank you,

Kyle

Kyle Noftall, RN, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly AEFI Report
Date: Thursday, July 15, 2021 9:17:33 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-07-15.docx
COVID19_AEFI_Weekly_Report_2021-07-15.pdf

Hi Heather and Sableen,

This week's COVID19 AEFI report is attached.

Thank you,

Kyle

Kyle Noftall, RN, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to July 10, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including July 10, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been three reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[8,9]

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AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously

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Definitions

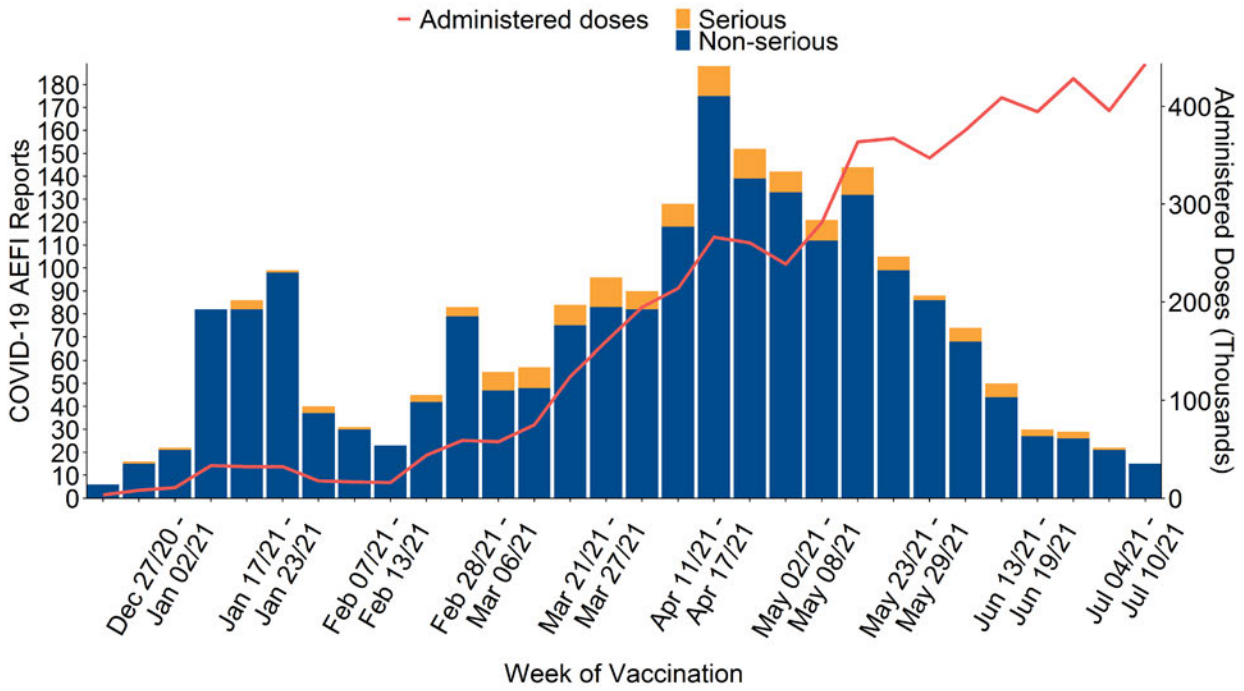
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of July 10, 2021, there have been 5,671,624 COVID-19 vaccine doses administered in BC and 2,203 COVID-19 AEFI reports (38.8 reports per 100,000 doses administered)
- 158 reports (7.2%) met the serious definition, for a rate of 2.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and anaesthesia/paraesthesia

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jul. 10, 2021 **(N=2,203)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including July 10, 2021, a total of 5,671,624 doses have been administered. During this period, there have been 2,203 AEFI reports following a COVID-19 vaccine, for a reporting rate of 38.8 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

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	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**2,203**	**198**	**59**	**656**	**1,289**
Non-serious reports	2,045	180	54	612	1,198
Serious reports	158	18	5	44	91
Proportion serious	7.2%	9.1%	8.5%	6.7%	7.1%

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	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
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Dose 1 rate	51.9	88.8	98.7	70.3	42.3
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Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred fifty-eight reports (7.2%) were considered serious (refer to serious AEFI definition above). Of these, 146 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis, 33 for a neurological diagnosis (including three for transverse myelitis, five for seizure, 17 for stroke, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and three Guillain-Barre Syndrome), 32 for cardiac events (including 14 for myocardial infarction, 15 for myopericarditis, and three for an arrhythmia), and 15 for a respiratory condition (13 pulmonary embolism, one respiratory distress, and one for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Ten hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, and three were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

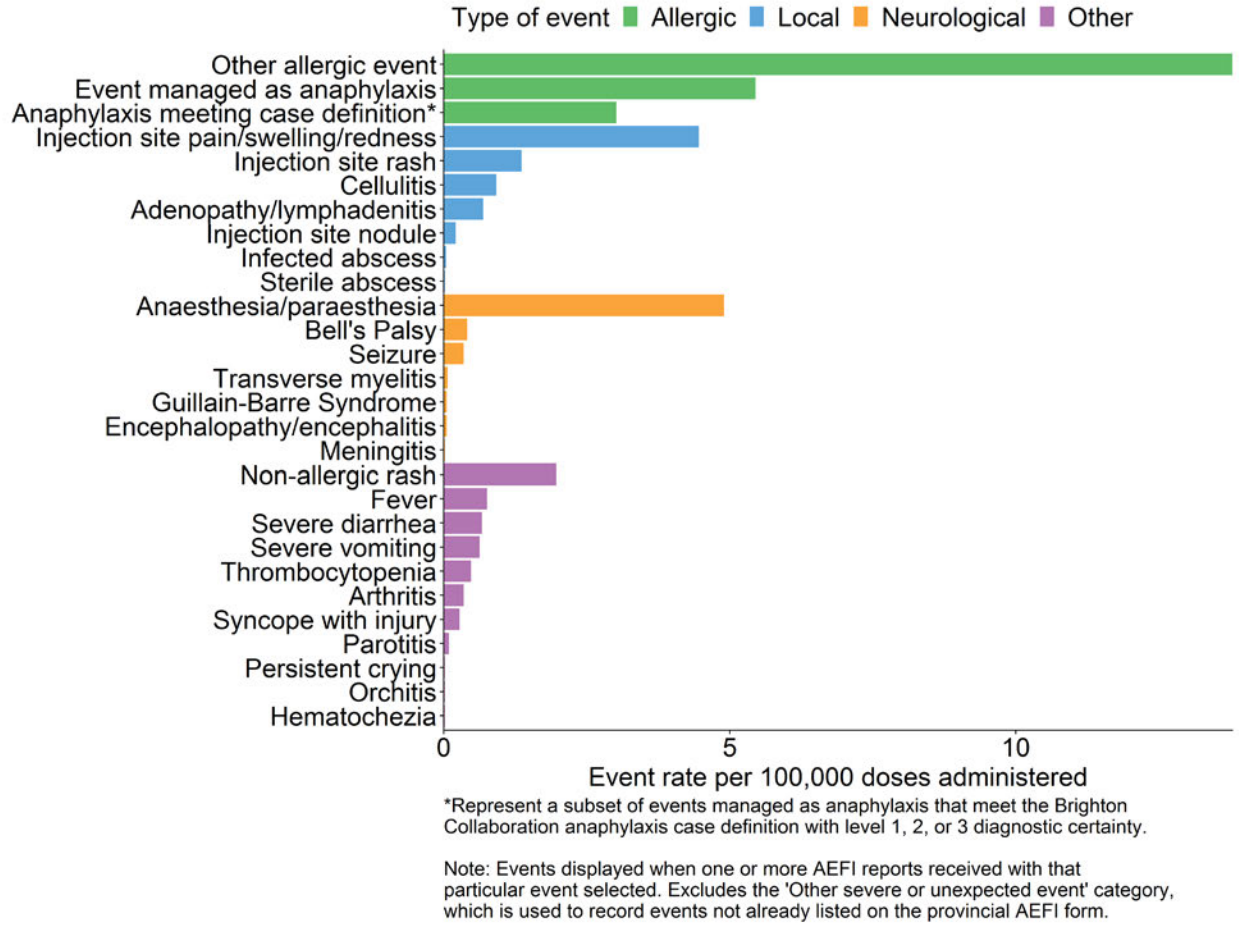
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fourteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

For six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. Finally, one death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,203 AEFI reports received up to July 10, 2021 contained a total of 2,826 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and anaesthesia/paraesthesia (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 10, 2021 **(N=2,826)**



Event Descriptions

Three hundred nine reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 171 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-two reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15] None of these reports were confirmed by microbial testing.

Fifty-seven reports contained a diagnosed neurological event. Twenty-three individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty individuals reported seizures, including twelve with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, and one had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. Finally, there were three reports for individuals hospitalized with Guillain-Barre Syndrome (GBS) who have since been discharged. A possible infectious cause of GBS was not identified in two cases, and the other followed a recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] There have been two reports of sudden hearing loss verified by audiology testing. One individual had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Both individuals recovered their hearing with treatment. One US study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were twenty-four reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were nine reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Six of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an “other serious” event when not its own discrete event on the provincial AEFI report form. Amongst these events, 83 were for various thrombotic/ thromboembolic conditions. These included 18 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 17 pulmonary embolisms, 27 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One “other serious” report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. The individual has since been discharged after being treated in hospital. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been three non-fatal confirmed cases of TTS reported in BC to date, all in adults in their 30s or 40s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital.

There have been 37 reports of pericarditis/myocarditis. Eighteen individuals had a diagnosis of pericarditis alone, five had myocarditis, and 14 had myopericarditis. Ages ranged from 16 to 95 with a median of 44 years, and 22 were male. Thirteen had received Moderna vaccine, 21 had Pfizer vaccine, and three had AstraZeneca/COVISHIELD; eleven of the events occurred after a second dose (five Pfizer and six Moderna). Some had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. One met the diagnostic criteria to be considered a definite case according to the draft Brighton Collaboration myocarditis case definition.[21] This individual also presented with signs of sepsis but no infective agent was identified. Myocarditis is being investigated as a possible safety signal after mRNA vaccines. An association between mRNA vaccines and myopericarditis was observed in adolescents and young adults in the United States, but at this time event rates reported in Canada have been within the expected background rates for these conditions.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on July 14, 2021. Only AEFIs reported and doses administered up to July 10, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and

finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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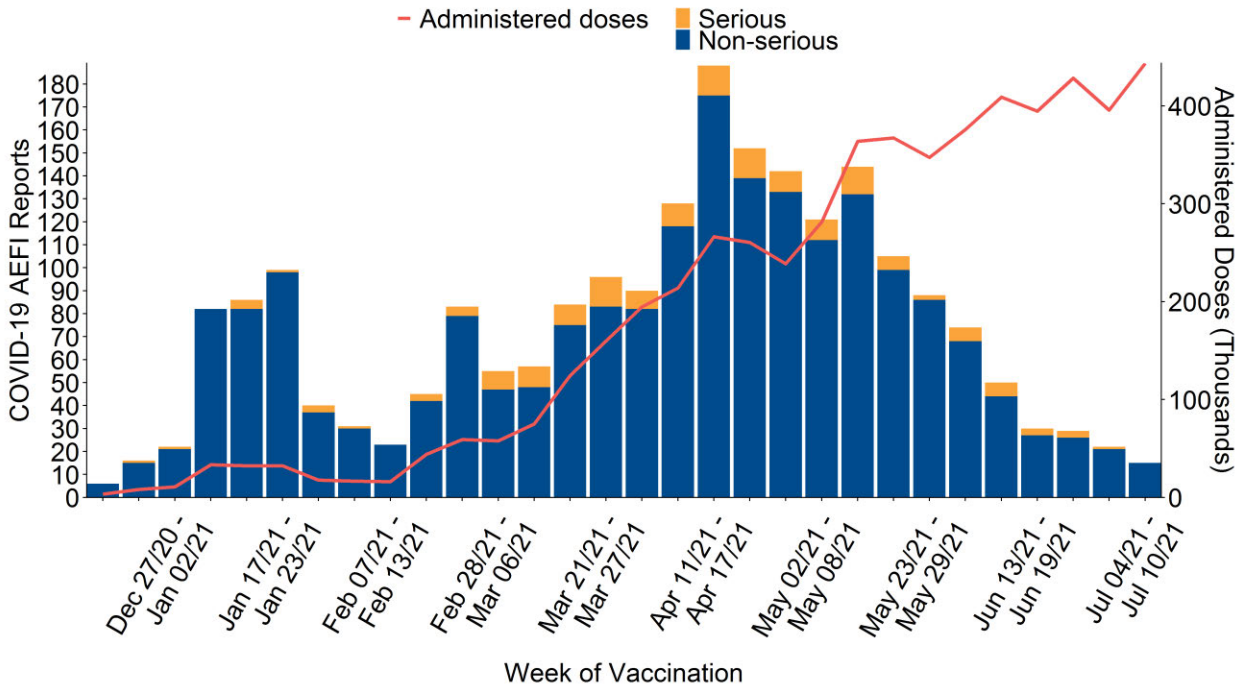

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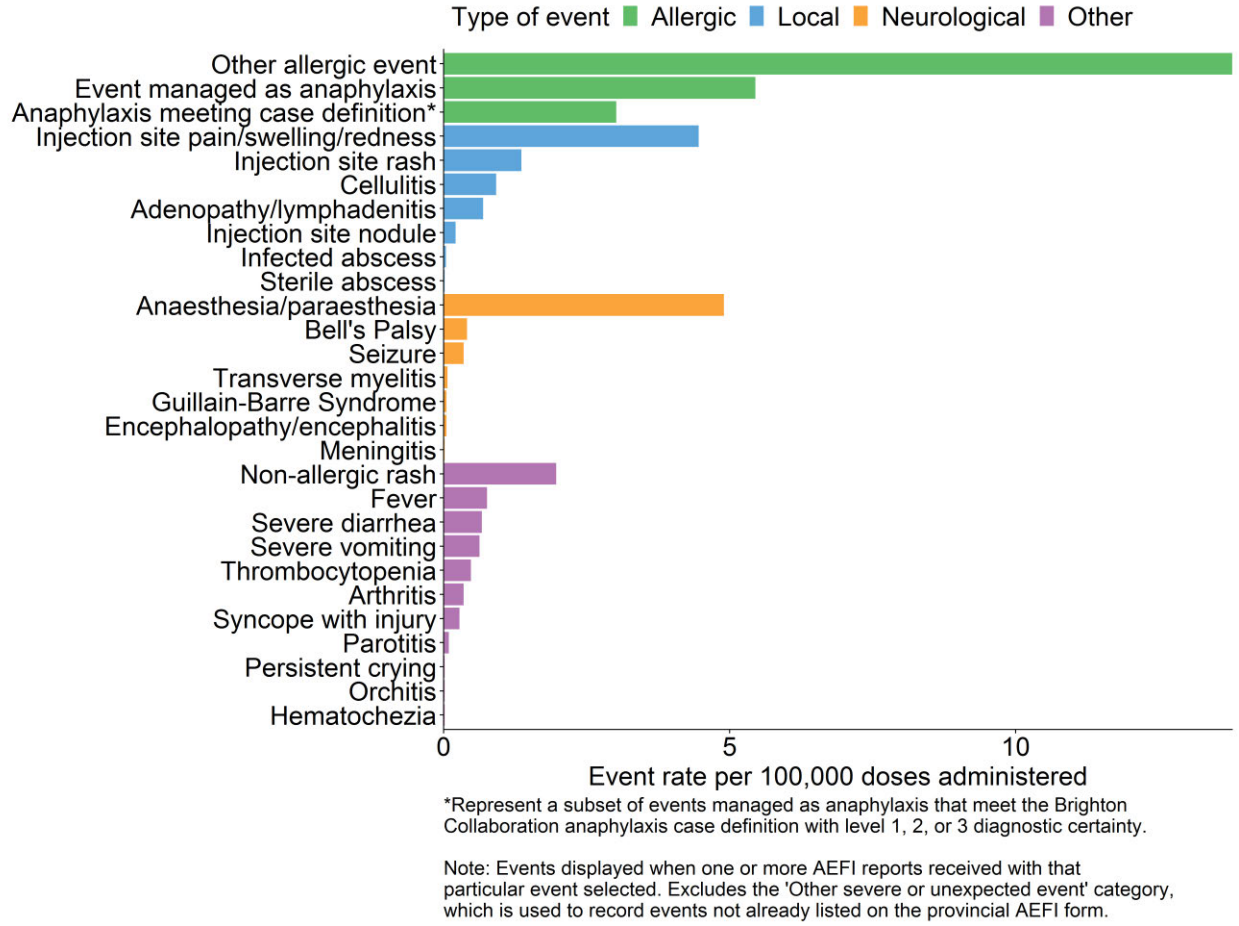
For six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. Finally, one death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,203 AEFI reports received up to July 10, 2021 contained a total of 2,826 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and anaesthesia/paraesthesia (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 10, 2021 **(N=2,826)**



Event Descriptions

Three hundred nine reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 171 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-two reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15] None of these reports were confirmed by microbial testing.

Fifty-seven reports contained a diagnosed neurological event. Twenty-three individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty individuals reported seizures, including twelve with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, and one had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. Finally, there were three reports for individuals hospitalized with Guillain-Barre Syndrome (GBS) who have since been discharged. A possible infectious cause of GBS was not identified in two cases, and the other followed a recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] There have been two reports of sudden hearing loss verified by audiology testing. One individual had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Both individuals recovered their hearing with treatment. One US study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were twenty-four reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were nine reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Six of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 83 were for various thrombotic/ thromboembolic conditions. These included 18 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 17 pulmonary embolisms, 27 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. The individual has since been discharged after being treated in hospital. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been three non-fatal confirmed cases of TTS reported in BC to date, all in adults in their 30s or 40s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital.

There have been 37 reports of pericarditis/myocarditis. Eighteen individuals had a diagnosis of pericarditis alone, five had myocarditis, and 14 had myopericarditis. Ages ranged from 16 to 95 with a median of 44 years, and 22 were male. Thirteen had received Moderna vaccine, 21 had Pfizer vaccine, and three had AstraZeneca/COVISHIELD; eleven of the events occurred after a second dose (five Pfizer and six Moderna). Some had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. One met the diagnostic criteria to be considered a definite case according to the draft Brighton Collaboration myocarditis case definition.[21] This individual also presented with signs of sepsis but no infective agent was identified. Myocarditis is being investigated as a possible safety signal after mRNA vaccines. An association between mRNA vaccines and myopericarditis was observed in adolescents and young adults in the United States, but at this time event rates reported in Canada have been within the expected background rates for these conditions.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on July 14, 2021. Only AEFIs reported and doses administered up to July 10, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and

finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Minhas, Sableen
To: Noftall, Kyle [BCCDC]; Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: Weekly AEFI Report
Date: Thursday, July 15, 2021 11:43:44 AM

Thanks Kyle!

From: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>
Sent: Thursday, July 15, 2021 9:18 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Weekly AEFI Report

Hi Heather and Sableen,

This week's COVID19 AEFI report is attached.

Thank you,

Kyle

Kyle Noftall, RN, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Noftall, Kyle [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly COVID19 AEFI Report
Date: Thursday, July 22, 2021 10:11:38 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-07-22.docx
COVID19_AEFI_Weekly_Report_2021-07-22.pdf

Hi Heather and Sableen,
Attached is this week's AEFI report for posting.
Out of curiosity, have there been many views of these reports? We are starting to consider when to scale back the frequency of generating the reports – possibly once the immunization campaign winds down near the end of summer.
Thanks,
Kyle

Kyle Noftall, RN, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to July 17, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including July 17, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been three reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[8,9]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously

unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

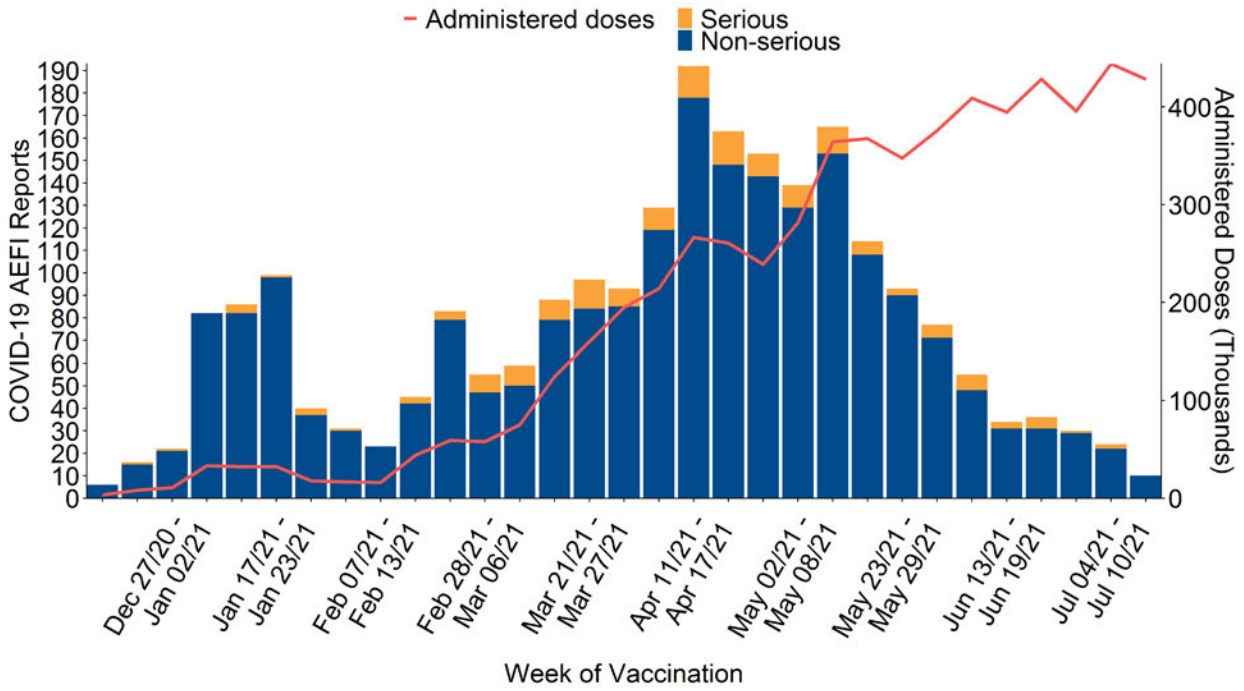
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of July 17, 2021, there have been 6,105,728 COVID-19 vaccine doses administered in BC and 2,339 COVID-19 AEFI reports (38.3 reports per 100,000 doses administered)
- 169 reports (7.2%) met the serious definition, for a rate of 2.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and anaesthesia/paraesthesia

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jul. 17, 2021 **(N=2,339)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including July 17, 2021, a total of 6,105,728 doses have been administered. During this period, there have been 2,339 AEFI reports following a COVID-19 vaccine, for a reporting rate of 38.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jul. 17, 2021 **(N=2,339)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**2,339**	**206**	**62**	**698**	**1,372**
Non-serious reports	2,170	185	57	651	1,276
Serious reports	169	21	5	47	96
Proportion serious	7.2%	10.2%	8.1%	6.7%	7%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2,067	201	61	609	1,195
Dose 2 reports	270	5	1	89	175
Total doses administered	**6,105,728**	**316,031**	**67,533**	**1,452,292**	**4,269,663**
Dose 1 administered	3,837,761	217,633	59,807	850,252	2,709,866
Dose 2 administered	2,267,967	98,398	7,726	602,040	1,559,797
Total reporting rate	**38.3**	**65.2**	**91.8**	**48.1**	**32.1**
Serious rate	2.8	6.6	7.4	3.2	2.2
Dose 1 rate	53.9	92.4	102.0	71.6	44.1
Dose 2 rate	11.9	5.1	12.9	14.8	11.2

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred sixty-nine reports (7.2%) were considered serious (refer to serious AEFI definition above). Of these, 157 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 36 for a neurological diagnosis (including three for transverse myelitis, six for seizure, 18 for stroke, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and four Guillain-Barre Syndrome), 35 for cardiac events (including 14 for myocardial infarction, 18 for myopericarditis, and three for an arrhythmia), and 16 for a respiratory condition (14 pulmonary embolism, one respiratory distress, and one for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Eleven hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, and three were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

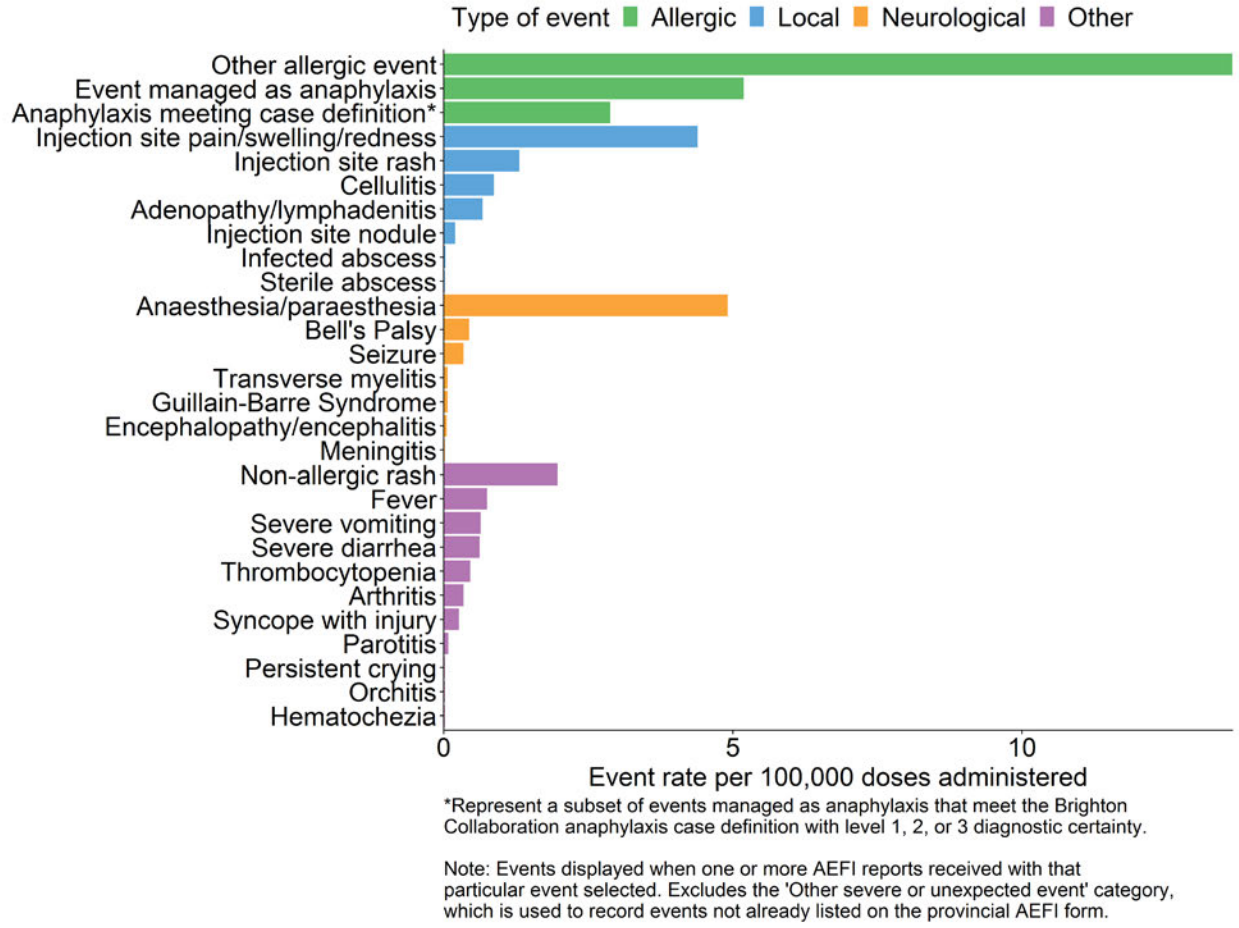
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fourteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

For six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. Finally, one death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,339 AEFI reports received up to July 17, 2021 contained a total of 2,991 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and anaesthesia/paraesthesia (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 17, 2021 **(N=2,991)**



Event Descriptions

Three hundred seventeen reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 176 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-three reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15] None of these reports were confirmed by microbial testing.

Sixty-three reports contained a diagnosed neurological event. Twenty-seven individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-one individuals reported seizures, including 13 with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, and one had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were four reports for individuals hospitalized with Guillain-Barre Syndrome (GBS) who have since been discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases, and the other followed a recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been two reports of sudden hearing loss verified by audiology testing. One individual had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Both individuals recovered their hearing with treatment. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

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the provincial AEFI report form. Amongst these events, 86 were for various thrombotic/ thromboembolic conditions. These included 19 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 18 pulmonary embolisms, 28 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to July 17, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including July 17, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been three reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[8,9]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously

unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

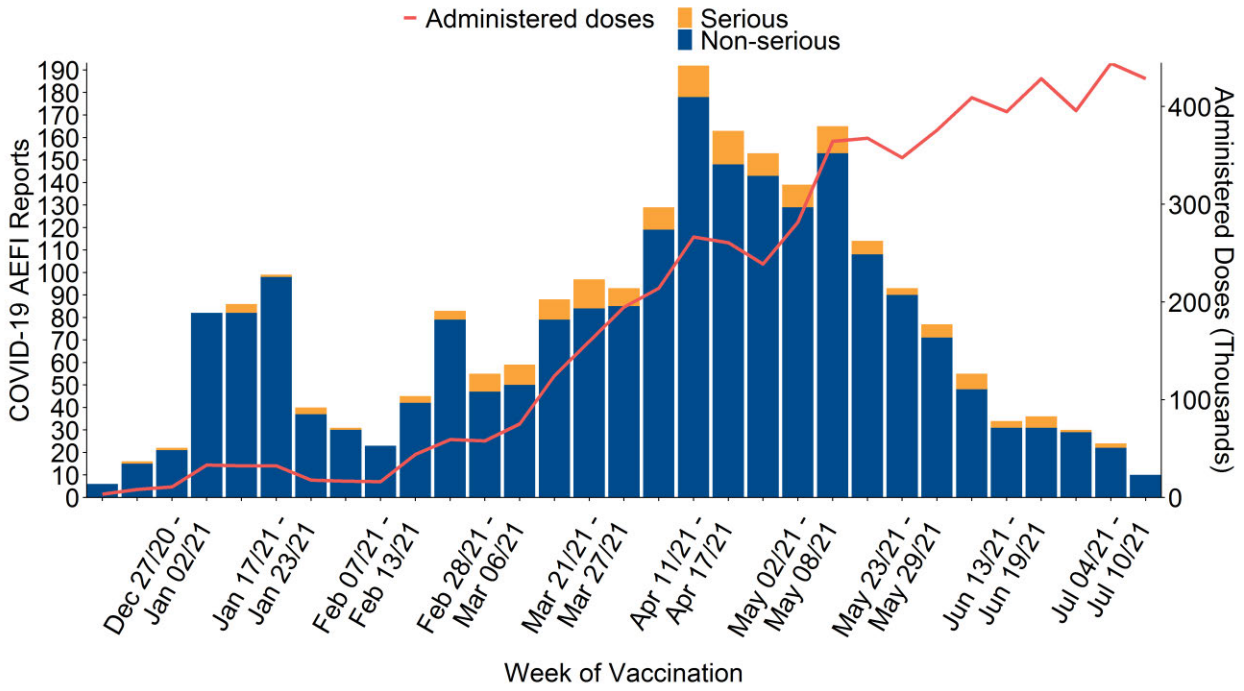
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of July 17, 2021, there have been 6,105,728 COVID-19 vaccine doses administered in BC and 2,339 COVID-19 AEFI reports (38.3 reports per 100,000 doses administered)
- 169 reports (7.2%) met the serious definition, for a rate of 2.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and anaesthesia/paraesthesia

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jul. 17, 2021 **(N=2,339)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including July 17, 2021, a total of 6,105,728 doses have been administered. During this period, there have been 2,339 AEFI reports following a COVID-19 vaccine, for a reporting rate of 38.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jul. 17, 2021 **(N=2,339)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**2,339**	**206**	**62**	**698**	**1,372**
Non-serious reports	2,170	185	57	651	1,276
Serious reports	169	21	5	47	96
Proportion serious	7.2%	10.2%	8.1%	6.7%	7%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2,067	201	61	609	1,195
Dose 2 reports	270	5	1	89	175
Total doses administered	**6,105,728**	**316,031**	**67,533**	**1,452,292**	**4,269,663**
Dose 1 administered	3,837,761	217,633	59,807	850,252	2,709,866
Dose 2 administered	2,267,967	98,398	7,726	602,040	1,559,797
Total reporting rate	**38.3**	**65.2**	**91.8**	**48.1**	**32.1**
Serious rate	2.8	6.6	7.4	3.2	2.2
Dose 1 rate	53.9	92.4	102.0	71.6	44.1
Dose 2 rate	11.9	5.1	12.9	14.8	11.2

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred sixty-nine reports (7.2%) were considered serious (refer to serious AEFI definition above). Of these, 157 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 36 for a neurological diagnosis (including three for transverse myelitis, six for seizure, 18 for stroke, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and four Guillain-Barre Syndrome), 35 for cardiac events (including 14 for myocardial infarction, 18 for myopericarditis, and three for an arrhythmia), and 16 for a respiratory condition (14 pulmonary embolism, one respiratory distress, and one for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Eleven hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, and three were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

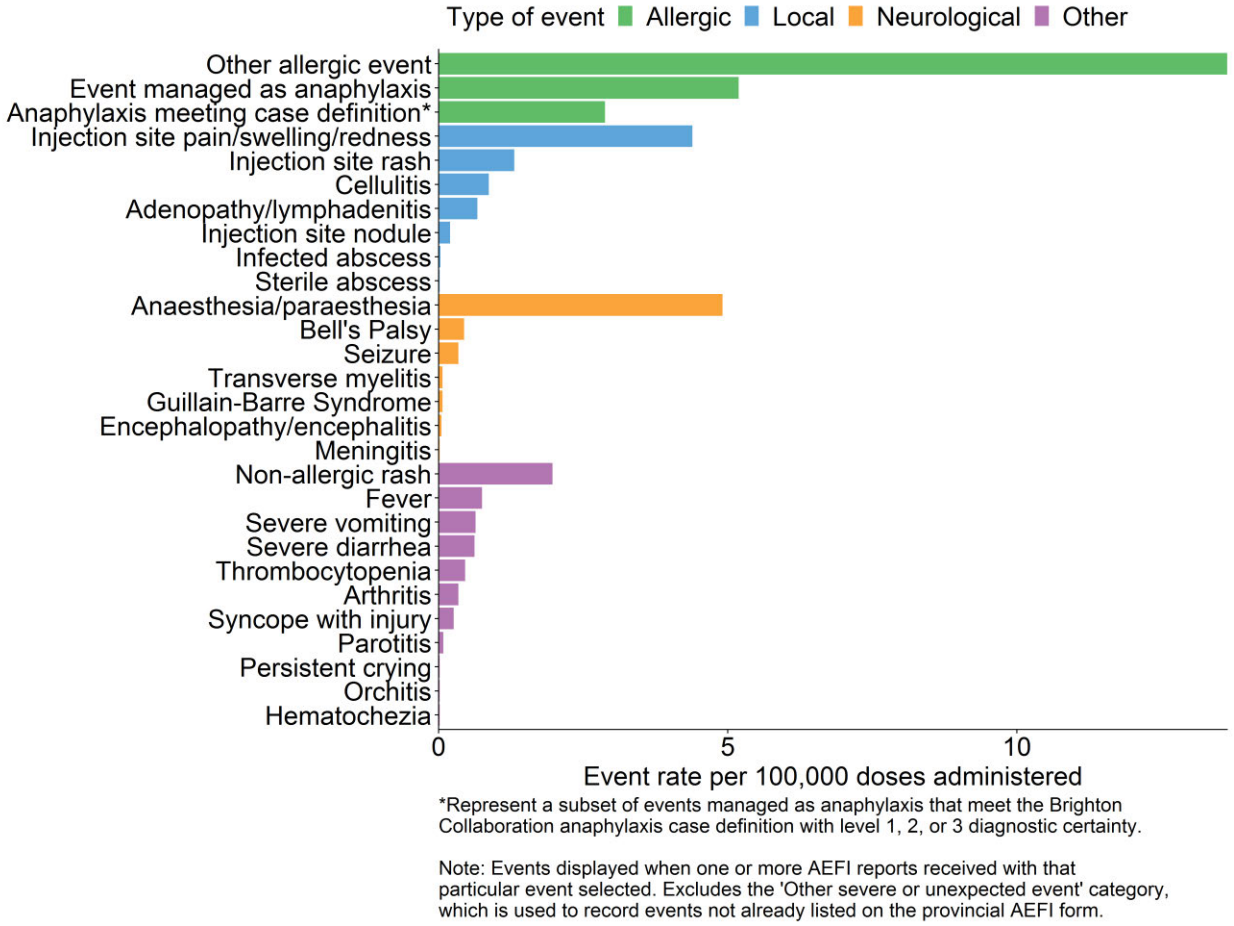
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fourteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

For six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. Finally, one death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,339 AEFI reports received up to July 17, 2021 contained a total of 2,991 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and anaesthesia/paraesthesia (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 17, 2021 **(N=2,991)**



Event Descriptions

Three hundred seventeen reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 176 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

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From: Noftall, Kyle [BCCDC]
To: Minhas, Sableen; Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: Weekly COVID19 AEFI Report
Date: Friday, July 23, 2021 9:37:59 AM

Thanks very much Sableen. That is helpful to know. As long as it wasn't 10 people reading them a week, I'm okay with it ☺
Cheers,
Kyle

Kyle Noftall, RN, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

I respectfully acknowledge that I live, work and play on the unceded territory of the xʷməθkwəy̓əm, Skwxwú7mesh, Stó:lō and Səl̓ilwətaʔ/Selilwitulh Nations.

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From: Minhas, Sableen <sableen.minhas@phsa.ca>
Sent: Friday, July 23, 2021 9:23 AM
To: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: RE: Weekly COVID19 AEFI Report

Hi Kyle,
In total, all the AEFI reports to date have had 4,905 page views (cumulative). The most viewed report had 491 pageviews (COVID19_AEFI_Weekly_Report_2021-05-06.pdf). On an average these reports have >300 page views and a good amount of time spent on page (average time spent: 4 minutes 35 seconds).
I'd interpret it as even thought traffic's low, people who do read the report are interested in the content. Does this information help?

Sableen Minhas
Communications Specialist
BC Centre for Disease Control
Provincial Health Services Authority

From: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>
Sent: Thursday, July 22, 2021 10:12 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Weekly COVID19 AEFI Report

Hi Heather and Sableen,
Attached is this week's AEFI report for posting.
Out of curiosity, have there been many views of these reports? We are starting to consider when to

scale back the frequency of generating the reports – possibly once the immunization campaign winds down near the end of summer.

Thanks,

Kyle

Kyle Noftall, RN, MPH

Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
Tel 604-707-2537
Fax 604-707-2515

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From: Amos, Heather [BCCDC]
To: Minhas, Sableen
Subject: RE: Weekly COVID19 AEFI Report
Date: Friday, July 23, 2021 11:15:54 AM

I'm impressed by these numbers!

From: Minhas, Sableen <sableen.minhas@phsa.ca>
Sent: Friday, July 23, 2021 9:23 AM
To: Noftall, Kyle [BCCDC] <Kyle.Noftall@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
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BC Centre for Disease Control
Provincial Health Services Authority

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Kyle

Kyle Noftall, RN, MPH
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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]; Noftall, Kyle [BCCDC]
Subject: Weekly COVID-19 AEFI Report
Date: Thursday, July 29, 2021 9:39:58 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-07-29.docx
COVID19_AEFI_Weekly_Report_2021-07-29.pdf

Hello all,

Please find attached the weekly COVID-19 AEFI report for posting to the website.

Thank you,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

Tel (604)707-2537

Fax (604)707-2515

I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to July 24, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including July 24, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered; three of these meet the definition of '. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[8,9]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously

unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

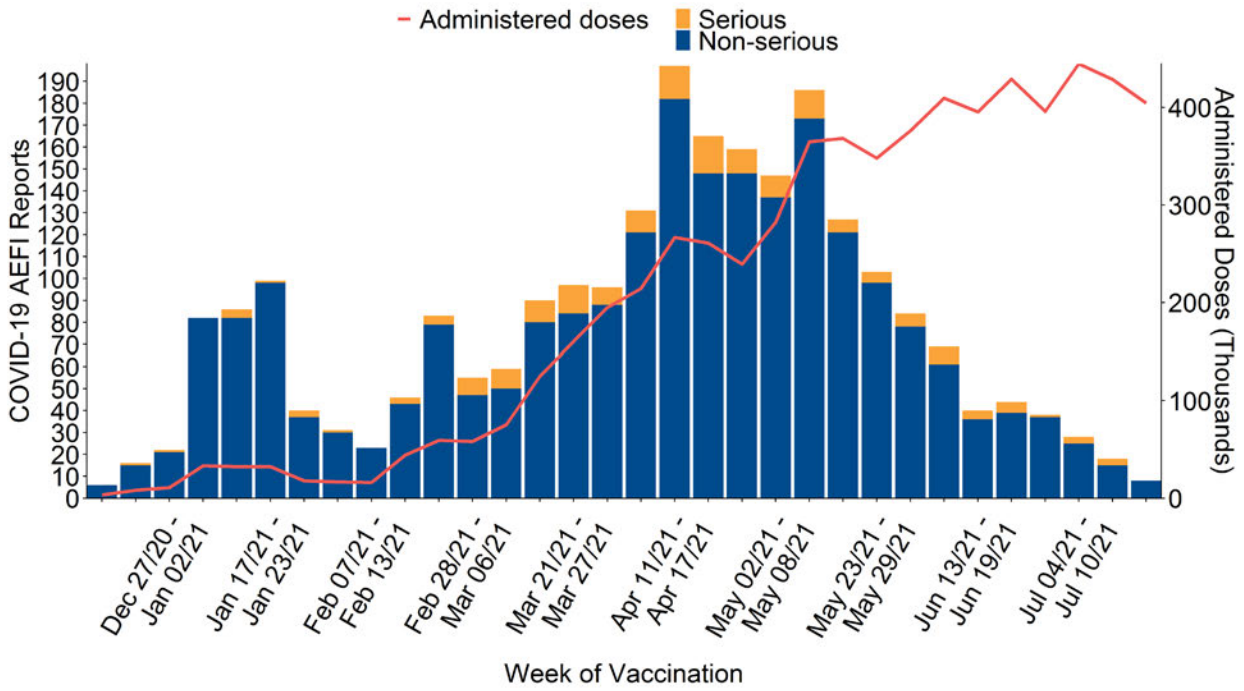
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of July 24, 2021, there have been 6,515,885 COVID-19 vaccine doses administered in BC and 2,475 COVID-19 AEFI reports (38.0 reports per 100,000 doses administered)
- 183 reports (7.4%) met the serious definition, for a rate of 2.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and event managed as anaphylaxis

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jul. 24, 2021 **(N=2,475)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including July 24, 2021, a total of 6,515,885 doses have been administered. During this period, there have been 2,475 AEFI reports following a COVID-19 vaccine, for a reporting rate of 38 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jul. 24, 2021 **(N=2,475)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**2,475**	**210**	**63**	**744**	**1,457**
Non-serious reports	2,292	187	58	693	1,353
Serious reports	183	23	5	51	104
Proportion serious	7.4%	11%	7.9%	6.9%	7.1%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2,153	202	62	637	1,251
Dose 2 reports	319	8	1	107	203
Total doses administered	**6,515,885**	**317,007**	**67,631**	**1,551,979**	**4,579,268**
Dose 1 administered	3,879,100	218,040	59,863	870,717	2,730,480
Dose 2 administered	2,636,785	98,967	7,768	681,262	1,848,788
Total reporting rate	**38.0**	**66.2**	**93.2**	**47.9**	**31.8**
Serious rate	2.8	7.3	7.4	3.3	2.3
Dose 1 rate	55.5	92.6	103.6	73.2	45.8
Dose 2 rate	12.1	8.1	12.9	15.7	11.0

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred eighty-three reports (7.4%) were considered serious (refer to serious AEFI definition above). Of these, 170 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 39 for a neurological diagnosis (including three for transverse myelitis, six for seizure, 20 for stroke, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and five Guillain-Barre Syndrome), 37 for cardiac events (including 14 for myocardial infarction, 20 for myopericarditis, and three for an arrhythmia), and 16 for a respiratory condition (14 pulmonary embolism, one respiratory distress, and one for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Eleven hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, and four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

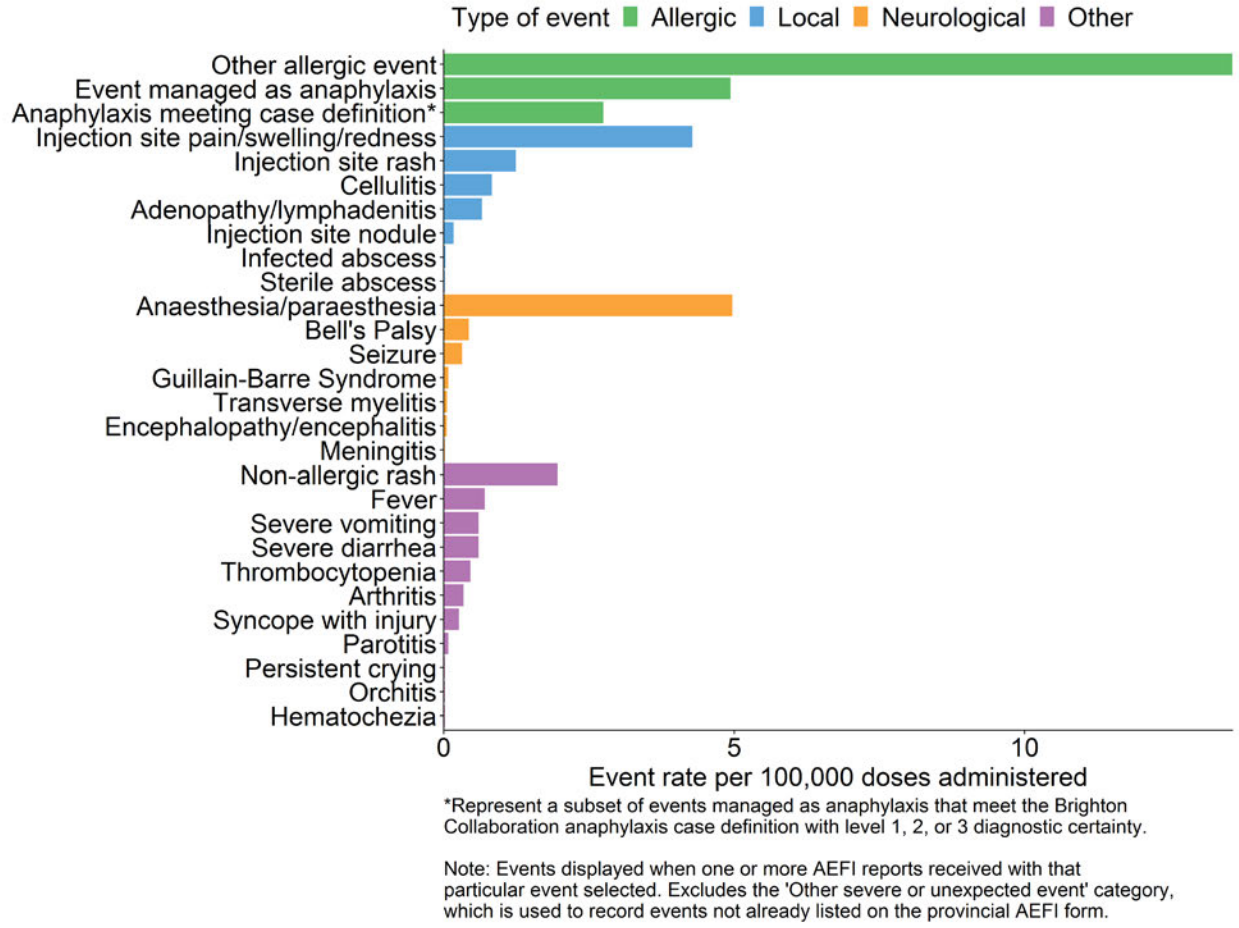
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fourteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

For six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. Finally, one death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,475 AEFI reports received up to July 24, 2021 contained a total of 3,162 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 24, 2021 **(N=3,162)**



Event Descriptions

Three hundred twenty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 179 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-four reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15] None of these reports were confirmed by microbial testing.

Sixty-six reports contained a diagnosed neurological event. Twenty-eight individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-one individuals reported seizures, including 13 with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were five reports for individuals hospitalized with Guillain-Barre Syndrome (GBS) who have since been discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 26 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were nine reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Six of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 87 were for various thrombotic/ thromboembolic conditions. These included 21 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 18 pulmonary embolisms, 28 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. The individual has since been discharged after being treated in hospital. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 46 reports of pericarditis/myocarditis. Twenty-three individuals had a diagnosis of pericarditis alone, six had myocarditis, and 17 had myopericarditis. Ages ranged from 16 to 95 with a median of 44.5 years, and 25 were male. Eighteen had received Moderna vaccine, 24 had Pfizer vaccine, and four had AstraZeneca/COVISHIELD; sixteen of the events occurred after a second dose (six Pfizer and ten Moderna). Some had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. Three met the diagnostic criteria to be considered a definite case of myocarditis according to the Brighton Collaboration myocarditis case definition, while 22 were either not a case or had insufficient details to be assigned a level.[21] Myopericarditis is being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[4-7,12,22]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on July 28, 2021. Only AEFIs reported and doses administered up to July 24, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to July 24, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including July 24, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered; three of these meet the definition of '. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[8,9]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously

unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

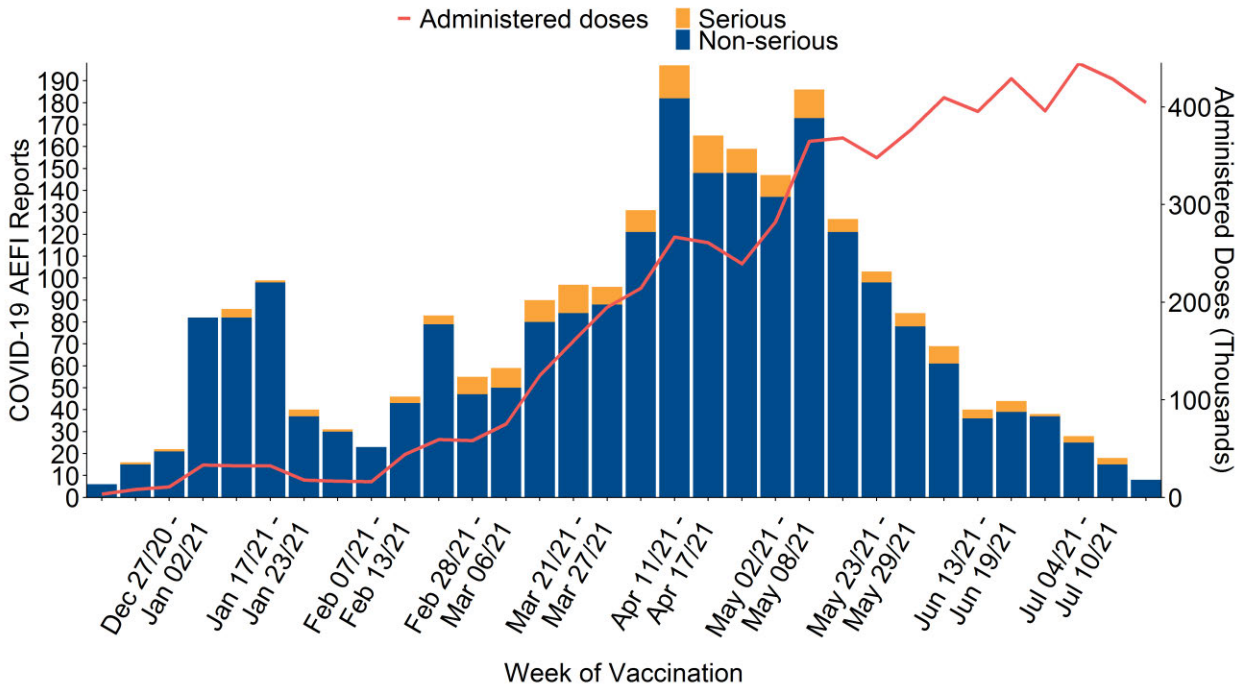
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of July 24, 2021, there have been 6,515,885 COVID-19 vaccine doses administered in BC and 2,475 COVID-19 AEFI reports (38.0 reports per 100,000 doses administered)
- 183 reports (7.4%) met the serious definition, for a rate of 2.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and event managed as anaphylaxis

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jul. 24, 2021 **(N=2,475)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including July 24, 2021, a total of 6,515,885 doses have been administered. During this period, there have been 2,475 AEFI reports following a COVID-19 vaccine, for a reporting rate of 38 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jul. 24, 2021 **(N=2,475)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**2,475**	**210**	**63**	**744**	**1,457**
Non-serious reports	2,292	187	58	693	1,353
Serious reports	183	23	5	51	104
Proportion serious	7.4%	11%	7.9%	6.9%	7.1%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2,153	202	62	637	1,251
Dose 2 reports	319	8	1	107	203
Total doses administered	**6,515,885**	**317,007**	**67,631**	**1,551,979**	**4,579,268**
Dose 1 administered	3,879,100	218,040	59,863	870,717	2,730,480
Dose 2 administered	2,636,785	98,967	7,768	681,262	1,848,788
Total reporting rate	**38.0**	**66.2**	**93.2**	**47.9**	**31.8**
Serious rate	2.8	7.3	7.4	3.3	2.3
Dose 1 rate	55.5	92.6	103.6	73.2	45.8
Dose 2 rate	12.1	8.1	12.9	15.7	11.0

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred eighty-three reports (7.4%) were considered serious (refer to serious AEFI definition above). Of these, 170 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 39 for a neurological diagnosis (including three for transverse myelitis, six for seizure, 20 for stroke, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and five Guillain-Barre Syndrome), 37 for cardiac events (including 14 for myocardial infarction, 20 for myopericarditis, and three for an arrhythmia), and 16 for a respiratory condition (14 pulmonary embolism, one respiratory distress, and one for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Eleven hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, and four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

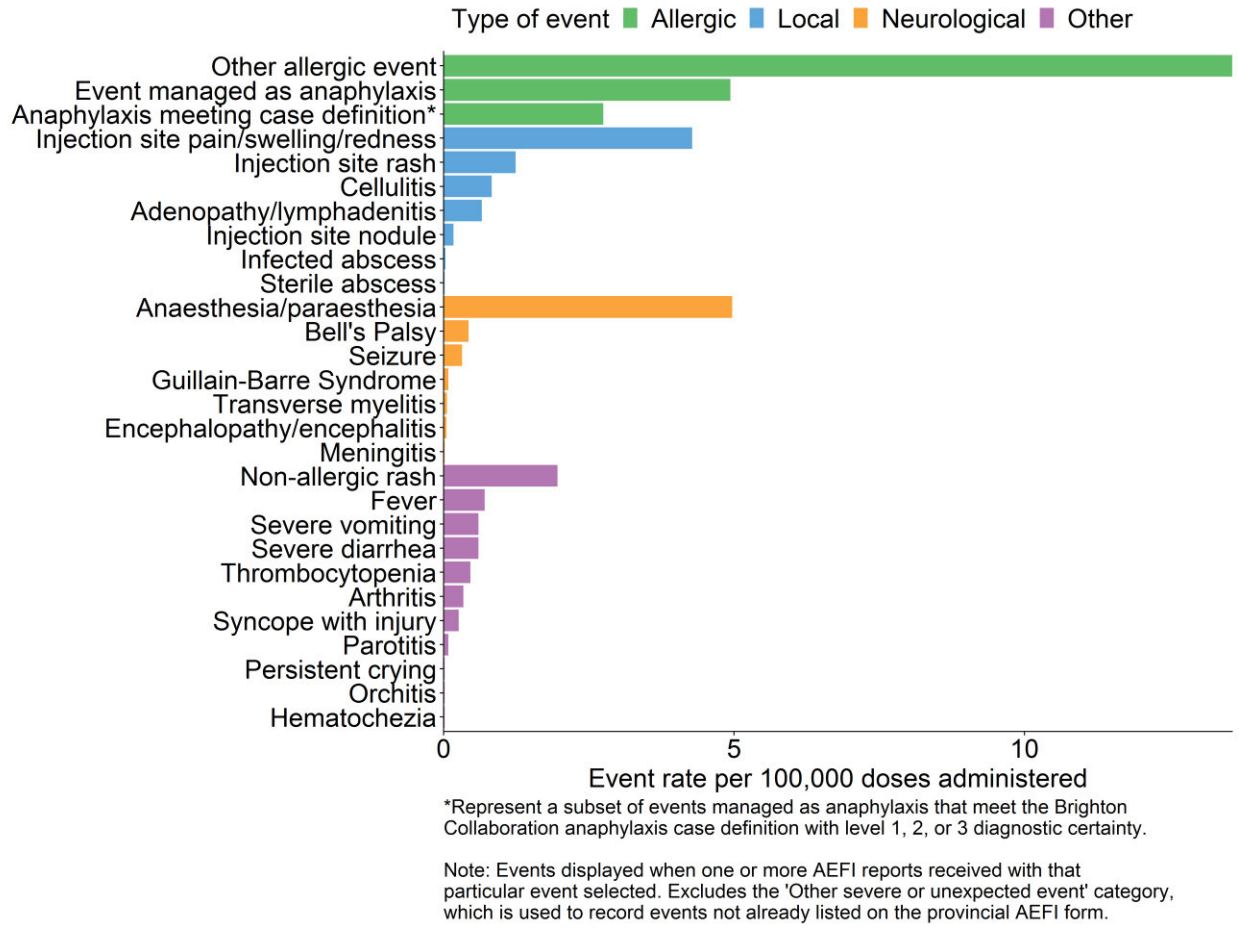
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fourteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

For six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. Finally, one death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,475 AEFI reports received up to July 24, 2021 contained a total of 3,162 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 24, 2021 **(N=3,162)**



*Represent a subset of events managed as anaphylaxis that meet the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.

Note: Events displayed when one or more AEFI reports received with that particular event selected. Excludes the 'Other severe or unexpected event' category, which is used to record events not already listed on the provincial AEFI form.

Event Descriptions

Three hundred twenty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 179 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-four reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15] None of these reports were confirmed by microbial testing.

Sixty-six reports contained a diagnosed neurological event. Twenty-eight individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-one individuals reported seizures, including 13 with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were five reports for individuals hospitalized with Guillain-Barre Syndrome (GBS) who have since been discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 26 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were nine reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Six of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 87 were for various thrombotic/ thromboembolic conditions. These included 21 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 18 pulmonary embolisms, 28 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. The individual has since been discharged after being treated in hospital. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 46 reports of pericarditis/myocarditis. Twenty-three individuals had a diagnosis of pericarditis alone, six had myocarditis, and 17 had myopericarditis. Ages ranged from 16 to 95 with a median of 44.5 years, and 25 were male. Eighteen had received Moderna vaccine, 24 had Pfizer vaccine, and four had AstraZeneca/COVISHIELD; sixteen of the events occurred after a second dose (six Pfizer and ten Moderna). Some had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. Three met the diagnostic criteria to be considered a definite case of myocarditis according to the Brighton Collaboration myocarditis case definition, while 22 were either not a case or had insufficient details to be assigned a level.[21] Myopericarditis is being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[4-7,12,22]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on July 28, 2021. Only AEFIs reported and doses administered up to July 24, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Dalati, Hadi [BCCDC]
To: Naus, Monika [BCCDC]; Amos, Heather [BCCDC]; Minhas, Sableen
Subject: Weekly COVID-19 AEFI Report
Date: Thursday, August 05, 2021 3:46:34 PM
Attachments: COVID19_AEFI_Weekly_Report_2021-08-05.pdf
COVID19_AEFI_Weekly_Report_2021-08-05.docx

Hello all,

Apologies for the delay, please find attached the weekly COVID-19 AEFI report for posting to the website.

Thank you,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

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BC Centre for Disease Control

Provincial Health Services Authority

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

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Definitions

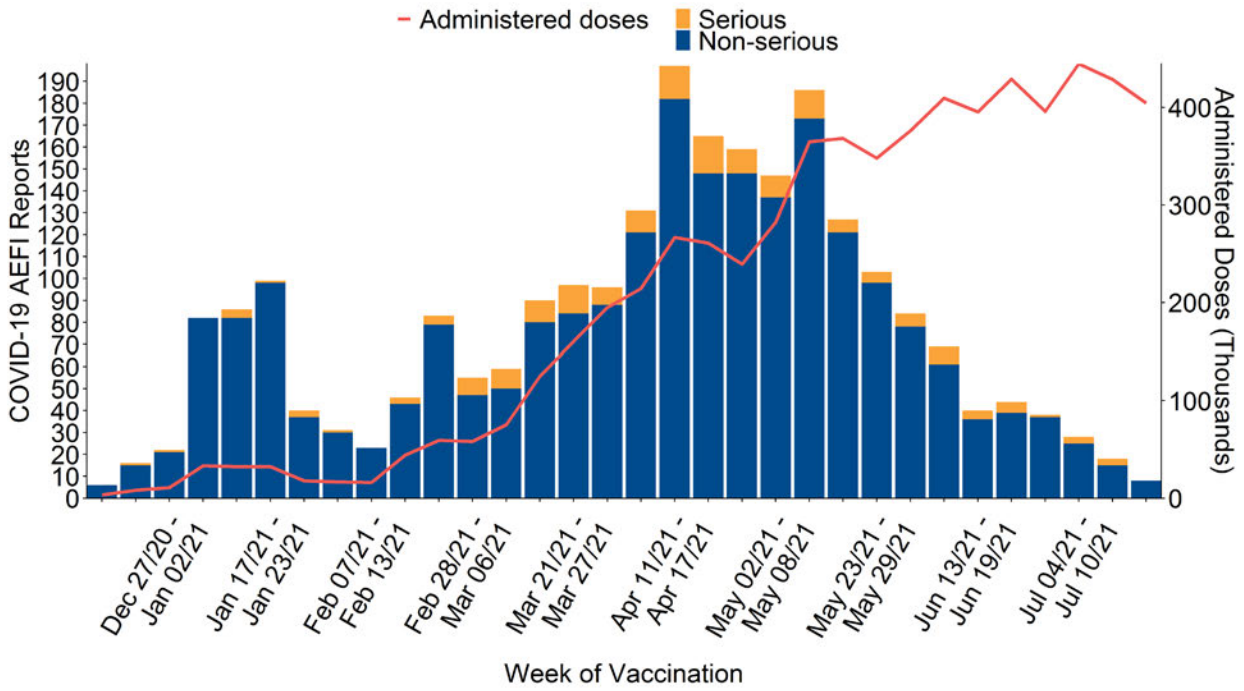
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of July 24, 2021, there have been 6,515,885 COVID-19 vaccine doses administered in BC and 2,475 COVID-19 AEFI reports (38.0 reports per 100,000 doses administered)
- 183 reports (7.4%) met the serious definition, for a rate of 2.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and event managed as anaphylaxis

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jul. 24, 2021 **(N=2,475)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including July 24, 2021, a total of 6,515,885 doses have been administered. During this period, there have been 2,475 AEFI reports following a COVID-19 vaccine, for a reporting rate of 38 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

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		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**2,475**	**210**	**63**	**744**	**1,457**
Non-serious reports	2,292	187	58	693	1,353
Serious reports	183	23	5	51	104
Proportion serious	7.4%	11%	7.9%	6.9%	7.1%

	COVID-19 Vaccine*				
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Serious rate	2.8	7.3	7.4	3.3	2.3
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Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred eighty-three reports (7.4%) were considered serious (refer to serious AEFI definition above). Of these, 170 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 39 for a neurological diagnosis (including three for transverse myelitis, six for seizure, 20 for stroke, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and five Guillain-Barre Syndrome), 37 for cardiac events (including 14 for myocardial infarction, 20 for myopericarditis, and three for an arrhythmia), and 16 for a respiratory condition (14 pulmonary embolism, one respiratory distress, and one for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Eleven hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, and four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

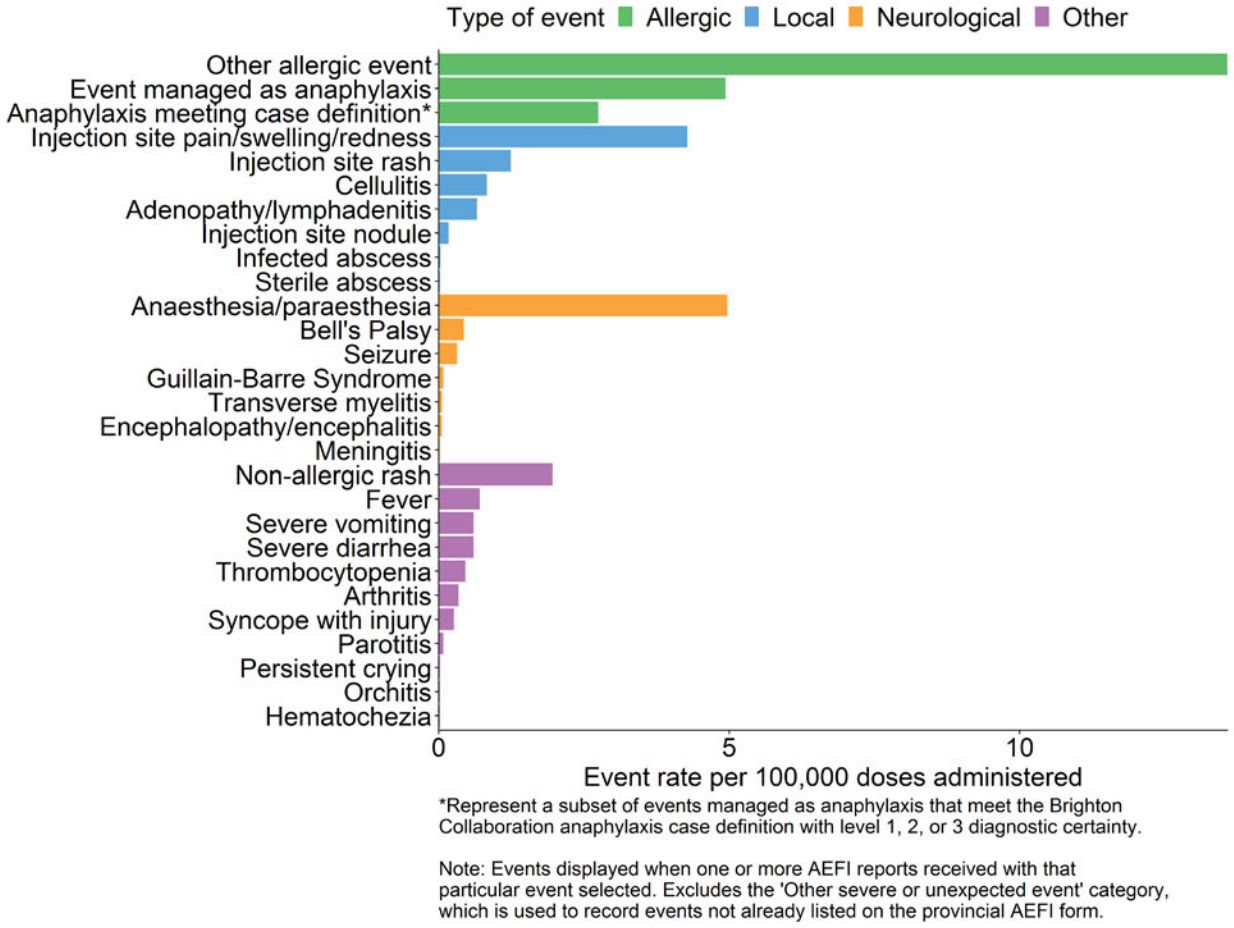
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fourteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based on the individuals' medical history. Two deaths occurred in elderly individuals with underlying medical conditions; the coroner deemed these deaths not unexpected and further investigation into the cause of death was not conducted. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

For six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. Finally, one death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,475 AEFI reports received up to July 24, 2021 contained a total of 3,162 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 24, 2021 **(N=3,162)**



Event Descriptions

Three hundred twenty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 179 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-four reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15] None of these reports were confirmed by microbial testing.

Sixty-six reports contained a diagnosed neurological event. Twenty-eight individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-one individuals reported seizures, including 13 with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were five reports for individuals hospitalized with Guillain-Barre Syndrome (GBS) who have since been discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 26 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were nine reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Six of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 87 were for various thrombotic/ thromboembolic conditions. These included 21 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 18 pulmonary embolisms, 28 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. The individual has since been discharged after being treated in hospital. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 46 reports of pericarditis/myocarditis. Twenty-three individuals had a diagnosis of pericarditis alone, six had myocarditis, and 17 had myopericarditis. Ages ranged from 16 to 95 with a median of 44.5 years, and 25 were male. Eighteen had received Moderna vaccine, 24 had Pfizer vaccine, and four had AstraZeneca/COVISHIELD; sixteen of the events occurred after a second dose (six Pfizer and ten Moderna). Some had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. Three met the diagnostic criteria to be considered a definite case of myocarditis according to the Brighton Collaboration myocarditis case definition, while 22 were either not a case or had insufficient details to be assigned a level.[21] Myopericarditis is being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[4-7,12,22]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on July 28, 2021. Only AEFIs reported and doses administered up to July 24, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to July 24, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including July 24, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered; three of these meet the definition of '. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines at rates of about 1 in 50,000 to 1 in 100,000 recipients.[8,9]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

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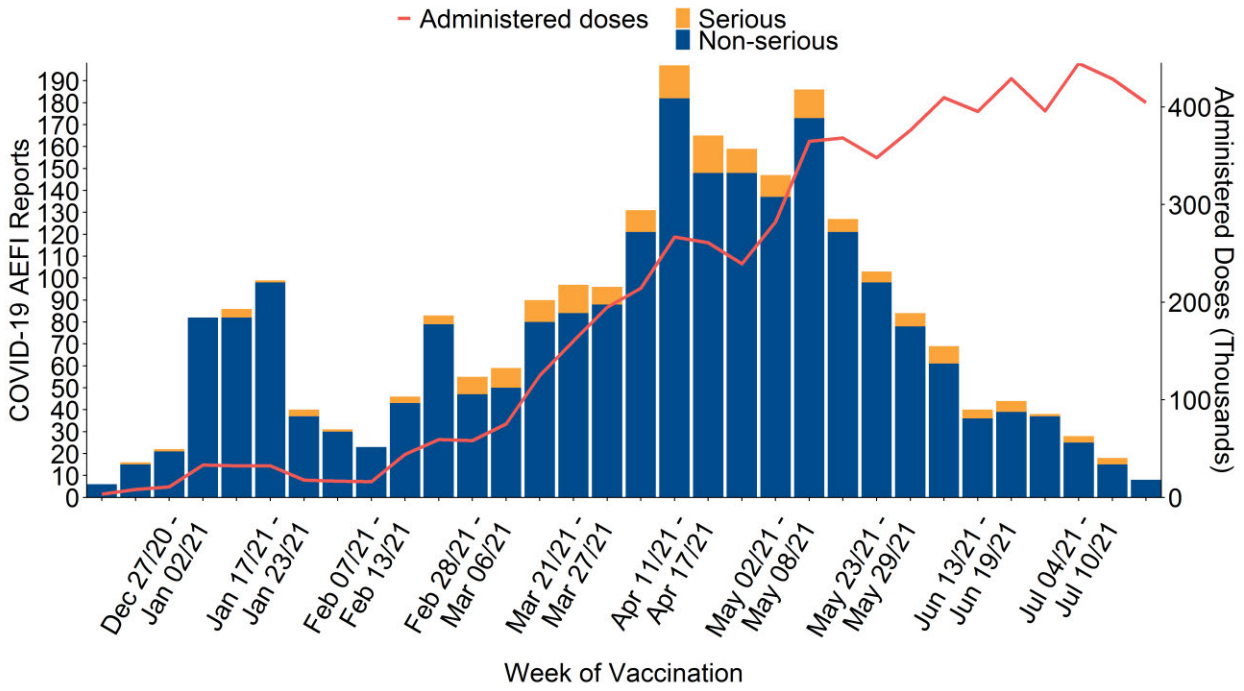

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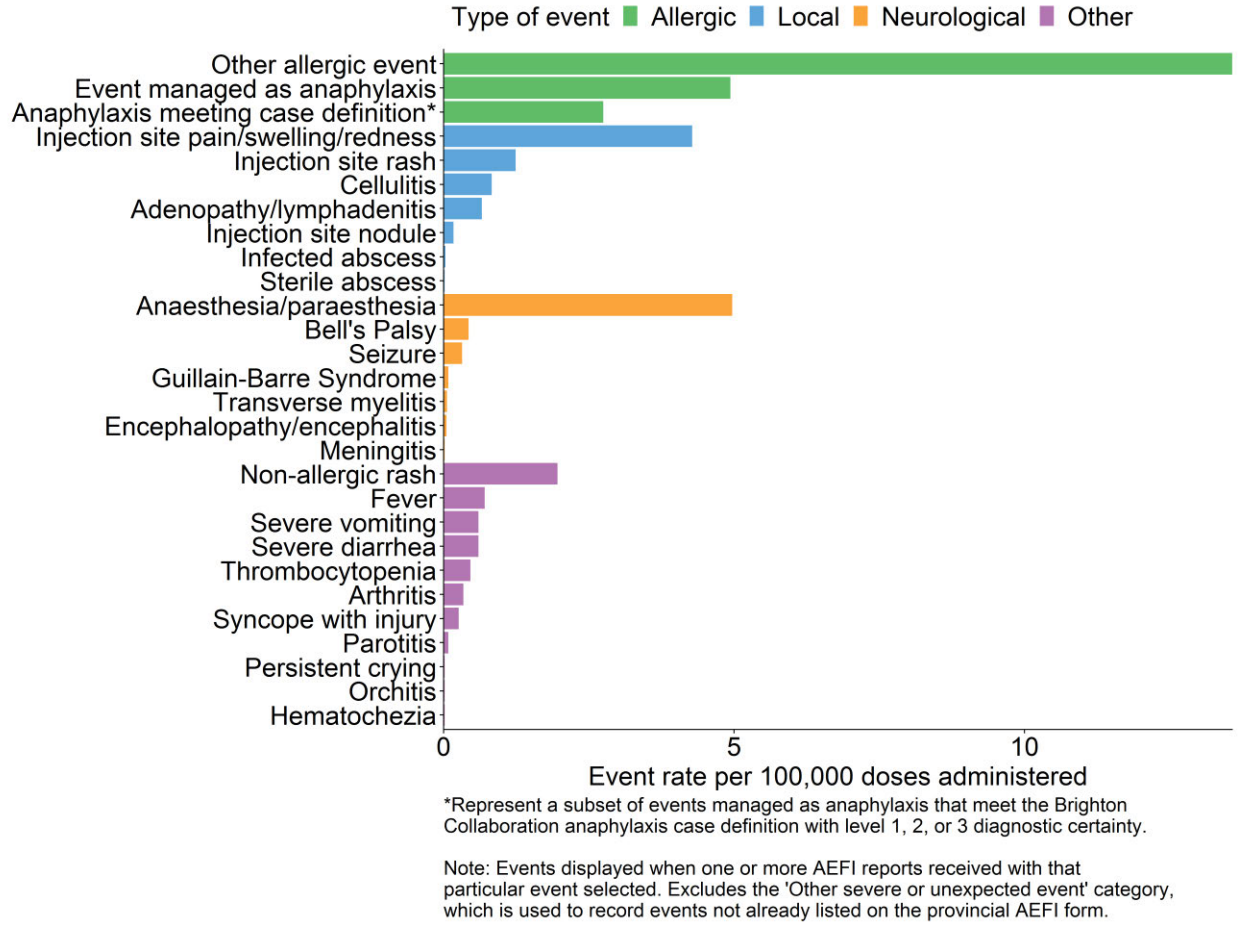
A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,475 AEFI reports received up to July 24, 2021 contained a total of 3,162 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 24, 2021 **(N=3,162)**



*Represent a subset of events managed as anaphylaxis that meet the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.

Note: Events displayed when one or more AEFI reports received with that particular event selected. Excludes the 'Other severe or unexpected event' category, which is used to record events not already listed on the provincial AEFI form.

Event Descriptions

Three hundred twenty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 179 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-four reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15] None of these reports were confirmed by microbial testing.

Sixty-six reports contained a diagnosed neurological event. Twenty-eight individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-one individuals reported seizures, including 13 with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were five reports for individuals hospitalized with Guillain-Barre Syndrome (GBS) who have since been discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 26 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were nine reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Six of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an "other serious" event when not its own discrete event on the provincial AEFI report form. Amongst these events, 87 were for various thrombotic/ thromboembolic conditions. These included 21 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 18 pulmonary embolisms, 28 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. The individual has since been discharged after being treated in hospital. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 46 reports of pericarditis/myocarditis. Twenty-three individuals had a diagnosis of pericarditis alone, six had myocarditis, and 17 had myopericarditis. Ages ranged from 16 to 95 with a median of 44.5 years, and 25 were male. Eighteen had received Moderna vaccine, 24 had Pfizer vaccine, and four had AstraZeneca/COVISHIELD; sixteen of the events occurred after a second dose (six Pfizer and ten Moderna). Some had alternate explanations including rheumatic diseases or genetic syndrome associated with cardiac disorders. Three met the diagnostic criteria to be considered a definite case of myocarditis according to the Brighton Collaboration myocarditis case definition, while 22 were either not a case or had insufficient details to be assigned a level.[21] Myopericarditis is being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[4-7,12,22]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on July 28, 2021. Only AEFIs reported and doses administered up to July 24, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Dalati, Hadi [BCCDC]
To: Minhas, Sableen; Naus, Monika [BCCDC]; Amos, Heather [BCCDC]
Subject: RE: Weekly COVID-19 AEFI Report
Date: Thursday, August 05, 2021 4:16:48 PM
Attachments: COVID19_AEFI_Weekly_Report_2021_08_04.docx
COVID19_AEFI_Weekly_Report_2021_08_04.pdf

Hi Sableen,
Apologies, I seem to have accidentally attached the wrong files. Please find the correct report attached.
Thank you for catching that.
Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ílwətaʔ/Selilwitulh (TsleilWaututh) Nations.

From: Minhas, Sableen <sableen.minhas@phsa.ca>
Sent: Thursday, August 05, 2021 4:11 PM
To: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Subject: RE: Weekly COVID-19 AEFI Report
Hi Hadi,
Just to confirm: Is the reporting period for this report Dec 13, 2020 – July 24, 2021?
The report last week was for the same period and that seems a little off.

Sableen Minhas
Communications Specialist
BC Centre for Disease Control
Provincial Health Services Authority
The report last week was for the same period.

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, August 05, 2021 3:47 PM
To: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Subject: Weekly COVID-19 AEFI Report
Hello all,
Apologies for the delay, please find attached the weekly COVID-19 AEFI report for posting to the website.
Thank you,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority

Tel (604)707-2537
Fax (604)707-2515
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl ̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to July 31, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including July 31, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher

than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

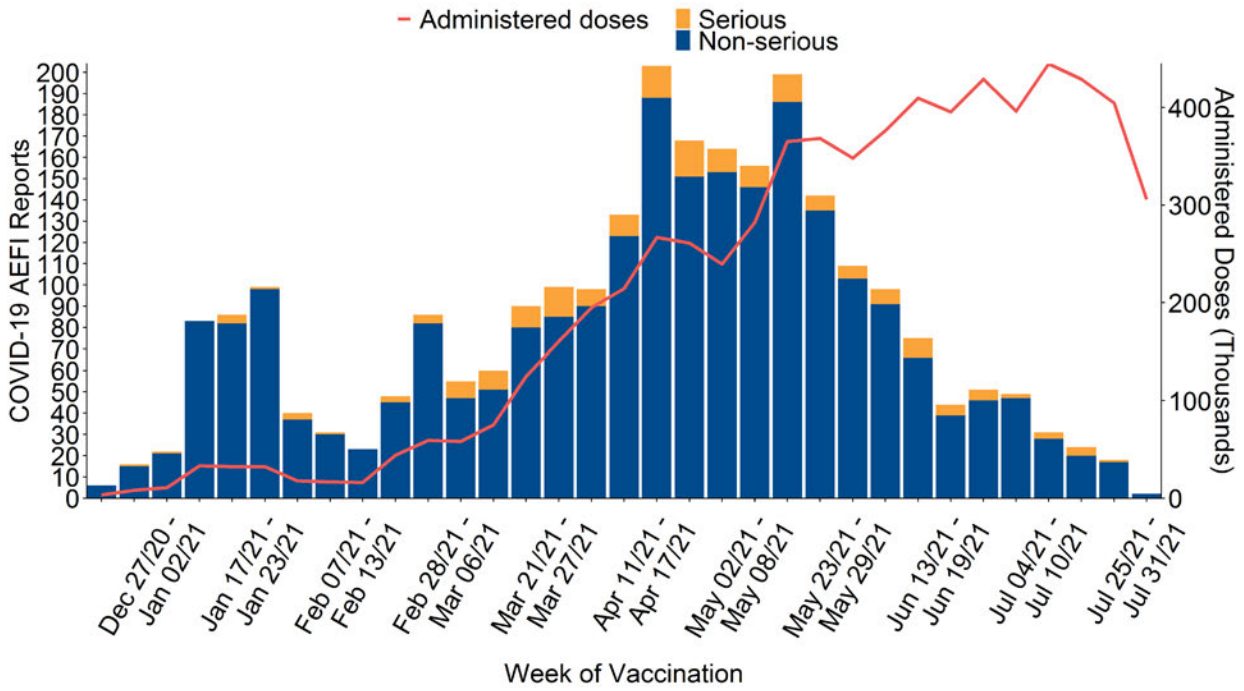
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of July 31, 2021, there have been 6,824,940 COVID-19 vaccine doses administered in BC and 2,608 COVID-19 AEFI reports (38.2 reports per 100,000 doses administered)
- 192 reports (7.4%) met the serious definition, for a rate of 2.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and event managed as anaphylaxis

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jul. 31, 2021 **(N=2,608)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including July 31, 2021, a total of 6,824,940 doses have been administered. During this period, there have been 2,608 AEFI reports following a COVID-19 vaccine, for a reporting rate of 38.2 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jul. 31, 2021 **(N=2,608)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**2608**	**214**	**65**	**790**	**1538**
Non-serious reports	2416	191	59	736	1429
Serious reports	192	23	6	54	109
Proportion serious	7.4%	10.7%	9.2%	6.8%	7.1%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2252	204	64	667	1316
Dose 2 reports	353	10	1	123	219
Total doses administered	**6,824,940**	**317,524**	**67,692**	**1,608,559**	**4,831,165**
Dose 1 administered	3,913,750	218,284	59,881	886,346	2,749,239
Dose 2 administered	2,911,190	99,240	7,811	722,213	2,081,926
Total reporting rate	**38.2**	**67.4**	**96.0**	**49.1**	**31.8**
Serious rate	2.8	7.2	8.9	3.4	2.3
Dose 1 rate	57.5	93.5	106.9	75.3	47.9
Dose 2 rate	12.1	10.1	12.8	17.0	10.5

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred ninety-two reports (7.4%) were considered serious (refer to serious AEFI definition above). Of these, 177 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 40 for a neurological diagnosis (including three for transverse myelitis, six for seizure, 21 for stroke, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and five Guillain-Barre Syndrome), 41 for cardiac events (including 14 for myocardial infarction, 24 for myopericarditis, and three for an arrhythmia), and 20 for a respiratory condition (17 pulmonary embolism, one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Eleven hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, and four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fifteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history. One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

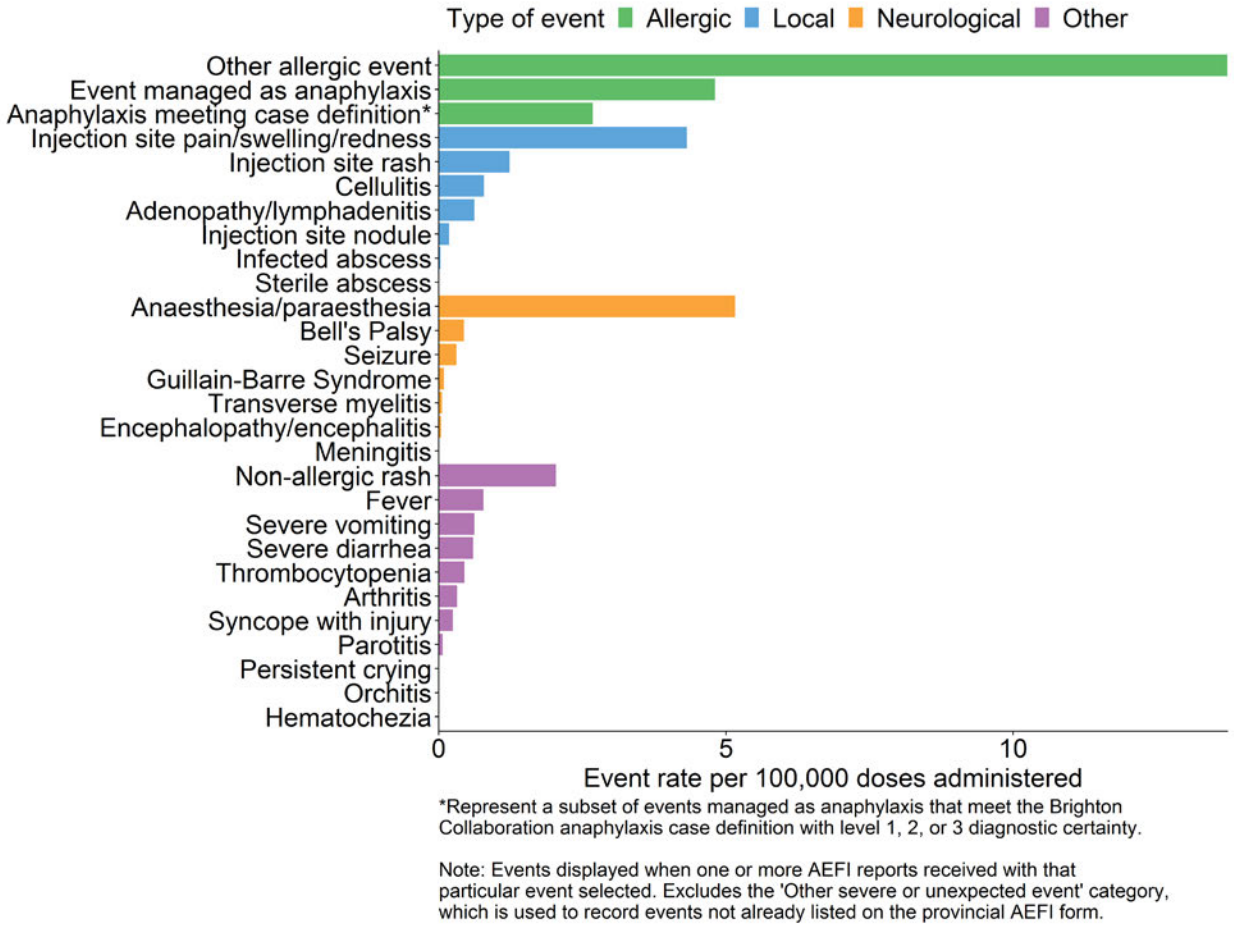
For six individuals, death was the outcome of cardiac arrest. Five of these were elderly

individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,608 AEFI reports received up to July 31, 2021 contained a total of 3,334 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 31, 2021 **(N=3,334)**



Event Descriptions

Three hundred twenty-eight reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 183 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-four reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15] None of these reports were confirmed by microbial testing.

Seventy reports contained a diagnosed neurological event. Thirty individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-one individuals reported seizures, including 13 with a history of a seizure disorder. Three individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were six reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), five of which have since been discharged and the sixth was never admitted. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 26 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were nine reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Six of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. Amongst these events, 86 were for various thrombotic/ thromboembolic conditions. These included 20 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 20 pulmonary emboli, 28 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

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There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 52 reports of pericarditis/myocarditis. Twenty-eight individuals had a diagnosis of pericarditis alone, six had myocarditis, and 18 had myopericarditis. Ages ranged from 16 to 95 with a median of 44 years, and 29 were male. Twenty-one had received Moderna vaccine, 26 had Pfizer vaccine, and five had AstraZeneca/COVISHIELD; 23 of the events occurred after a second dose (9 Pfizer and 14 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. Three myocarditis cases met the diagnostic criteria for level 1, 2 or 3 of the Brighton Collaboration case definition. Twenty-four cases of peri and/or myocarditis were either not a case or had insufficient details to be assigned a level.[21] Myopericarditis is being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Data Notes

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to July 31, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including July 31, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher

than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

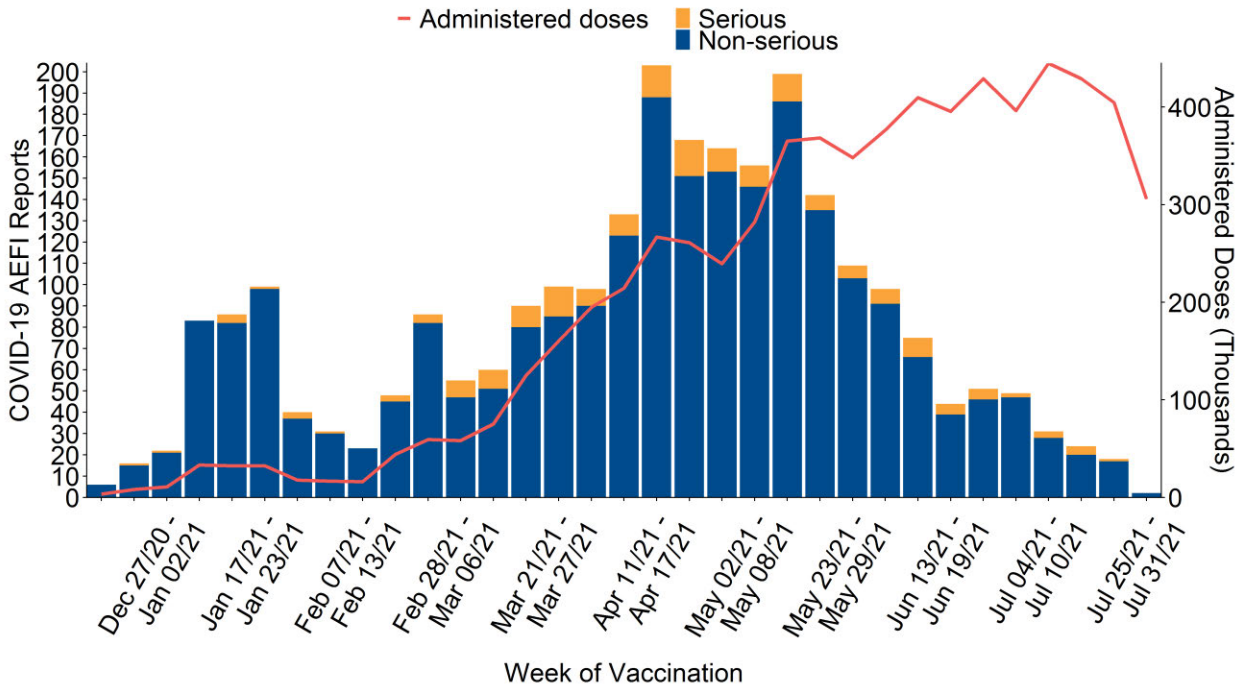
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of July 31, 2021, there have been 6,824,940 COVID-19 vaccine doses administered in BC and 2,608 COVID-19 AEFI reports (38.2 reports per 100,000 doses administered)
- 192 reports (7.4%) met the serious definition, for a rate of 2.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and event managed as anaphylaxis

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jul. 31, 2021 **(N=2,608)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including July 31, 2021, a total of 6,824,940 doses have been administered. During this period, there have been 2,608 AEFI reports following a COVID-19 vaccine, for a reporting rate of 38.2 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jul. 31, 2021 **(N=2,608)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**2608**	**214**	**65**	**790**	**1538**
Non-serious reports	2416	191	59	736	1429
Serious reports	192	23	6	54	109
Proportion serious	7.4%	10.7%	9.2%	6.8%	7.1%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2252	204	64	667	1316
Dose 2 reports	353	10	1	123	219
Total doses administered	**6,824,940**	**317,524**	**67,692**	**1,608,559**	**4,831,165**
Dose 1 administered	3,913,750	218,284	59,881	886,346	2,749,239
Dose 2 administered	2,911,190	99,240	7,811	722,213	2,081,926
Total reporting rate	**38.2**	**67.4**	**96.0**	**49.1**	**31.8**
Serious rate	2.8	7.2	8.9	3.4	2.3
Dose 1 rate	57.5	93.5	106.9	75.3	47.9
Dose 2 rate	12.1	10.1	12.8	17.0	10.5

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

One hundred ninety-two reports (7.4%) were considered serious (refer to serious AEFI definition above). Of these, 177 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 40 for a neurological diagnosis (including three for transverse myelitis, six for seizure, 21 for stroke, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and five Guillain-Barre Syndrome), 41 for cardiac events (including 14 for myocardial infarction, 24 for myopericarditis, and three for an arrhythmia), and 20 for a respiratory condition (17 pulmonary embolism, one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Eleven hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, and four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fifteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history. One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

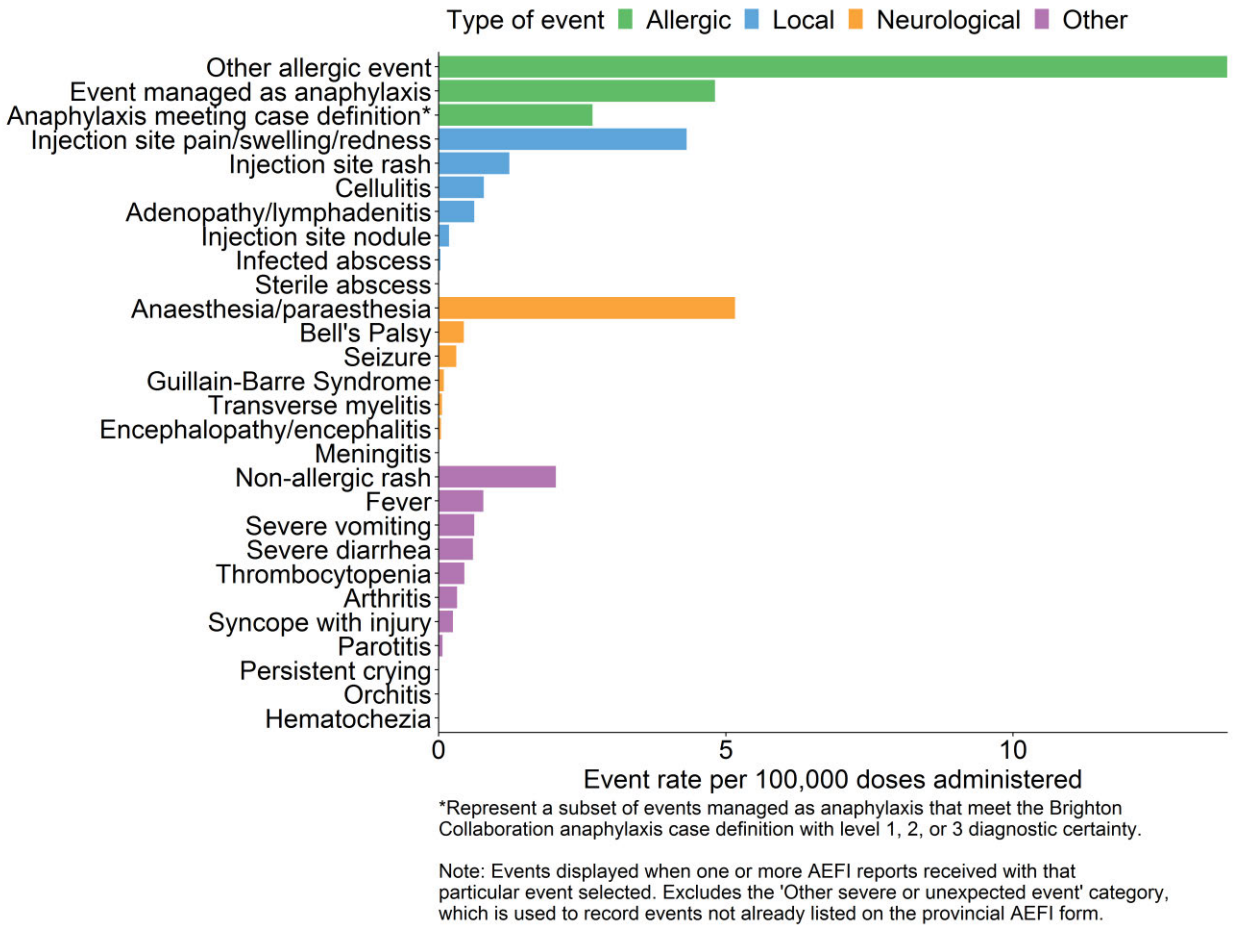
For six individuals, death was the outcome of cardiac arrest. Five of these were elderly

individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,608 AEFI reports received up to July 31, 2021 contained a total of 3,334 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 31, 2021 **(N=3,334)**



Event Descriptions

Three hundred twenty-eight reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 183 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-four reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15] None of these reports were confirmed by microbial testing.

Seventy reports contained a diagnosed neurological event. Thirty individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-one individuals reported seizures, including 13 with a history of a seizure disorder. Three individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were six reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), five of which have since been discharged and the sixth was never admitted. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 26 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were nine reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Six of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

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From: Minhas, Sableen
To: Dalati, Hadi [BCCDC]; Naus, Monika [BCCDC]; Amos, Heather [BCCDC]
Subject: RE: Weekly COVID-19 AEFI Report
Date: Thursday, August 05, 2021 4:19:54 PM

Thank you!

Sableen Minhas
Communications Specialist
BC Centre for Disease Control
Provincial Health Services Authority

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, August 05, 2021 4:17 PM
To: Minhas, Sableen <sableen.minhas@phsa.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Subject: RE: Weekly COVID-19 AEFI Report

Hi Sableen,

Apologies, I seem to have accidentally attached the wrong files. Please find the correct report attached.

Thank you for catching that.

Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaɁ/Selilwitulh (TsleilWaututh) Nations.

From: Minhas, Sableen <sableen.minhas@phsa.ca>
Sent: Thursday, August 05, 2021 4:11 PM
To: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Subject: RE: Weekly COVID-19 AEFI Report

Hi Hadi,

Just to confirm: Is the reporting period for this report Dec 13, 2020 – July 24, 2021?

The report last week was for the same period and that seems a little off.

Sableen Minhas
Communications Specialist
BC Centre for Disease Control
Provincial Health Services Authority

The report last week was for the same period.

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, August 05, 2021 3:47 PM
To: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Subject: Weekly COVID-19 AEFI Report

Hello all,

Apologies for the delay, please find attached the weekly COVID-19 AEFI report for posting to the website.

Thank you,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

Tel (604)707-2537

Fax (604)707-2515

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From: Dalati, Hadi [BCCDC]
To: Minhas, Sableen; Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Weekly COVID-19 AEFI Report
Date: Thursday, August 12, 2021 10:28:23 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-08-12.pdf
COVID19_AEFI_Weekly_Report_2021-08-12.docx

Hello all,

Please find attached this week's COVID-19 AEFI report for posting on the website.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

Tel (604)707-2537

Fax (604)707-2515

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to August 7, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including August 7, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher

than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

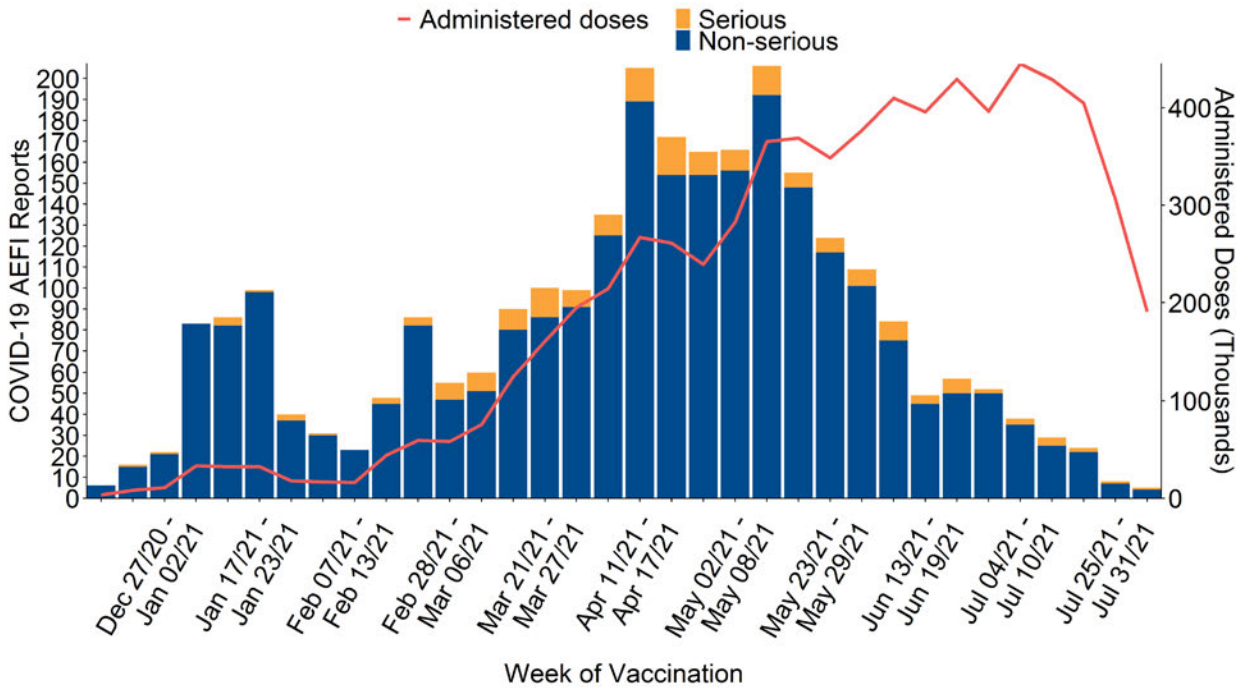
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of August 7, 2021, there have been 7,018,676 COVID-19 vaccine doses administered in BC and 2,727 COVID-19 AEFI reports (38.9 reports per 100,000 doses administered)
- 201 reports (7.4%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and event managed as anaphylaxis

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Aug. 7, 2021 **(N=2,727)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including August 7, 2021, a total of 7,018,676 doses have been administered. During this period, there have been 2,727 AEFI reports following a COVID-19 vaccine, for a reporting rate of 38.9 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Aug. 7, 2021 **(N=2,727)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**2727**	**219**	**65**	**829**	**1613**
Non-serious reports	2526	196	59	772	1498
Serious reports	201	23	6	57	115
Proportion serious	7.4%	10.5%	9.2%	6.9%	7.1%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2326	208	64	691	1362
Dose 2 reports	397	11	1	138	247
Total doses administered	**7,018,676**	**318,070**	**67,645**	**1,642,195**	**4,990,766**
Dose 1 administered	3,946,364	218,594	59,823	900,008	2,767,939
Dose 2 administered	3,072,312	99,476	7,822	742,187	2,222,827
Total reporting rate	**38.9**	**68.9**	**96.1**	**50.5**	**32.3**
Serious rate	2.9	7.2	8.9	3.5	2.3
Dose 1 rate	58.9	95.2	107.0	76.8	49.2
Dose 2 rate	12.9	11.1	12.8	18.6	11.1

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

Two hundred one reports (7.4%) were considered serious (refer to serious AEFI definition above). Of these, 187 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 81 for circulatory system events (including 21 for stroke, 17 for pulmonary embolism, 14 for myocardial infarction, 26 for myopericarditis, and three for an arrhythmia), 20 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and six Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Seventeen hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, of which, four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

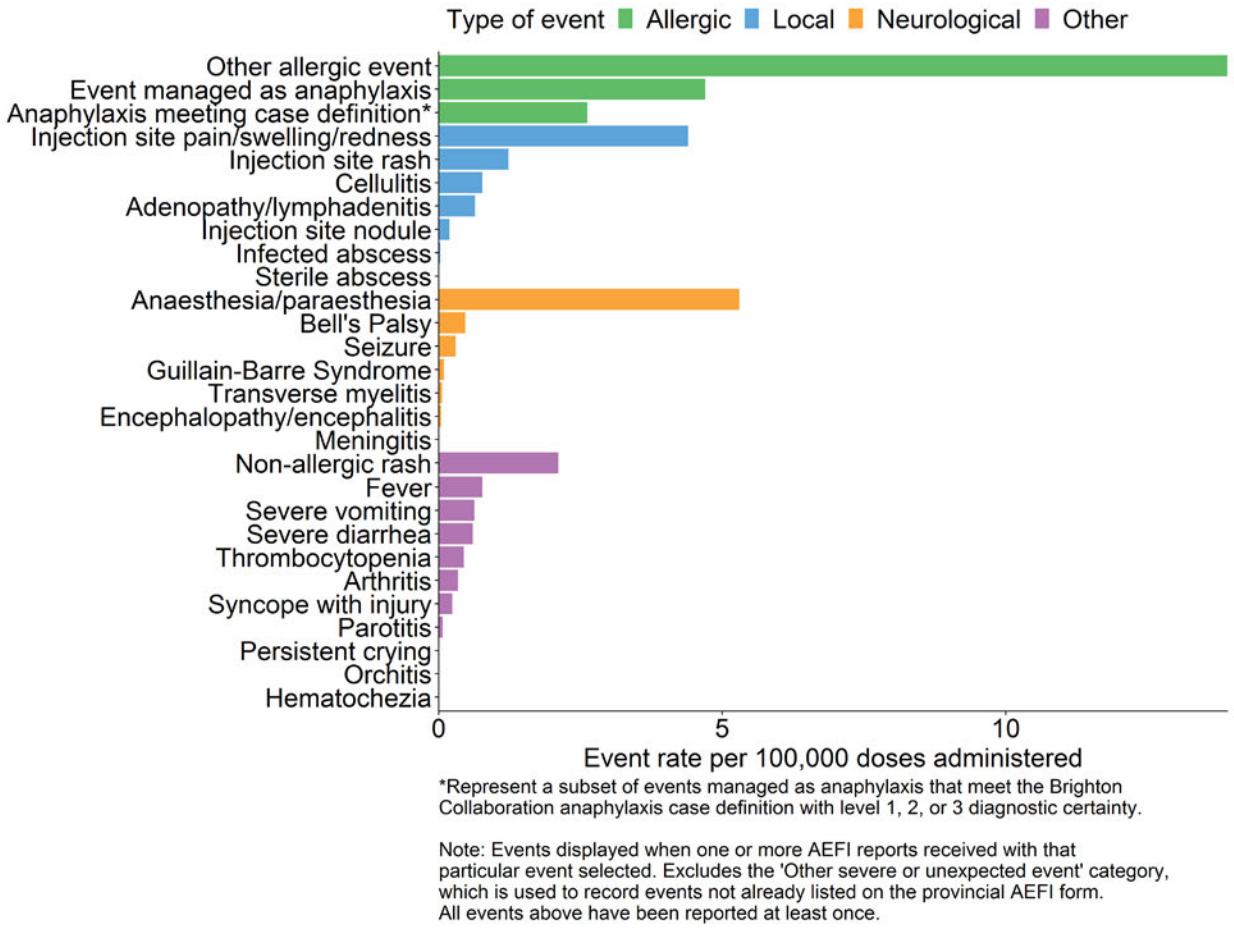
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fifteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history. One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

For six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,727 AEFI reports received up to August 7, 2021 contained a total of 3,479 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 7, 2021 **(N=3,479)**



Event Descriptions

Three hundred thirty reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 184 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-four reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15]

Seventy two reports contained a diagnosed neurological event. Thirty-three individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-one individuals reported seizures, including 13 with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were six reports for individuals with Guillain-Barre Syndrome (GBS), five of which were hospitalized and have since been discharged while the sixth was not admitted. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 27 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were ten reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an “other serious” event when they do not have their own discrete event on the provincial AEFI report form. Amongst these events, 98 were for various thrombotic/ thromboembolic conditions. These included 22 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 23 pulmonary emboli, 32 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One “other serious” report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 59 reports of pericarditis/myocarditis. Twenty-nine individuals were diagnosed with pericarditis alone, ten with myocarditis alone, and 20 with myopericarditis. Ages ranged from 14 to 95 with a median of 43.2 years, and 34 were male. Twenty-one had received Moderna vaccine, 33 had Pfizer vaccine, and five had AstraZeneca/COVISHIELD. Twenty-three of these events occurred after a second dose (11 Pfizer and 12 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. All ten of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirteen (out of 29) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Fourteen (out of 20) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis. [21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on August 11, 2021. Only AEFIs reported and doses administered up to August 7, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to August 7, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including August 7, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

No safety signals have been identified in association with the mRNA reports received in BC to date. These vaccines have demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] BC is reporting higher rates of anaphylaxis than many other Canadian jurisdictions, but about half of these had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events, which are nevertheless managed as anaphylaxis out of an abundance of caution, and reported thereafter. Serious events have not been reported at rates higher than expected compared to background rates. Canada and BC are monitoring the occurrence of myocarditis and pericarditis following recognition of an association with mRNA vaccines in the USA in young adults and adolescents.[5-7]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher

than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

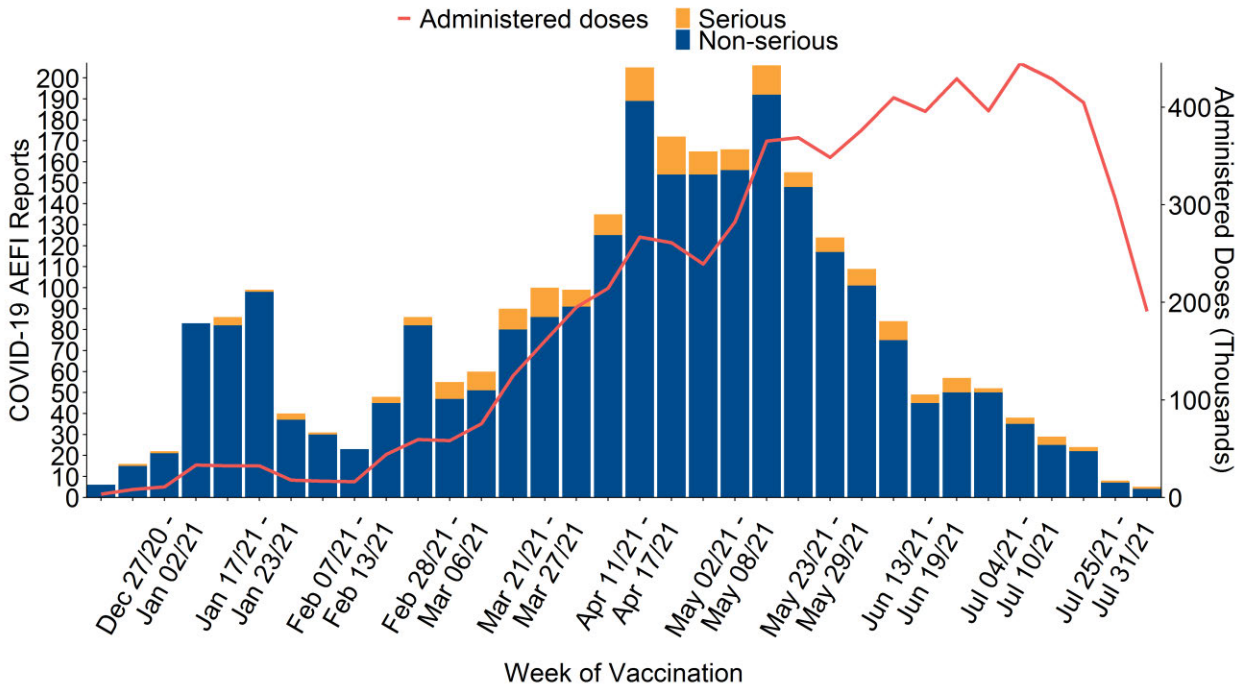
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of August 7, 2021, there have been 7,018,676 COVID-19 vaccine doses administered in BC and 2,727 COVID-19 AEFI reports (38.9 reports per 100,000 doses administered)
- 201 reports (7.4%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and event managed as anaphylaxis

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Aug. 7, 2021 **(N=2,727)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including August 7, 2021, a total of 7,018,676 doses have been administered. During this period, there have been 2,727 AEFI reports following a COVID-19 vaccine, for a reporting rate of 38.9 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Aug. 7, 2021 **(N=2,727)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**2727**	**219**	**65**	**829**	**1613**
Non-serious reports	2526	196	59	772	1498
Serious reports	201	23	6	57	115
Proportion serious	7.4%	10.5%	9.2%	6.9%	7.1%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2326	208	64	691	1362
Dose 2 reports	397	11	1	138	247
Total doses administered	**7,018,676**	**318,070**	**67,645**	**1,642,195**	**4,990,766**
Dose 1 administered	3,946,364	218,594	59,823	900,008	2,767,939
Dose 2 administered	3,072,312	99,476	7,822	742,187	2,222,827
Total reporting rate	**38.9**	**68.9**	**96.1**	**50.5**	**32.3**
Serious rate	2.9	7.2	8.9	3.5	2.3
Dose 1 rate	58.9	95.2	107.0	76.8	49.2
Dose 2 rate	12.9	11.1	12.8	18.6	11.1

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

Two hundred one reports (7.4%) were considered serious (refer to serious AEFI definition above). Of these, 187 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 81 for circulatory system events (including 21 for stroke, 17 for pulmonary embolism, 14 for myocardial infarction, 26 for myopericarditis, and three for an arrhythmia), 20 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and six Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Seventeen hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, of which, four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

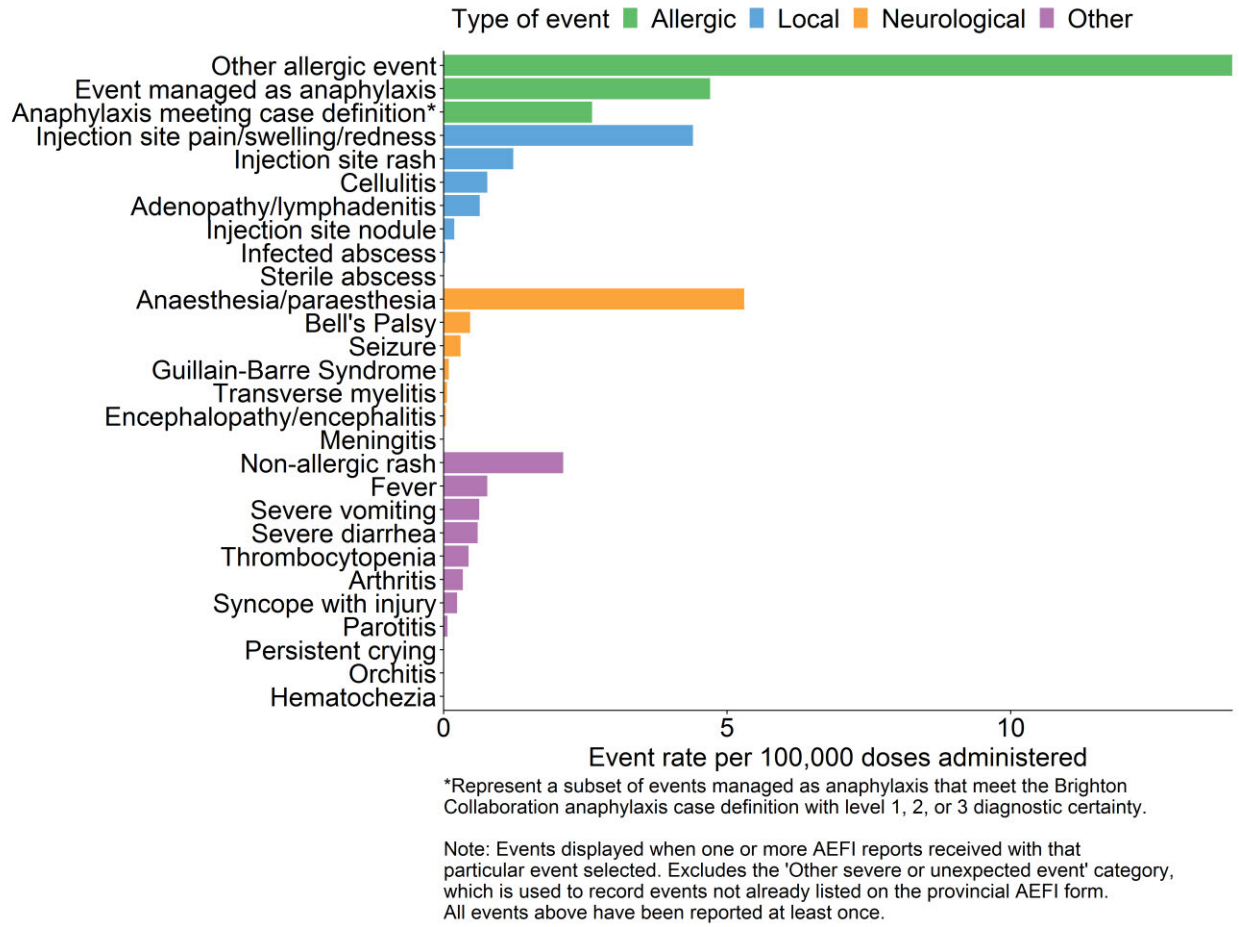
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fifteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history. One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

For six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,727 AEFI reports received up to August 7, 2021 contained a total of 3,479 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 7, 2021 **(N=3,479)**



*Represent a subset of events managed as anaphylaxis that meet the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.

Note: Events displayed when one or more AEFI reports received with that particular event selected. Excludes the 'Other severe or unexpected event' category, which is used to record events not already listed on the provincial AEFI form. All events above have been reported at least once.

Event Descriptions

Three hundred thirty reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 184 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-four reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.[15]

Seventy two reports contained a diagnosed neurological event. Thirty-three individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-one individuals reported seizures, including 13 with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were six reports for individuals with Guillain-Barre Syndrome (GBS), five of which were hospitalized and have since been discharged while the sixth was not admitted. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 27 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were ten reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. Amongst these events, 98 were for various thrombotic/ thromboembolic conditions. These included 22 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 23 pulmonary emboli, 32 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 59 reports of pericarditis/myocarditis. Twenty-nine individuals were diagnosed with pericarditis alone, ten with myocarditis alone, and 20 with myopericarditis. Ages ranged from 14 to 95 with a median of 43.2 years, and 34 were male. Twenty-one had received Moderna vaccine, 33 had Pfizer vaccine, and five had AstraZeneca/COVISHIELD. Twenty-three of these events occurred after a second dose (11 Pfizer and 12 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. All ten of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirteen (out of 29) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Fourteen (out of 20) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis. [21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on August 11, 2021. Only AEFIs reported and doses administered up to August 7, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From:	Dalati, Hadi [BCCDC]
To:	Minhas, Sableen; Amos, Heather [BCCDC]
Cc:	Naus, Monika [BCCDC]
Subject:	Weekly COVID-19 AEFI Report
Date:	Thursday, August 19, 2021 1:48:03 PM
Attachments:	COVID19_AEFI_Weekly_Report_2021-08-19.docx COVID19_AEFI_Weekly_Report_2021-08-19.pdf

Hello all,

Please find attached this week's COVID-19 AEFI report for posting on the website.

Best,

Hadi Dalati, MPH

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to August 14, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including August 14, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

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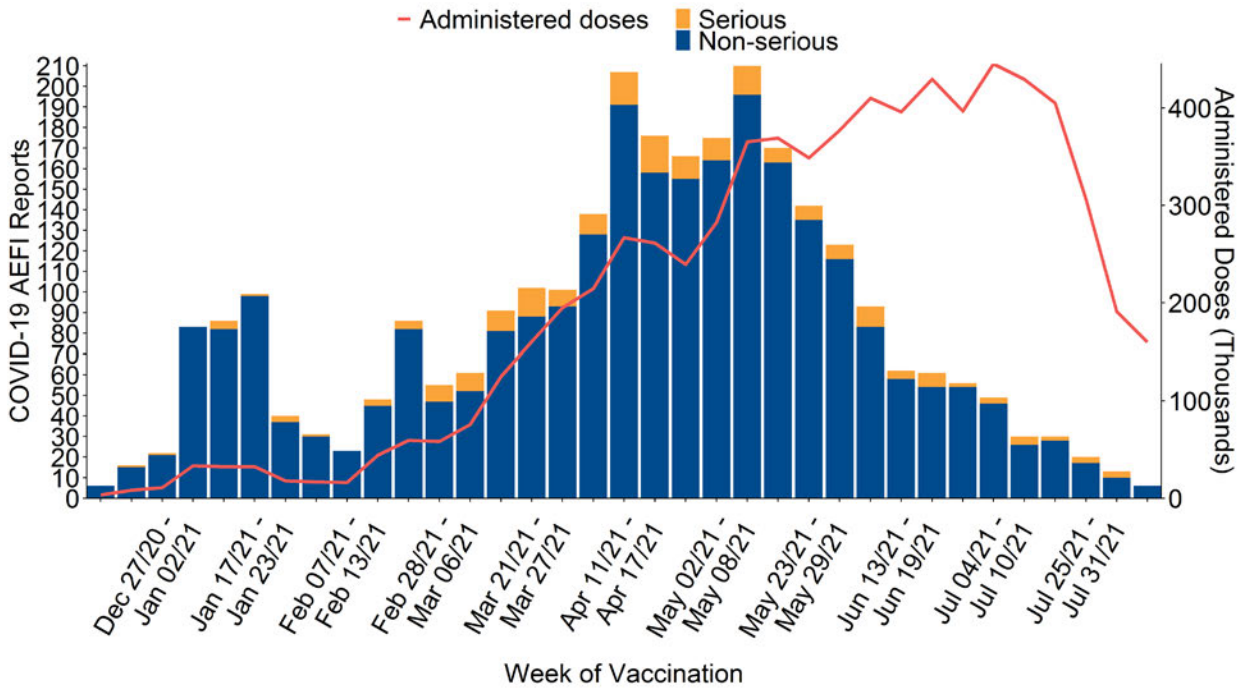
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of August 14, 2021, there have been 7,183,127 COVID-19 vaccine doses administered in BC and 2,877 COVID-19 AEFI reports (40.1 reports per 100,000 doses administered)
- 206 reports (7.2%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and event managed as anaphylaxis

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Aug. 14, 2021 **(N=2,877)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including August 14, 2021, a total of 7,183,127 doses have been administered. During this period, there have been 2,877 AEFI reports following a COVID-19 vaccine, for a reporting rate of 40.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

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Non-serious reports	2671	198	59	809	1604
Serious reports	206	23	6	60	117
Proportion serious	7.2%	10.4%	9.2%	6.9%	6.8%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
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Dose 2 reports	442	12	1	151	278
Total doses administered	**7,183,127**	**318,537**	**67,612**	**1,696,441**	**5,100,537**
Dose 1 administered	3,975,165	218,860	59,761	912,078	2,784,466
Dose 2 administered	3,207,962	99,677	7,851	784,363	2,316,071
Total reporting rate	**40.1**	**69.4**	**96.1**	**51.2**	**33.7**
Serious rate	2.9	7.2	8.9	3.5	2.3
Dose 1 rate	61.2	95.5	107.1	78.7	51.8
Dose 2 rate	13.8	12.0	12.7	19.3	12.0

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine (n=1). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

Two hundred six reports (7.2%) were considered serious (refer to serious AEFI definition above). Of these, 192 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 86 for circulatory system events (including 21 for stroke, 17 for pulmonary embolism, 14 for myocardial infarction, 31 for myopericarditis, and three for an arrhythmia), 20 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and six Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Seventeen hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, of which, four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fifteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history. One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

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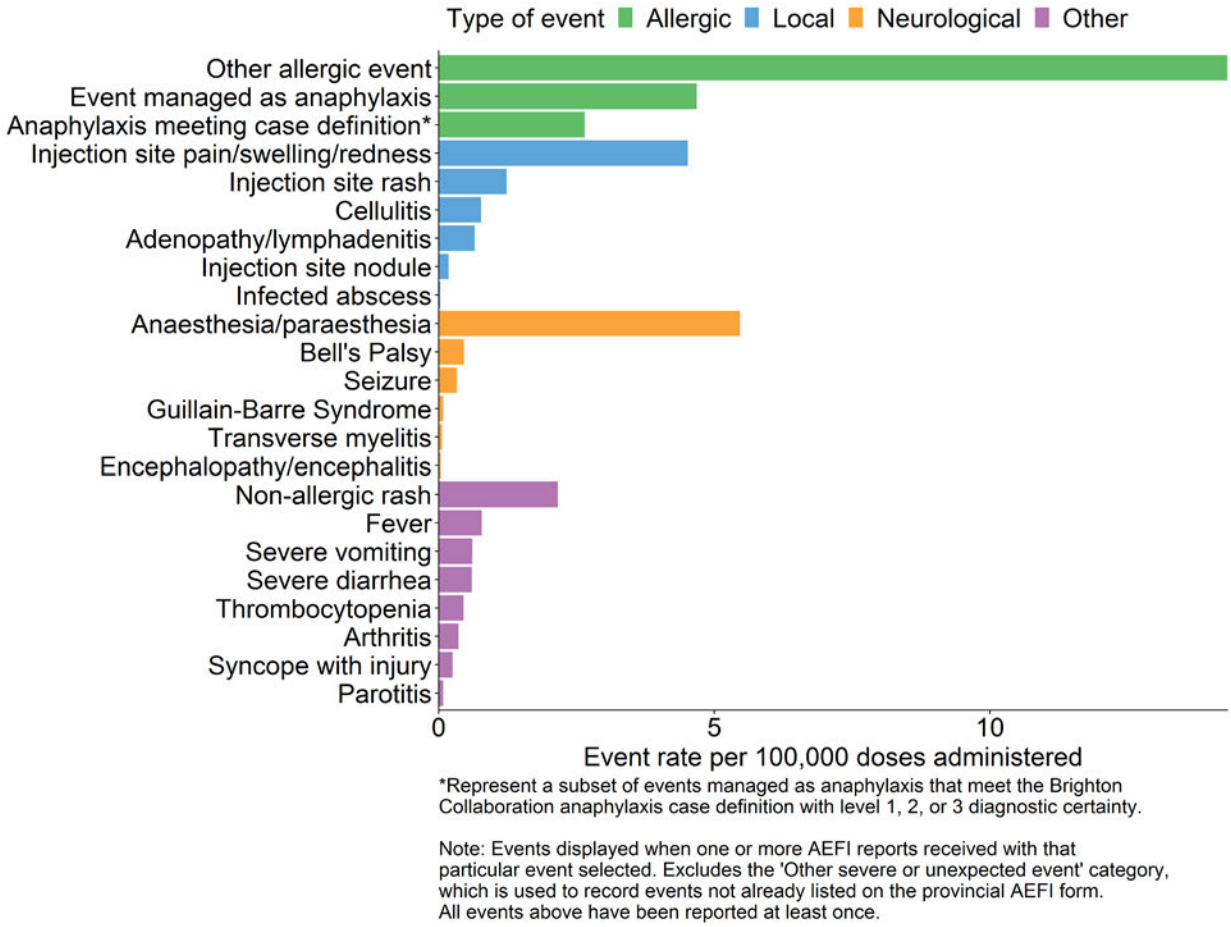
Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 2,877 AEFI reports received up to August 14, 2021 contained a total of 3,656 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 14, 2021 **(N=3,656)**



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Three hundred thirty-six reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 190 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-five reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, a reaction described by "others", rather than cellulitis.[15]

Seventy two reports contained a diagnosed neurological event. Thirty-three individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-one individuals reported seizures, including 13 with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were six reports for individuals with Guillain-Barre Syndrome (GBS), five of which were hospitalized and have since been discharged while the sixth was not admitted. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 28 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were eleven reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. Amongst these events, 99 were for various thrombotic/ thromboembolic conditions. These included 22 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 23 pulmonary emboli, 33 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 65 reports of pericarditis/myocarditis. Thirty-one individuals were diagnosed with pericarditis alone, fourteen with myocarditis alone, and 20 with myopericarditis. Ages ranged from 14 to 95 with a median of 42.3 years, and 39 were male. Twenty-three had received Moderna vaccine, 37 had Pfizer vaccine, and five had AstraZeneca/COVISHIELD. Twenty-seven of these events occurred after a second dose (13 Pfizer and 14 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. All fourteen of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirteen (out of 31) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Fourteen (out of 20) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis.[21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on August 18, 2021. Only AEFIs reported and doses administered up to August 14, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to August 14, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including August 14, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

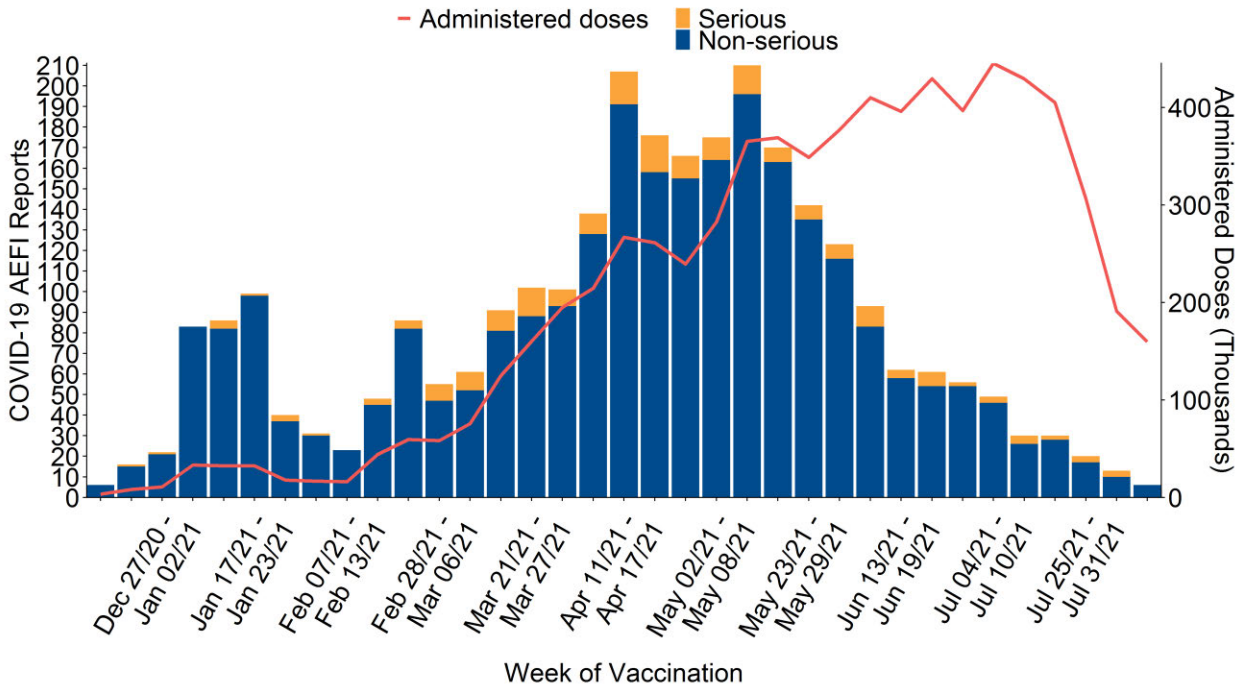
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of August 14, 2021, there have been 7,183,127 COVID-19 vaccine doses administered in BC and 2,877 COVID-19 AEFI reports (40.1 reports per 100,000 doses administered)
- 206 reports (7.2%) met the serious definition, for a rate of 2.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and event managed as anaphylaxis

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Aug. 14, 2021 **(N=2,877)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including August 14, 2021, a total of 7,183,127 doses have been administered. During this period, there have been 2,877 AEFI reports following a COVID-19 vaccine, for a reporting rate of 40.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Aug. 14, 2021 **(N=2,877)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**2877**	**221**	**65**	**869**	**1721**
Non-serious reports	2671	198	59	809	1604
Serious reports	206	23	6	60	117
Proportion serious	7.2%	10.4%	9.2%	6.9%	6.8%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2434	209	64	718	1442
Dose 2 reports	442	12	1	151	278
Total doses administered	**7,183,127**	**318,537**	**67,612**	**1,696,441**	**5,100,537**
Dose 1 administered	3,975,165	218,860	59,761	912,078	2,784,466
Dose 2 administered	3,207,962	99,677	7,851	784,363	2,316,071
Total reporting rate	**40.1**	**69.4**	**96.1**	**51.2**	**33.7**
Serious rate	2.9	7.2	8.9	3.5	2.3
Dose 1 rate	61.2	95.5	107.1	78.7	51.8
Dose 2 rate	13.8	12.0	12.7	19.3	12.0

Note: Rates calculated per 100,000 doses administered
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Serious Reports

Two hundred six reports (7.2%) were considered serious (refer to serious AEFI definition above). Of these, 192 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 86 for circulatory system events (including 21 for stroke, 17 for pulmonary embolism, 14 for myocardial infarction, 31 for myopericarditis, and three for an arrhythmia), 20 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and six Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Seventeen hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, of which, four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

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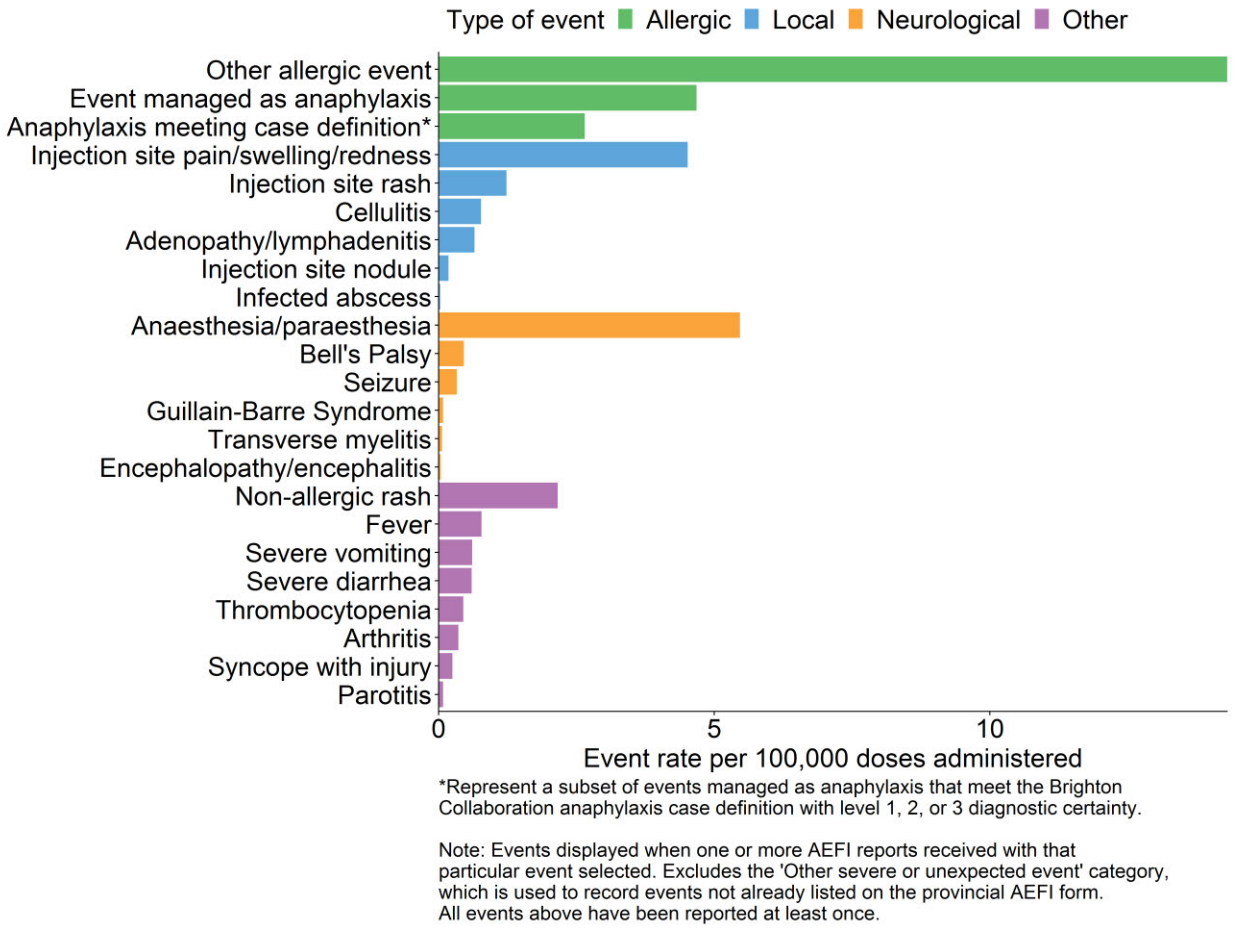

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There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 65 reports of pericarditis/myocarditis. Thirty-one individuals were diagnosed with pericarditis alone, fourteen with myocarditis alone, and 20 with myopericarditis. Ages ranged from 14 to 95 with a median of 42.3 years, and 39 were male. Twenty-three had received Moderna vaccine, 37 had Pfizer vaccine, and five had AstraZeneca/COVISHIELD. Twenty-seven of these events occurred after a second dose (13 Pfizer and 14 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. All fourteen of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirteen (out of 31) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Fourteen (out of 20) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis.[21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on August 18, 2021. Only AEFIs reported and doses administered up to August 14, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Dalati, Hadi [BCCDC]
To: Minhas, Sableen; Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Weekly COVID-19 AEFI Report
Date: Thursday, August 26, 2021 12:32:10 PM
Attachments: COVID19_AEFI_Weekly_Report_2021-08-26.docx
COVID19_AEFI_Weekly_Report_2021-08-26.pdf

Hello all,

Please find attached this week's COVID-19 AEFI report for posting on the website.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

Tel (604)707-2537

Fax (604)707-2515

I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to August 21, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including August 21, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

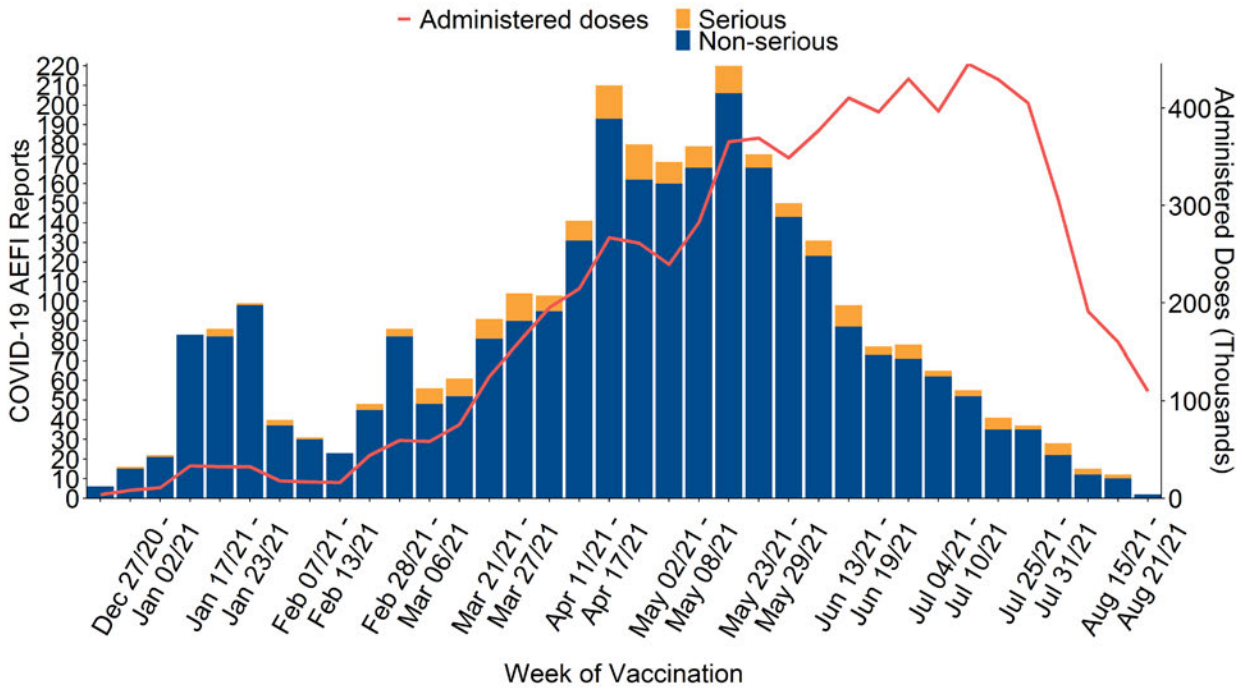
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of August 21, 2021, there have been 7,296,850 COVID-19 vaccine doses administered in BC and 3,020 COVID-19 AEFI reports (41.4 reports per 100,000 doses administered)
- 217 reports (7.2%) met the serious definition, for a rate of 3.0 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Aug. 21, 2021 **(N=3,020)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including August 21, 2021, a total of 7,296,850 doses have been administered. During this period, there have been 3,020 AEFI reports following a COVID-19 vaccine, for a reporting rate of 41.4 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Aug. 21, 2021 **(N=3,020)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3020**	**228**	**66**	**918**	**1808**
Non-serious reports	2803	203	60	855	1685
Serious reports	217	25	6	63	123
Proportion serious	7.2%	11%	9.1%	6.9%	6.8%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2521	211	65	750	1495
Dose 2 reports	498	17	1	168	312
Total doses administered	**7,296,850**	**318,990**	**67,612**	**1,743,806**	**5,166,442**
Dose 1 administered	4,002,016	219,126	59,737	922,762	2,800,391
Dose 2 administered	3,294,834	99,864	7,875	821,044	2,366,051
Total reporting rate	**41.4**	**71.5**	**97.6**	**52.6**	**35.0**
Serious rate	3.0	7.8	8.9	3.6	2.4
Dose 1 rate	63.0	96.3	108.8	81.3	53.4
Dose 2 rate	15.1	17.0	12.7	20.5	13.2

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine. Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

Two hundred seventeen reports (7.2%) were considered serious (refer to serious AEFI definition above). Of these, 202 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 93 for circulatory system events (including 22 for stroke, 17 for pulmonary embolism, 14 for myocardial infarction, 37 for myopericarditis, and three for an arrhythmia), 20 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and six Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Seventeen hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, of which, four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fifteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history. One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

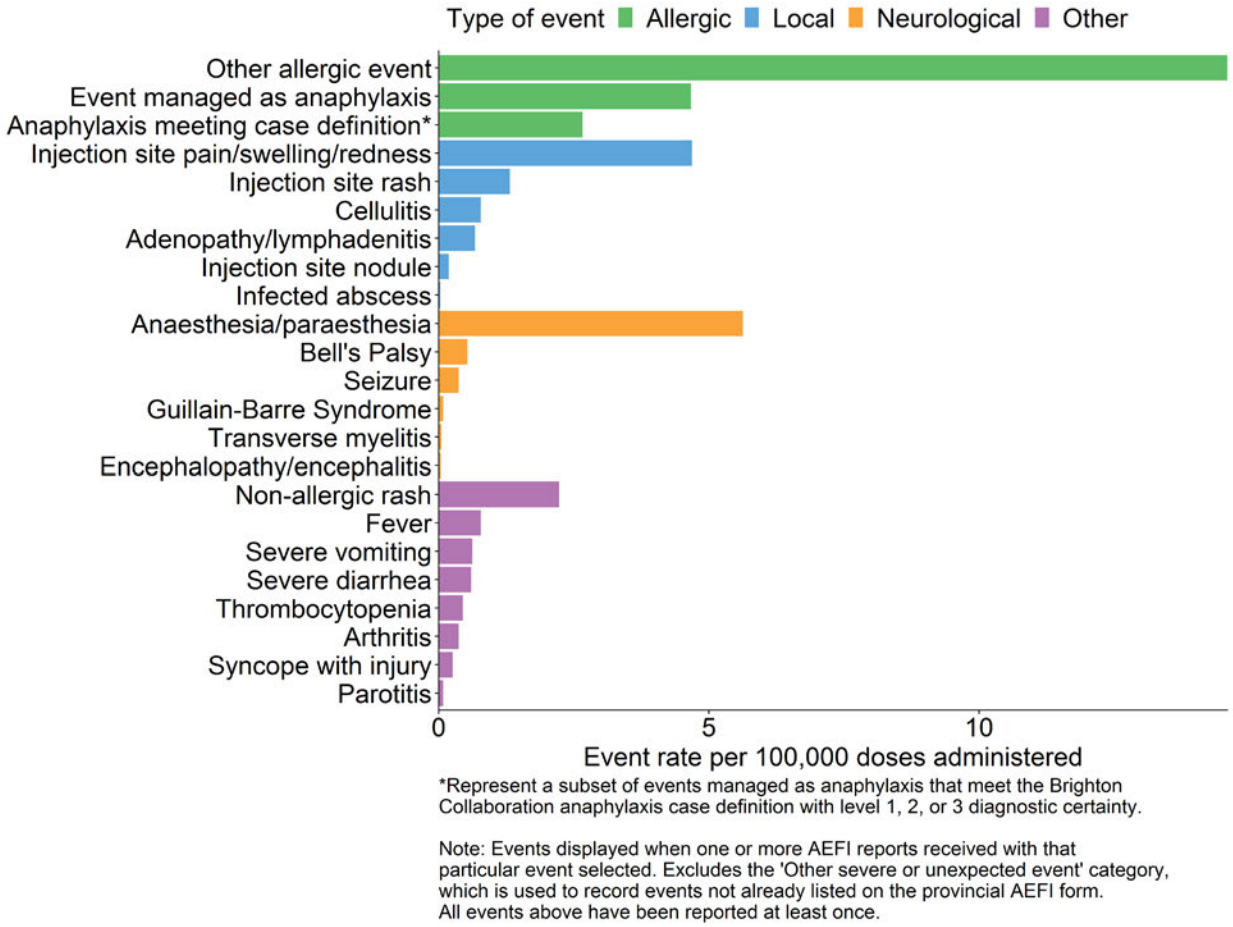
For six individuals, death was the outcome of cardiac arrest. Five of these were elderly

individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,020 AEFI reports received up to August 21, 2021 contained a total of 3,826 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 21, 2021 **(N=3,826)**



Event Descriptions

Three hundred forty-one reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 194 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-seven reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, a reaction described by "others", rather than cellulitis.[15]

Ninety reports contained a diagnosed neurological event. Forty-five individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-seven individuals reported seizures, including 13 with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were six reports for individuals with Guillain-Barre Syndrome (GBS), five of which were hospitalized and have since been discharged while the sixth was not admitted. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 28 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were eleven reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an “other serious” event when they do not have their own discrete event on the provincial AEFI report form. Amongst these events, 102 were for various thrombotic/ thromboembolic conditions. These included 23 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 24 pulmonary emboli, 34 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One “other serious” report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 73 reports of pericarditis/myocarditis. Thirty-four individuals were diagnosed with pericarditis alone, sixteen with myocarditis alone, and 23 with myopericarditis. Ages ranged from 14 to 95 with a median of 41.6 years, and 46 were male. Twenty-five had received Moderna vaccine, 43 had Pfizer vaccine, and five had AstraZeneca/COVISHIELD. Thirty-four of these events occurred after a second dose (18 Pfizer and 16 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. All sixteen of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Sixteen (out of 34) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Sixteen (out of 23) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis.[21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to August 21, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including August 21, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

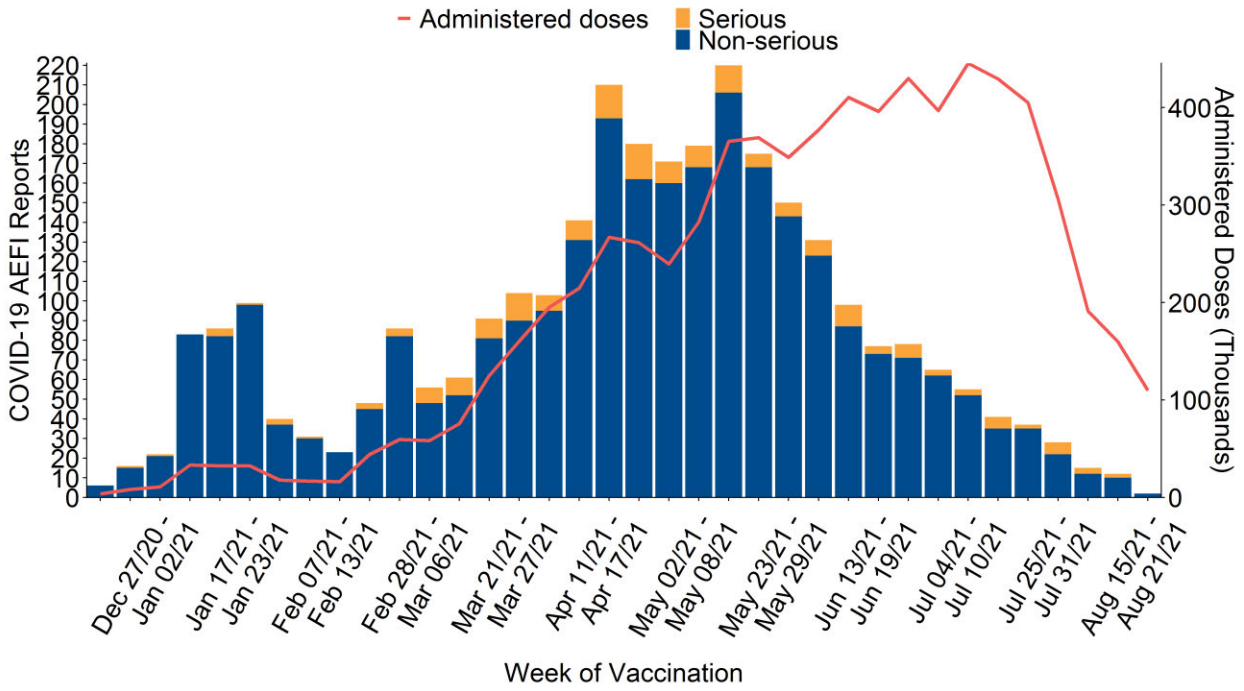
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of August 21, 2021, there have been 7,296,850 COVID-19 vaccine doses administered in BC and 3,020 COVID-19 AEFI reports (41.4 reports per 100,000 doses administered)
- 217 reports (7.2%) met the serious definition, for a rate of 3.0 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Aug. 21, 2021 **(N=3,020)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including August 21, 2021, a total of 7,296,850 doses have been administered. During this period, there have been 3,020 AEFI reports following a COVID-19 vaccine, for a reporting rate of 41.4 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Aug. 21, 2021 **(N=3,020)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3020**	**228**	**66**	**918**	**1808**
Non-serious reports	2803	203	60	855	1685
Serious reports	217	25	6	63	123
Proportion serious	7.2%	11%	9.1%	6.9%	6.8%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2521	211	65	750	1495
Dose 2 reports	498	17	1	168	312
Total doses administered	**7,296,850**	**318,990**	**67,612**	**1,743,806**	**5,166,442**
Dose 1 administered	4,002,016	219,126	59,737	922,762	2,800,391
Dose 2 administered	3,294,834	99,864	7,875	821,044	2,366,051
Total reporting rate	**41.4**	**71.5**	**97.6**	**52.6**	**35.0**
Serious rate	3.0	7.8	8.9	3.6	2.4
Dose 1 rate	63.0	96.3	108.8	81.3	53.4
Dose 2 rate	15.1	17.0	12.7	20.5	13.2

Note: Rates calculated per 100,000 doses administered
* Some reports had an unspecified COVID-19 vaccine. Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

Two hundred seventeen reports (7.2%) were considered serious (refer to serious AEFI definition above). Of these, 202 individuals were admitted to hospital. These included 14 individuals hospitalized after anaphylaxis, 93 for circulatory system events (including 22 for stroke, 17 for pulmonary embolism, 14 for myocardial infarction, 37 for myopericarditis, and three for an arrhythmia), 20 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and six Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). One hospitalization each occurred for a pregnancy related complication, capillary leak syndrome, and rhabdomyolysis. Seventeen hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, of which, four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fifteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history. One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

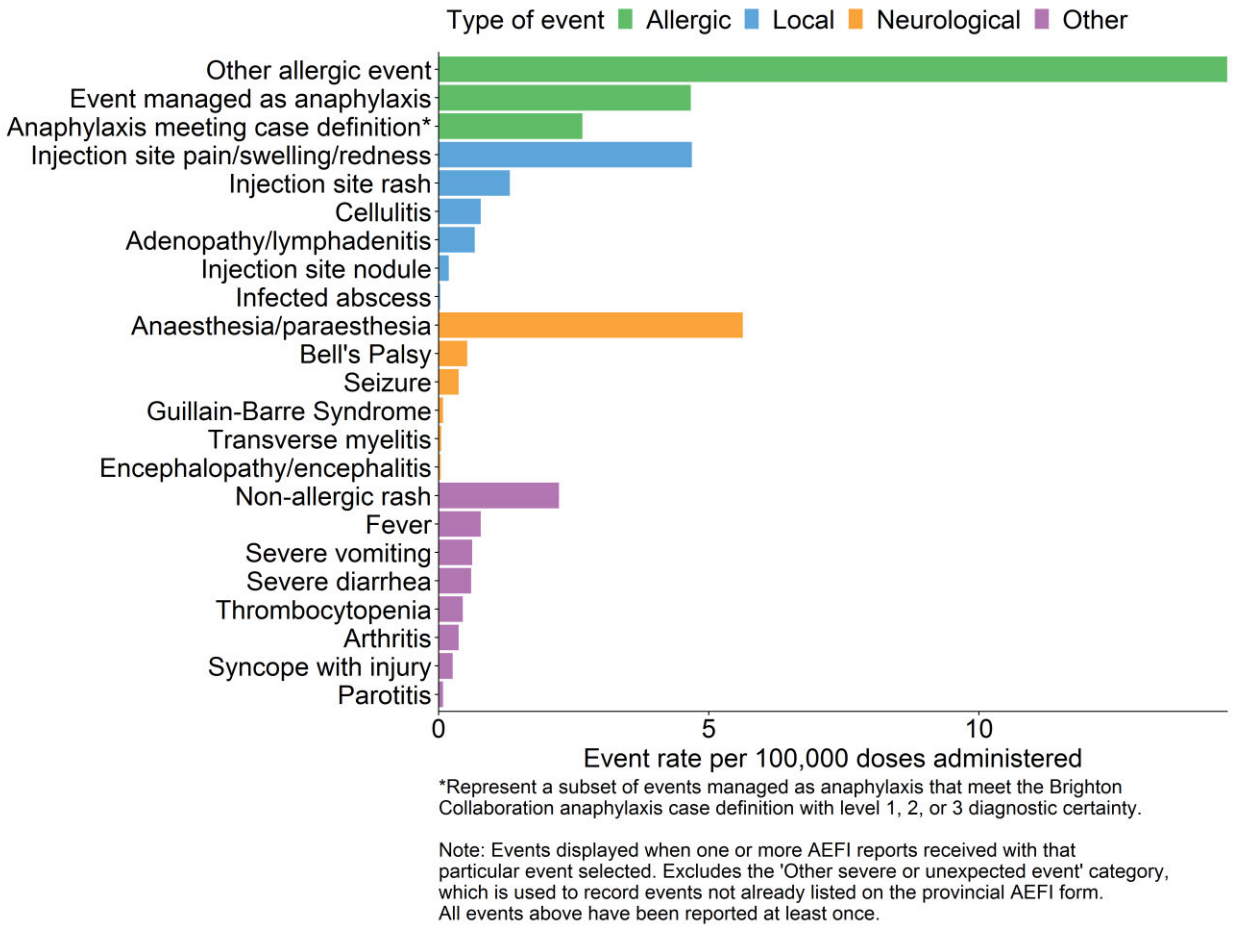
For six individuals, death was the outcome of cardiac arrest. Five of these were elderly

individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,020 AEFI reports received up to August 21, 2021 contained a total of 3,826 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 21, 2021 **(N=3,826)**



Event Descriptions

Three hundred forty-one reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 194 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-seven reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, a reaction described by "others", rather than cellulitis.[15]

Ninety reports contained a diagnosed neurological event. Forty-five individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. One additional individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. Twenty-seven individuals reported seizures, including 13 with a history of a seizure disorder. Two individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were six reports for individuals with Guillain-Barre Syndrome (GBS), five of which were hospitalized and have since been discharged while the sixth was not admitted. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 28 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were eleven reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. Amongst these events, 102 were for various thrombotic/ thromboembolic conditions. These included 23 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 24 pulmonary emboli, 34 deep vein thromboses, and six superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 73 reports of pericarditis/myocarditis. Thirty-four individuals were diagnosed with pericarditis alone, sixteen with myocarditis alone, and 23 with myopericarditis. Ages ranged from 14 to 95 with a median of 41.6 years, and 46 were male. Twenty-five had received Moderna vaccine, 43 had Pfizer vaccine, and five had AstraZeneca/COVISHIELD. Thirty-four of these events occurred after a second dose (18 Pfizer and 16 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. All sixteen of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Sixteen (out of 34) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Sixteen (out of 23) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis.[21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on August 25, 2021. Only AEFIs reported and doses administered up to August 21, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Minhas, Sableen
To: Dalati, Hadi [BCCDC]; Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: Weekly COVID-19 AEFI Report
Date: Thursday, August 26, 2021 1:02:54 PM

Thanks Hadi!
Sableen

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, August 26, 2021 12:32 PM
To: Minhas, Sableen <sableen.minhas@phsa.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Weekly COVID-19 AEFI Report

Hello all,

Please find attached this week's COVID-19 AEFI report for posting on the website.

Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ílwətaʔ/Selilwitulh (TsleilWaututh) Nations.

From: Dalati, Hadi [BCCDC]
To: Minhas, Sableen; Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: Weekly COVID-19 AEFI Report
Date: Thursday, September 02, 2021 1:23:42 PM
Attachments: COVID19_AEFI_Weekly_Report_2021-09-02.docx
COVID19_AEFI_Weekly_Report_2021-09-02.pdf

Hello all,

Please find attached this week's COVID-19 AEFI report for posting on the website.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to August 28, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including August 28, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

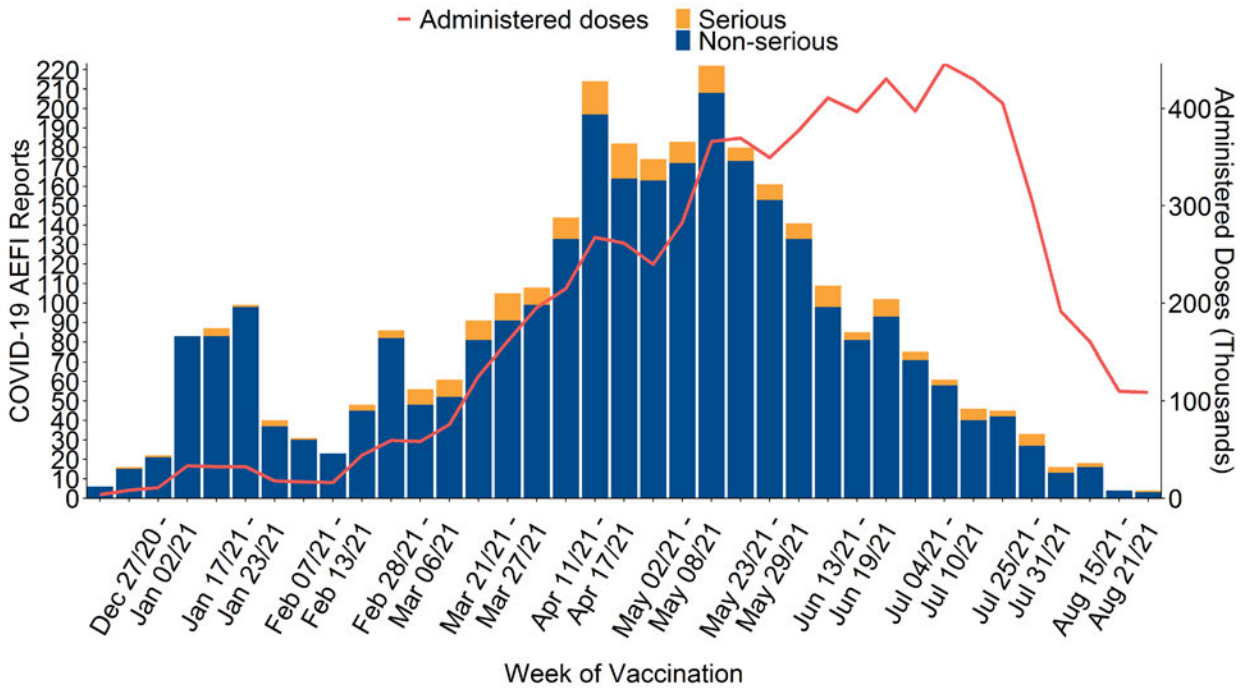
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of August 28, 2021, there have been 7,412,652 COVID-19 vaccine doses administered in BC and 3,161 COVID-19 AEFI reports (42.6 reports per 100,000 doses administered)
- 225 reports (7.1%) met the serious definition, for a rate of 3.0 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Aug. 28, 2021 **(N=3,161)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including August 28, 2021, a total of 7,412,652 doses have been administered. During this period, there have been 3,161 AEFI reports following a COVID-19 vaccine, for a reporting rate of 42.6 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Aug. 28, 2021 **(N=3,161)**

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Total reports	**3161**	**238**	**66**	**973**	**1884**
Non-serious reports	2936	212	60	906	1758
Serious reports	225	26	6	67	126
Proportion serious	7.1%	10.9%	9.1%	6.9%	6.7%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Dose 1 reports	2606	220	65	783	1538
Dose 2 reports	554	18	1	190	345
Total doses administered	**7,412,652**	**321,460**	**66,020**	**1,788,371**	**5,236,801**
Dose 1 administered	4,049,651	221,001	58,348	939,479	2,830,823
Dose 2 administered	3,363,001	100,459	7,672	848,892	2,405,978
Total reporting rate	**42.6**	**74.0**	**100.0**	**54.4**	**36.0**
Serious rate	3.0	8.1	9.1	3.7	2.4
Dose 1 rate	64.4	99.5	111.4	83.3	54.3
Dose 2 rate	16.5	17.9	13.0	22.4	14.3

Note: Rates calculated per 100,000 doses administered

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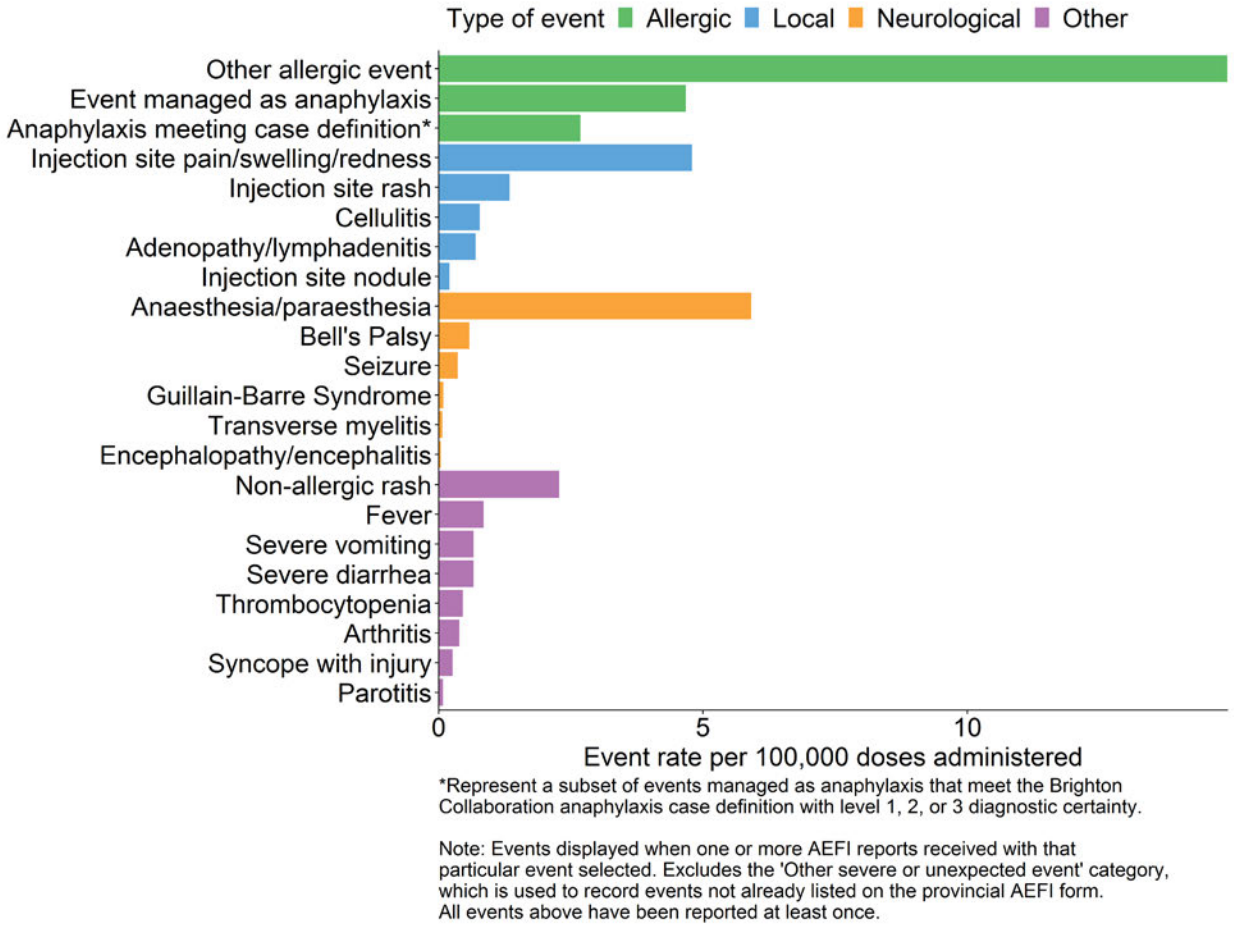
Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,161 AEFI reports received up to August 28, 2021 contained a total of 4,008 adverse events for a ratio of 1.3 events per COVID-

19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 28, 2021 **(N=4,008)**



Event Descriptions

Three hundred forty-seven reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 199 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-eight reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, a reaction described by “others”, rather than cellulitis.[15]

Ninety reports contained a diagnosed neurological event. Forty-three individuals experienced Bell’s Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to

hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. Another individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. One additional individual was initially reported as having transverse myelitis but their exams were inconsistent with that diagnosis. She has been discharged home pending further follow up. Twenty-seven individuals reported seizures, including 13 with a history of a seizure disorder. Three individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were seven reports for individuals with Guillain-Barre Syndrome (GBS), they were hospitalized and have since been discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 34 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were ten reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Two hundred twenty-five reports (7.1%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 210 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis, 106 for circulatory system events (including 22 for stroke, 25 for pulmonary embolism, 14 for myocardial infarction, 42 for myopericarditis, and three for an arrhythmia), 21 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and seven Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). Two hospitalizations occurred for rhabdomyolysis, one of which was also suspected of having myocarditis. One hospitalization each occurred for a pregnancy related complication, and capillary leak syndrome. Eighteen hospitalizations were for thrombocytopenia alone or

associated with a concurrent condition, of which, four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fifteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history. One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

For six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. Amongst these events, 104 were for various thrombotic/ thromboembolic conditions. These included 23 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 25 pulmonary emboli, 34 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of

AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 79 reports of pericarditis/myocarditis. Thirty-seven individuals were diagnosed with pericarditis alone, nineteen with myocarditis alone, and 23 with myopericarditis. Ages ranged from 14 to 95 with a median of 41.7 years, and 50 were male. Twenty-eight had received Moderna vaccine, 46 had Pfizer vaccine, and five had AstraZeneca/COVISHIELD. Thirty-seven of these events occurred after a second dose (19 Pfizer and 18 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. Eighteen of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Nineteen (out of 37) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Sixteen (out of 23) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis.[21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on September 1, 2021. Only AEFIs reported and doses administered up to August 28, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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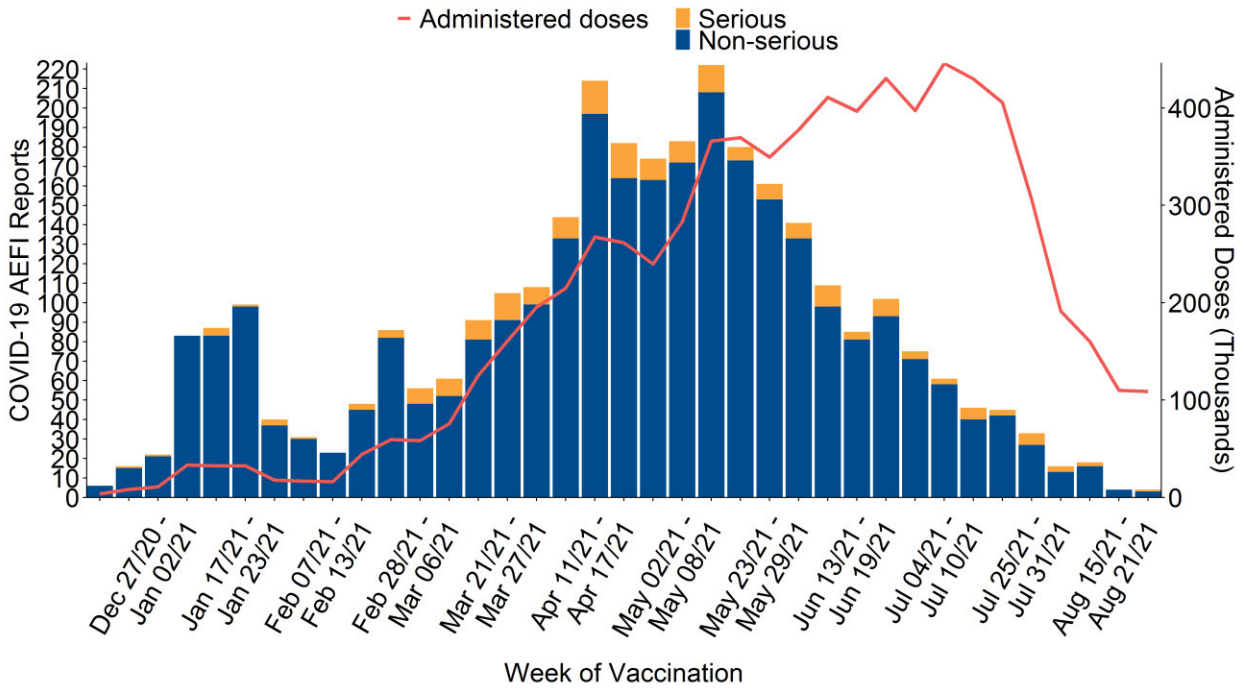

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Dose 1 reports	2606	220	65	783	1538
Dose 2 reports	554	18	1	190	345
Total doses administered	**7,412,652**	**321,460**	**66,020**	**1,788,371**	**5,236,801**
Dose 1 administered	4,049,651	221,001	58,348	939,479	2,830,823
Dose 2 administered	3,363,001	100,459	7,672	848,892	2,405,978
Total reporting rate	**42.6**	**74.0**	**100.0**	**54.4**	**36.0**
Serious rate	3.0	8.1	9.1	3.7	2.4
Dose 1 rate	64.4	99.5	111.4	83.3	54.3
Dose 2 rate	16.5	17.9	13.0	22.4	14.3

Note: Rates calculated per 100,000 doses administered

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3161**	**238**	**66**	**973**	**1884**
Non-serious reports	2936	212	60	906	1758
Serious reports	225	26	6	67	126
Proportion serious	7.1%	10.9%	9.1%	6.9%	6.7%
Dose 1 reports	2606	220	65	783	1538
Dose 2 reports	554	18	1	190	345
Total doses administered	**7,412,652**	**321,460**	**66,020**	**1,788,371**	**5,236,801**
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Dose 2 rate	16.5	17.9	13.0	22.4	14.3

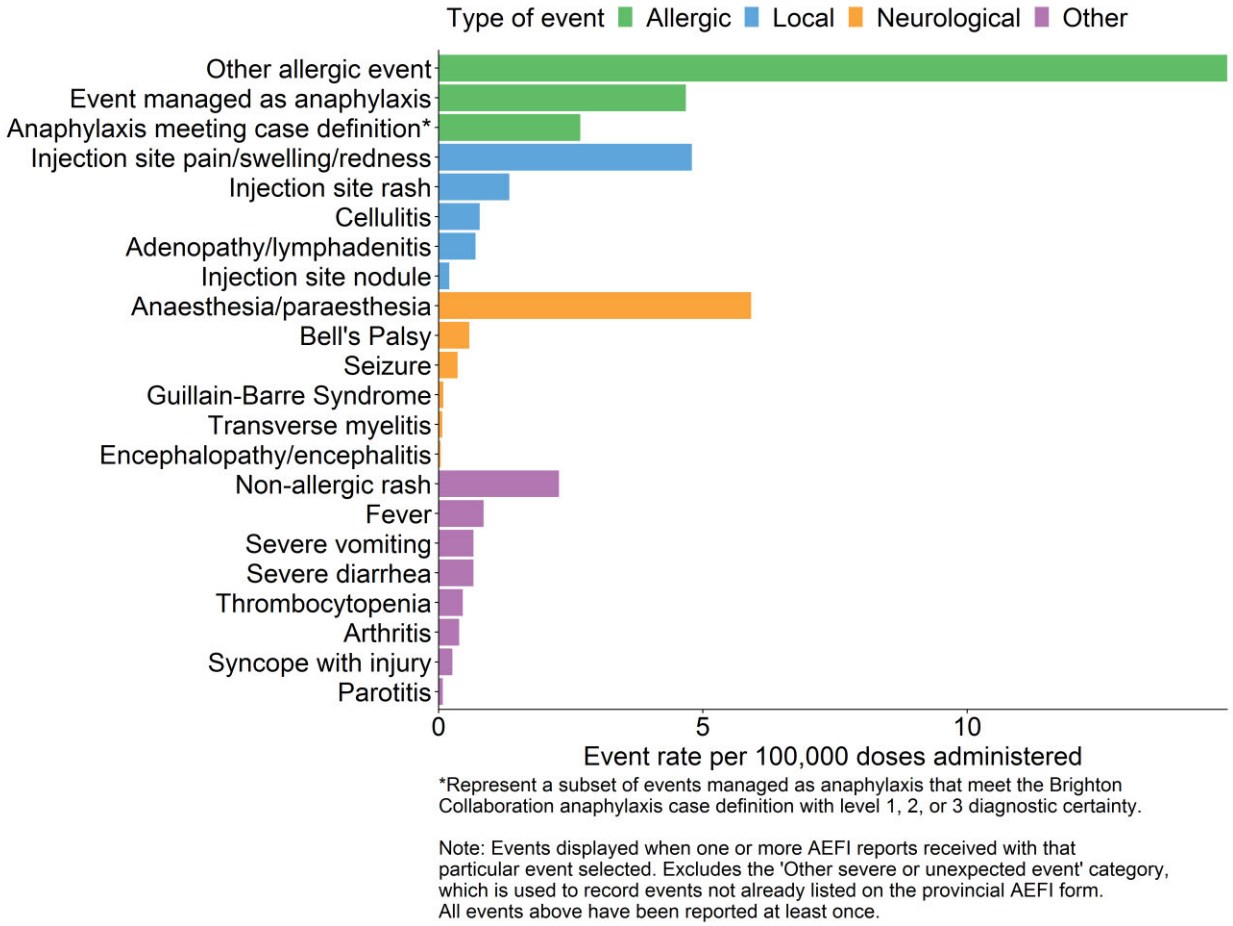
Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,161 AEFI reports received up to August 28, 2021 contained a total of 4,008 adverse events for a ratio of 1.3 events per COVID-

19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 28, 2021 **(N=4,008)**



Event Descriptions

Three hundred forty-seven reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 199 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-eight reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, a reaction described by “others”, rather than cellulitis.[15]

Ninety reports contained a diagnosed neurological event. Forty-three individuals experienced Bell’s Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to

hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. Another individual was investigated for transverse myelitis with a diagnosis made by clinical findings but not confirmed through diagnostic imaging. One additional individual was initially reported as having transverse myelitis but their exams were inconsistent with that diagnosis. She has been discharged home pending further follow up. Twenty-seven individuals reported seizures, including 13 with a history of a seizure disorder. Three individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy possibly related to a recent toxin exposure and was hospitalized. There were seven reports for individuals with Guillain-Barre Syndrome (GBS), they were hospitalized and have since been discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in three cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 34 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet result followed subsequently by normal results; in both the low platelet counts were assessed as due to lab error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were ten reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8]

Two hundred twenty-five reports (7.1%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 210 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis, 106 for circulatory system events (including 22 for stroke, 25 for pulmonary embolism, 14 for myocardial infarction, 42 for myopericarditis, and three for an arrhythmia), 21 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and seven Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). Two hospitalizations occurred for rhabdomyolysis, one of which was also suspected of having myocarditis. One hospitalization each occurred for a pregnancy related complication, and capillary leak syndrome. Eighteen hospitalizations were for thrombocytopenia alone or

associated with a concurrent condition, of which, four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fifteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history. One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

For six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction. Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions. One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. Amongst these events, 104 were for various thrombotic/ thromboembolic conditions. These included 23 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 25 pulmonary emboli, 34 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of

AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 79 reports of pericarditis/myocarditis. Thirty-seven individuals were diagnosed with pericarditis alone, nineteen with myocarditis alone, and 23 with myopericarditis. Ages ranged from 14 to 95 with a median of 41.7 years, and 50 were male. Twenty-eight had received Moderna vaccine, 46 had Pfizer vaccine, and five had AstraZeneca/COVISHIELD. Thirty-seven of these events occurred after a second dose (19 Pfizer and 18 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. Eighteen of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Nineteen (out of 37) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Sixteen (out of 23) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis.[21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on September 1, 2021. Only AEFIs reported and doses administered up to August 28, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly COVID-19 AEFI Report
Date: Thursday, September 09, 2021 5:10:57 PM
Attachments: COVID19_AEFI_Weekly_Report_2021-09-09.docx
COVID19_AEFI_Weekly_Report_2021-09-09.pdf

Hello all,

Please find attached this week's COVID-19 AEFI report for posting on the website.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

Tel (604)707-2537

Fax (604)707-2515

I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to September 4, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including September 4, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

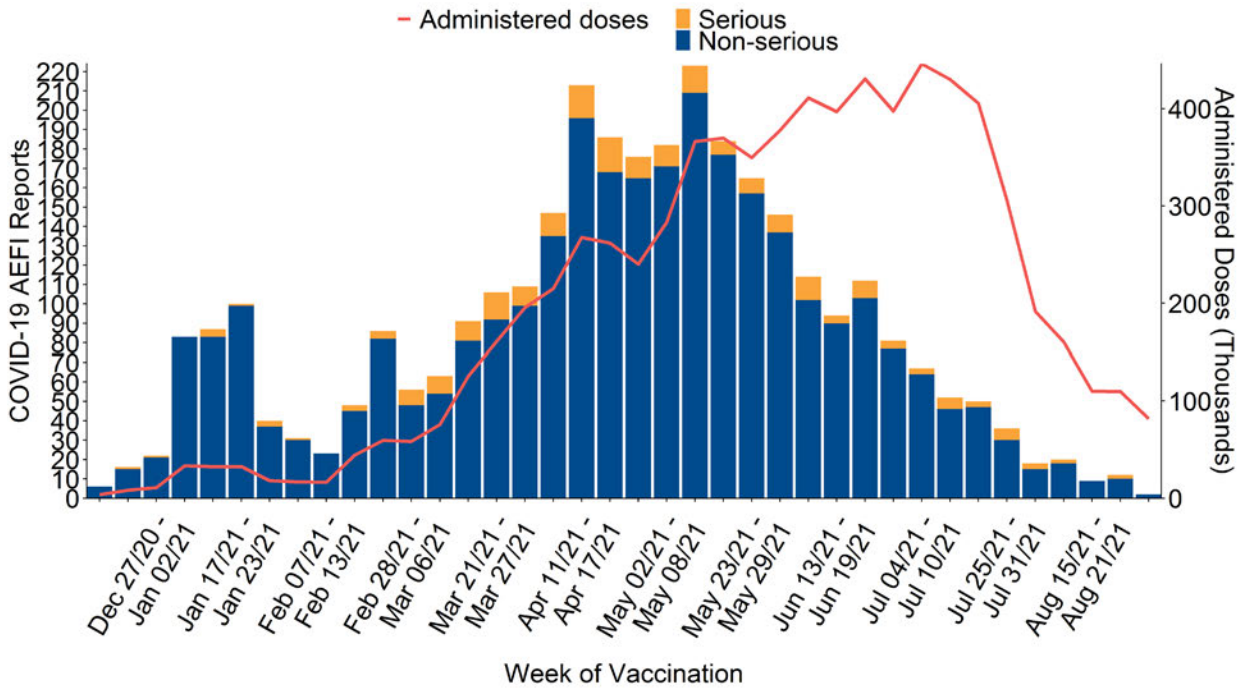
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of September 4, 2021, there have been 7,500,980 COVID-19 vaccine doses administered in BC and 3,256 COVID-19 AEFI reports (43.4 reports per 100,000 doses administered)
- 230 reports (7.1%) met the serious definition, for a rate of 3.1 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Sep. 4, 2021 **(N=3,256)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including September 4, 2021, a total of 7,500,980 doses have been administered. During this period, there have been 3,256 AEFI reports following a COVID-19 vaccine, for a reporting rate of 43.4 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 4, 2021 **(N=3,256)**

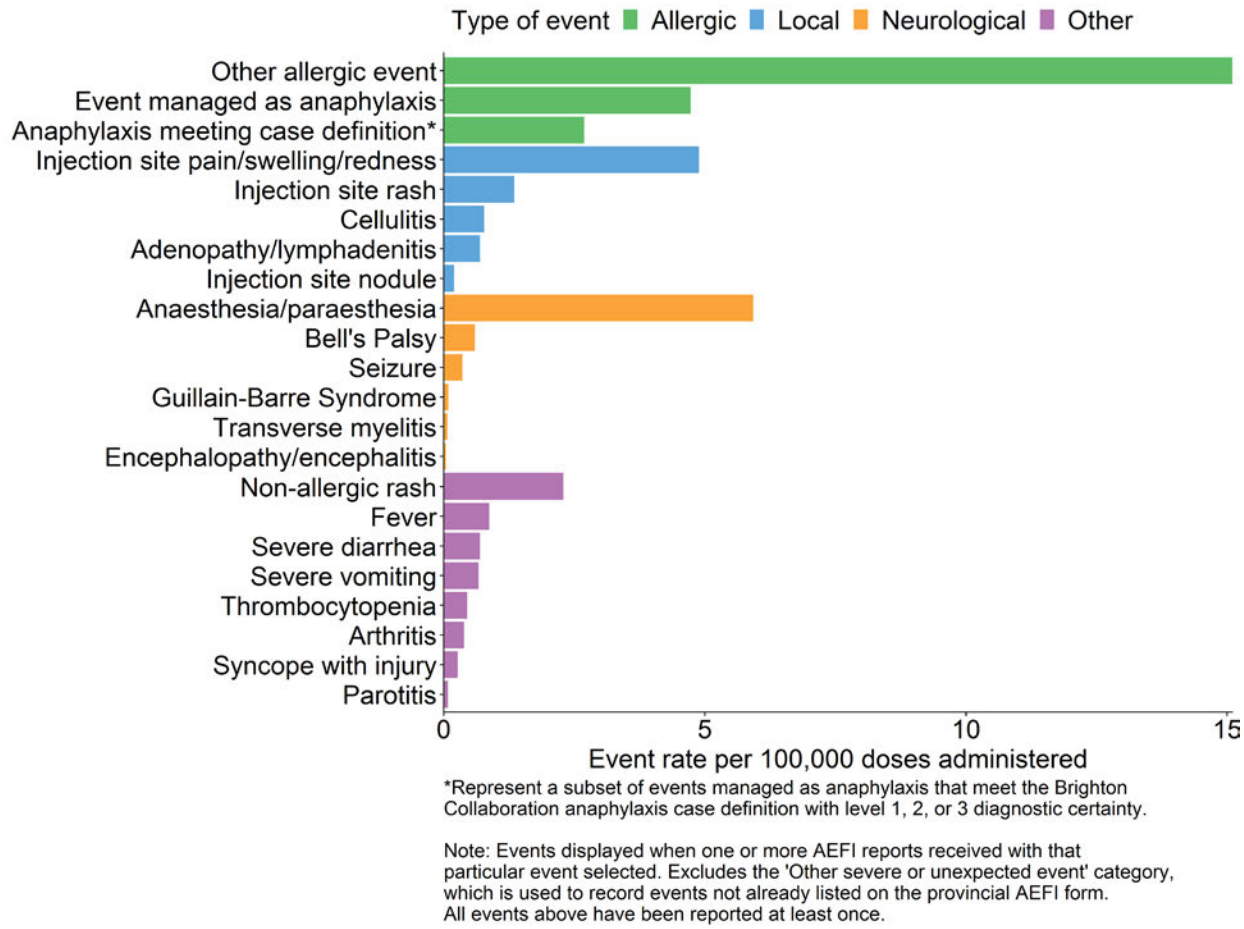
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3256**	**239**	**66**	**1011**	**1940**
Non-serious reports	3026	213	60	942	1811
Serious reports	230	26	6	69	129
Proportion serious	7.1%	10.9%	9.1%	6.8%	6.6%
Dose 1 reports	2671	220	65	812	1574
Dose 2 reports	584	19	1	199	365
Total doses administered	**7,500,980**	**321,951**	**66,169**	**1,820,737**	**5,292,123**
Dose 1 administered	4,086,880	221,293	58,434	951,911	2,855,242
Dose 2 administered	3,414,100	100,658	7,735	868,826	2,436,881
Total reporting rate	**43.4**	**74.2**	**99.7**	**55.5**	**36.7**
Serious rate	3.1	8.1	9.1	3.8	2.4
Dose 1 rate	65.4	99.4	111.2	85.3	55.1
Dose 2 rate	17.1	18.9	12.9	22.9	15.0

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,256 AEFI reports received up to September 4, 2021 contained a total of 4,123 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 4, 2021 **(N=4,123)**



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Three hundred fifty-five reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 202 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

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Ninety three reports contained a diagnosed neurological event. Forty-five individuals experienced Bell’s Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional two individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging and the other’s

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Serious events:

Two hundred thirty reports (7.1%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 215 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis, 101 for circulatory system events (including 22 for stroke, 18 for pulmonary embolism, 14 for myocardial infarction, 44 for myopericarditis, and three for an arrhythmia), 21 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and seven Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). Two hospitalizations occurred for rhabdomyolysis, one of which was also suspected of having myocarditis. One hospitalization each occurred for a pregnancy related complication, and capillary leak syndrome. Eighteen hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, of which four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms

but without a medically diagnosed event.
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fifteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
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'Other serious' events:

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. Amongst these events, 108 were for various thrombotic/ thromboembolic conditions. These included 23 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 14 myocardial infarctions, 27 pulmonary emboli, 36 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual

suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 85 reports of pericarditis/myocarditis. Forty-one individuals were diagnosed with pericarditis alone, nineteen with myocarditis alone, and 25 with myopericarditis. Ages ranged from 14 to 95 with a median of 40.7 years, and 54 were male. Thirty-one had received Moderna vaccine, 48 had Pfizer vaccine, and six had AstraZeneca/COVISHIELD. Forty-one of these events occurred after a second dose (19 Pfizer and 21 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. Eighteen of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Nineteen (out of 41) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Seventeen (out of 25) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis.[21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Data Notes

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to September 4, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including September 4, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

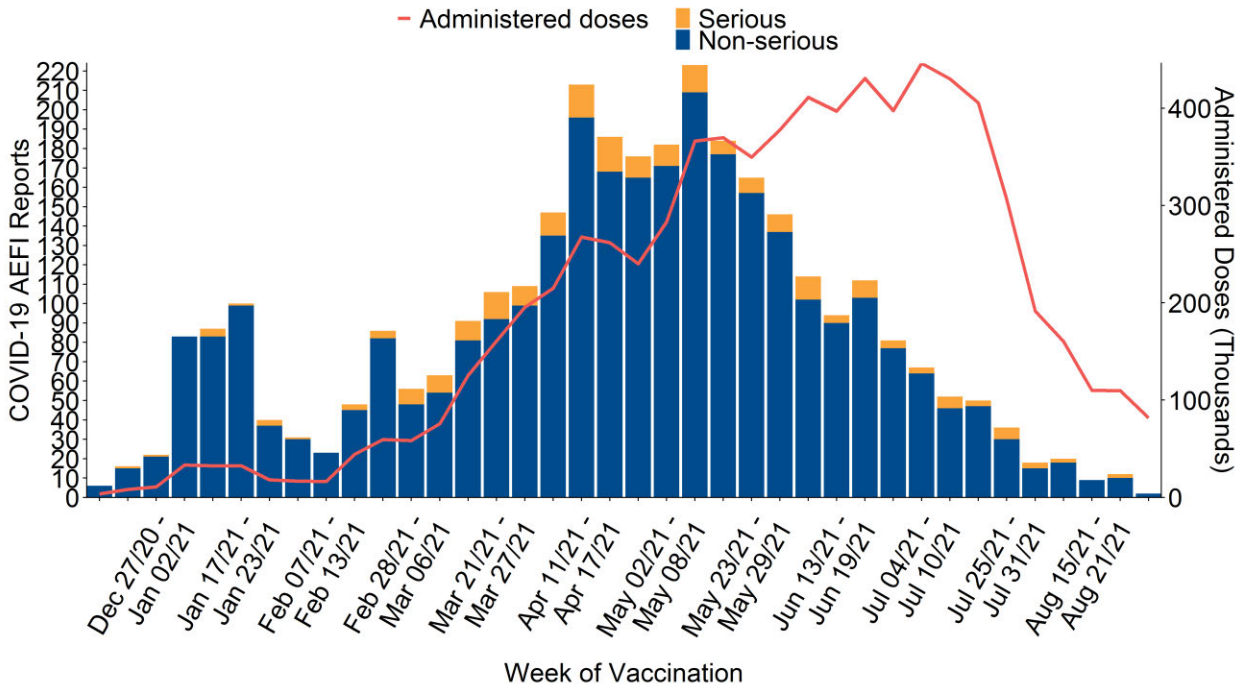
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of September 4, 2021, there have been 7,500,980 COVID-19 vaccine doses administered in BC and 3,256 COVID-19 AEFI reports (43.4 reports per 100,000 doses administered)
- 230 reports (7.1%) met the serious definition, for a rate of 3.1 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Sep. 4, 2021 **(N=3,256)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including September 4, 2021, a total of 7,500,980 doses have been administered. During this period, there have been 3,256 AEFI reports following a COVID-19 vaccine, for a reporting rate of 43.4 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 4, 2021 **(N=3,256)**

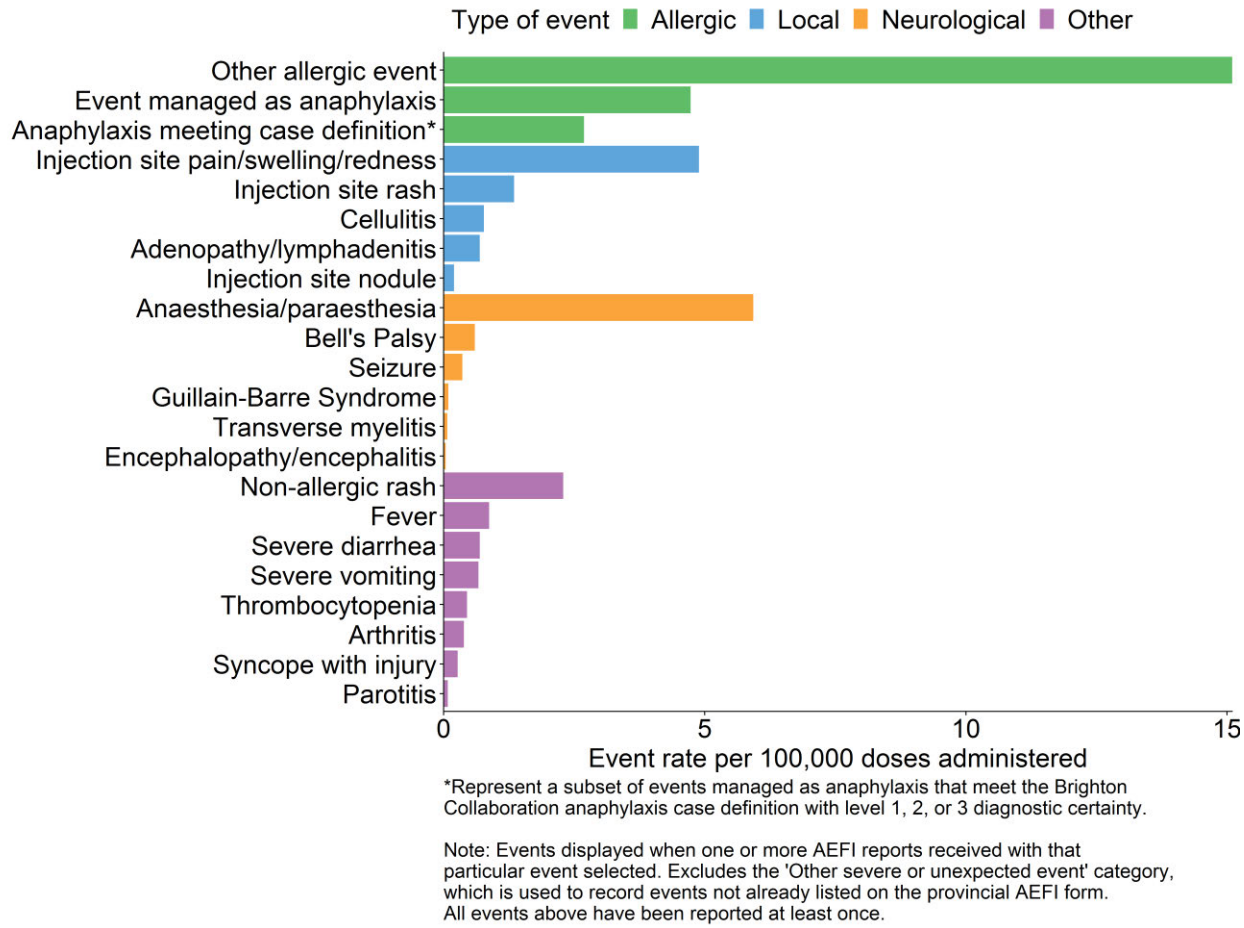
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3256**	**239**	**66**	**1011**	**1940**
Non-serious reports	3026	213	60	942	1811
Serious reports	230	26	6	69	129
Proportion serious	7.1%	10.9%	9.1%	6.8%	6.6%
Dose 1 reports	2671	220	65	812	1574
Dose 2 reports	584	19	1	199	365
Total doses administered	**7,500,980**	**321,951**	**66,169**	**1,820,737**	**5,292,123**
Dose 1 administered	4,086,880	221,293	58,434	951,911	2,855,242
Dose 2 administered	3,414,100	100,658	7,735	868,826	2,436,881
Total reporting rate	**43.4**	**74.2**	**99.7**	**55.5**	**36.7**
Serious rate	3.1	8.1	9.1	3.8	2.4
Dose 1 rate	65.4	99.4	111.2	85.3	55.1
Dose 2 rate	17.1	18.9	12.9	22.9	15.0

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,256 AEFI reports received up to September 4, 2021 contained a total of 4,123 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 4, 2021 **(N=4,123)**



Event Descriptions

Three hundred fifty-five reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 202 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-eight reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, a reaction described by “others”, rather than cellulitis.[15]

Ninety three reports contained a diagnosed neurological event. Forty-five individuals experienced Bell’s Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional two individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging and the other’s

workup was inconsistent with transverse myelitis. Twenty-seven individuals reported seizures, including 13 with a history of a seizure disorder. Three individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy probably related to a workplace toxin exposure and was hospitalized. There were seven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five cases but followed a recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

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From: Amos, Heather [BCCDC]
To: Dalati, Hadi [BCCDC]; Minhas, Sableen
Subject: RE: Weekly COVID-19 AEFI Report
Date: Thursday, September 09, 2021 5:18:55 PM

Thanks! We got it and will post.

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, September 09, 2021 5:09 PM
To: Minhas, Sableen <sableen.minhas@phsa.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Subject: RE: Weekly COVID-19 AEFI Report

Hello Sableen,

Yes apologies, Monika and I have been swamped with meetings today, we were just making our last few edits. Will be sent in a couple minutes!

Thank you,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

> **From:** Minhas, Sableen <sableen.minhas@phsa.ca>
> **Sent:** Thursday, September 09, 2021 4:17 PM
> **To:** Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
> **Subject:** RE: Weekly COVID-19 AEFI Report
>
> Hi Hadi,
>
> I haven't received the AEFI report today so far. Will it becoming in today?
>
> Regards,
>
> Sableen

> **From:** Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
> **Sent:** Thursday, September 02, 2021 1:24 PM
> **To:** Minhas, Sableen <sableen.minhas@phsa.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
> **Cc:** Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
> **Subject:** Weekly COVID-19 AEFI Report
>
> Hello all,
>
> Please find attached this week's COVID-19 AEFI report for posting on the website.
>
> Best,
>
> **Hadi Dalati, MPH**
> **Communicable Disease Epidemiologist**
> **Communicable Diseases and Immunization Service (CDIS)**
> **BC Centre for Disease Control**
> **Provincial Health Services Authority**

Tel (604)707-2537
Fax (604)707-2515
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ílwətaʔ/Selilwitulh (TsleilWaututh) Nations.

From:	Naus, Monika [BCCDC]
To:	Henry, Bonnie [EXT]; Gustafson, Reka [BCCDC]; Amos, Heather [BCCDC]
Subject:	BCCDC COVID vaccine AEFI summary report frequency
Date:	Wednesday, September 15, 2021 8:53:09 PM
Attachments:	COVID19_AEFI_Daily_Report_2021-09-15.html

Hi Bonnie, Reka and Heather,

We would like to drop the frequency of this public facing report down to every 2nd week instead of weekly. Please let me know if you agree to this.
The number of AEFI reports have declined as the number of doses administered has declined and interestingly enough with the higher proportion of dose 2s administered, and this would take a load off and allow us to focus on some subanalyses. We are still down one epidemiologist on our team.
Last week's report is here: http://www.bccdc.ca/Health-Info-Site/Documents/COVID-19_vaccine/AEFI_reports/COVID19_AEFI_Weekly_Report_2021-09-09.pdf
The page where these are located is here: see 'BC's weekly …' (which we will change to adjust the frequency)
http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccine-safety
The daily report that is posted to SharePoint and available to all BCIC members, all members of the Vaccine Safety working group, and the MHOs, will continue to be produced. It is available here, and in case you don't have access Bonnie (we have firewalls between us and the Ministry, while HA accounts are not a problem) it is enclosed, fyi.
Thank you,
Monika

Monika Naus MD FRCPC
Medical Director, Communicable Diseases & Immunization Service
Medical Head, Immunization Programs & Vaccine Preventable Diseases
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell 604.219.4524
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday)
mnds.assist@bccdc.ca Tel 604 707 2519
I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

BC Centre for Disease Control
Provincial Health Services Authority

BC COVID-19 AEFI Summary Report - September 15, 2021

British Columbia received its first shipment of COVID-19 vaccines during the week of December 13, 2020. By September 15, 2021 there have been a total of 7,611,937 doses administered and 3381 reports of an adverse event following immunization (AEFI) associated with COVID-19 vaccines, for a rate of 44.4 reports per 100,000 administered doses (Table 1, Table 2). Of the reports to date, 759 (22.4%) met one or more of the criteria to be considered serious (this serious definition differs from the public COVID-19 AEFI report posted weekly; refer to relevant footnote in Table 1 for serious AEFI definition). Some AEFI reports may include more than one adverse event. To date, there have been 4273 adverse events reported, giving a ratio of 1.3 events per COVID-19 AEFI report.

No serious safety concerns were identified in the clinical trials for the Pfizer or Moderna mRNA COVID-19 vaccines.[1,2] Lymphadenopathy was observed in 1% of vaccine recipients and more frequently than in placebo recipients. Bell's Palsy was identified rarely but more often in vaccine than placebo recipients, but there was no clear basis upon which to conclude a causal association. Delayed local reactions with onset seven days after vaccination were reported in the Moderna trial data.[2] Anaphylaxis has been identified in postmarketing surveillance, occurring at a rate of 1.11 events per 100,000 doses administered of the Pfizer mRNA vaccine[3] and 0.25 events per 100,000 doses administered for the Moderna mRNA vaccine.[4]

Table 1: Summary of reported AEFI following a COVID-19 vaccine, BC, Dec 20, 2020 to Sep 15, 2021 **(N=3381)**

	Last 4 Weeks				To Present Date			Comparison to Historic Flu AEFI				Comparison to H1N1 Flu AEFI			
	2021-34	2021-35	2021-36	2021-37	Cumulative COVID19 Count	Cumulative COVID19 Rate (per 100,000)[a]	Proportion of COVID19 Reports %	Historic Flu Rate (per 100,000)[b,c]	RR vs Historic Flu	Proportion of Historic Flu Reports %[b]	PRR vs Historic Flu	H1N1 Flu Rate (per 100,000)[d,e]	RR vs H1N1 Flu	Proportion of H1N1 Flu Reports[d]	PRR vs H1N1 Flu
AEFI Reports															
Total AEFI[f]	93	66	53	15	**3381**	**44.42**	**100.0**	6.63	**6.7**	100.0	**1.0**	32.48	**1.4**	100.0	**1.0**
Serious AEFI[g]	15	9	12	3	**759**	**9.97**	**22.4**	1.51	**6.6**	22.8	**1.0**	7.35	**1.4**	22.6	**1.0**
Events															
Anaphylaxis	7	2	1	0	**360**	**4.73**	**10.6**	0.49	**9.7**	7.4	**1.4**	2.76	**1.7**	8.5	**1.2**
Anaphylaxis Brighton levels 1/2/3[h]	4	1	1	0	**205**	**2.69**	**6.1**	0.20	**13.4**	3.0	**2.0**	NA	–	NA	–
Other allergic	22	18	12	3	**1163**	**15.28**	**34.4**	2.17	**7.0**	32.7	**1.1**	5.70	**2.7**	17.5	**2.0**
Bell's Palsy	1	1	3	0	**50**	**0.66**	**1.5**	0.02	**33.0**	0.3	**5.0**	0.06	**11.0**	0.2	**7.5**
GBS	0	0	0	0	**7**	**0.09**	**0.2**	0.03	**3.0**	0.5	**0.4**	0.12	**0.8**	0.4	**0.5**
Encephalitis	0	0	0	0	**3**	**0.04**	**0.1**	0.02	**2.0**	0.3	**0.3**	0.00	–	0.0	–
Transverse myelitis	1	0	0	0	**5**	**0.07**	**0.1**	0.00	–	0.0	–	0.00	–	0.0	–

Transverse myelitis	1	0	0	0	5	0.07	0.1	0.00	–	0.0	–	0.00	–	0.0	–
Seizure	1	0	0	0	28	0.37	0.8	0.29	1.3	4.3	0.2	1.53	0.2	4.7	0.2
Anaesthesia/ paraesthesia[l]	15	7	8	2	461	6.06	13.6	NA	–	NA	–	NA	–	NA	–
Thrombocytopenia	1	0	1	0	35	0.46	1.0	0.02	23.0	0.3	3.3	0.00	–	0.0	–
Cellulitis	0	0	0	0	58	0.76	1.7	0.25	3.0	3.8	0.4	0.37	2.1	1.1	1.5
Adenopathy/ lymphadenitis	2	2	2	1	56	0.74	1.7	0.08	9.2	1.3	1.3	0.43	1.7	1.3	1.3
Recommendations															
No further immunizations	0	0	1	0	110	1.45	3.3	0.25	5.8	3.8	0.9	0.67	2.2	2.1	1.6
Outcomes															
Hospitalization	5	6	7	2	228	3.00	6.7	0.20	15.0	3.0	2.2	3.00	1.0	9.2	0.7
Permanent disability	0	0	0	0	12	0.16	0.4	0.00	–	0.0	–	0.00	–	0.0	–
Death	0	0	0	1	16	0.21	0.5	0.02	10.5	0.3	1.7	0.18	1.2	0.6	0.8
Health Authority															
IHA	19	18	20	7	739	64.47	21.9	10.43	6.2	24.6	0.9	66.52	1.0	34.3	0.6

Health Authority															
IHA	19	18	20	7	**739**	**64.47**	**21.9**	10.43	**6.2**	24.6	**0.9**	66.52	**1.0**	34.3	**0.6**
FHA	36	18	2	0	**1163**	**41.19**	**34.4**	4.34	**9.5**	21.6	**1.6**	20.32	**2.0**	19.2	**1.8**
VCHA	15	7	6	0	**530**	**26.75**	**15.7**	2.28	**11.7**	10.2	**1.5**	10.19	**2.6**	9.6	**1.6**
VIHA	20	21	25	8	**686**	**52.79**	**20.3**	9.65	**5.5**	25.6	**0.8**	38.38	**1.4**	20.6	**1.0**
NHA	3	2	0	0	**262**	**72.47**	**7.7**	27.94	**2.6**	18.0	**0.4**	119.60	**0.6**	16.2	**0.5**
Age Group															
–	0	0	0	0	**1**	**50000.00**	**0.0**	NA	**–**	NA	**–**	NA	**–**	NA	**–**
<18	8	2	2	1	**99**	**11.33**	**2.9**	5.11	**2.2**	44.9	**0.1**	21.73	**0.5**	34.9	**0.1**
18-64	67	54	41	9	**2629**	**79.98**	**77.8**	1.43	**55.9**	46.4	**1.7**	10.69	**7.5**	58.7	**1.3**
Gender															
65+	18	10	10	5	**653**	**66.16**	**19.3**	0.95	**69.6**	8.6	**2.2**	5.24	**12.6**	6.4	**3.0**
Female	63	50	37	9	**2583**	**99.27**	**76.4**	2.37	**41.9**	60.4	**1.3**	16.67	**6.0**	69.8	**1.1**
Male	30	16	16	6	**798**	**31.35**	**23.6**	1.58	**19.8**	39.6	**0.6**	7.30	**4.3**	30.2	**0.8**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

–	0	0	0	0	**1**	**50000.00**	**0.0**	NA	–	NA	–	NA	–	NA	–
<18	8	2	2	1	**99**	**11.33**	**2.9**	5.11	**2.2**	44.9	**0.1**	21.73	**0.5**	34.9	**0.1**
18-64	67	54	41	9	**2629**	**79.98**	**77.8**	1.43	**55.9**	46.4	**1.7**	10.69	**7.5**	58.7	**1.3**
Gender															
65+	18	10	10	5	**653**	**66.16**	**19.3**	0.95	**69.6**	8.6	**2.2**	5.24	**12.6**	6.4	**3.0**
Female	63	50	37	9	**2583**	**99.27**	**76.4**	2.37	**41.9**	60.4	**1.3**	16.67	**6.0**	69.8	**1.1**
Male	30	16	16	6	**798**	**31.35**	**23.6**	1.58	**19.8**	39.6	**0.6**	7.30	**4.3**	30.2	**0.8**

Abbreviations:

RR =Rate Ratio; PRR = Proportional Reporting Ratio; GBS = Guillain Barre Syndrome

Notes:

[a] Rates for COVID-19 AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered; rates by age group and gender are per 100,000 population using the BC 2020 population estimate.

[b] Includes AEFI reports following influenza vaccines (excluding live attenuated) from the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons.

[c] Rates for Historic Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses distributed during the 2016/17, 2017/18, 2018/19, and 2019/20 influenza seasons; rates by age group and gender are per 100,000 population using the BC population estimates for 2016-2019.

[d] Includes AEFI reports following H1N1 influenza vaccines from the 2009 H1N1 pandemic.

[e] Rates for H1N1 Flu AEFI reports, events, recommendations/outcomes, and health authority are per 100,000 doses administered during the 2009 H1N1 pandemic; rates by age group and gender are per 100,000 population using the BC population estimates for 2009.

[f] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.

[g] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.

[h] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition. Unable to assign anaphylaxis levels to H1N1 Flu reports due to differences in the historical data.

[i] Anaesthesia/paraesthesia became a reportable event in 2019 and is therefore not available for comparison to Historic Flu or H1N1 Flu AEFI reports.

Table 2: Summary of reported AEFI following COVID-19 vaccine by agent, product, and lot number, BC, Dec 20, 2020 to Sep 15, 2021 **(N=3381)**

Vaccine information			Reports				Events														
Agent	Product	Lot Number	Total AEFI count[a]	Total AEFI rate[b]	Serious AEFI count[c]	Serious AEFI rate[b,c]	Anaphylaxis count	Anaphylaxis rate[b]	Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Se r
		016E21A	8	15.58	3	5.84	1	1.95	1	1.95	2	3.89	0	0.00	0	0.00	0	0.00	0	0.00	0	(
		042D21A	3	51.24	0	0.00	0	0.00	0	0.00	2	34.16	0	0.00	0	0.00	0	0.00	0	0.00	0	(
		043D21A	89	28.25	13	4.13	7	2.22	3	0.95	35	11.11	1	0.32	0	0.00	0	0.00	0	0.00	0	(
		044D21A	14	33.58	7	16.79	1	2.40	1	2.40	2	4.80	1	2.40	0	0.00	0	0.00	0	0.00	0	(
		045D21A	55	17.99	7	2.29	3	0.98	2	0.65	13	4.25	0	0.00	0	0.00	0	0.00	0	0.00	0	(
		052C21A	45	18.19	12	4.85	7	2.83	3	1.21	11	4.45	1	0.40	0	0.00	0	0.00	0	0.00	0	(
		093D21A	19	30.33	4	6.38	1	1.60	0	0.00	9	14.36	2	3.19	0	0.00	0	0.00	0	0.00	1	:
		300042460	117	567.05	25	121.17	8	38.77	3	14.54	41	198.71	1	4.85	0	0.00	0	0.00	0	0.00	0	(
		300042698	87	416.21	20	95.68	4	19.14	3	14.35	25	119.60	2	9.57	0	0.00	0	0.00	1	4.78	1	4
		300042722	35	149.43	8	34.16	2	8.54	2	8.54	16	68.31	1	4.27	0	0.00	0	0.00	0	0.00	0	(
		3000489	26	144.12	5	27.72	2	11.09	1	5.54	10	55.43	1	5.54	0	0.00	0	0.00	0	0.00	0	(
		3001176	66	110.05	15	25.01	5	8.34	3	5.00	17	28.35	0	0.00	0	0.00	0	0.00	0	0.00	0	(

Events																		Outcomes			
Anaphylaxis Brighton levels 1/2/3 count[d]	Anaphylaxis Brighton levels 1/2/3 rate[b,d]	Other allergic count	Other allergic rate[b]	Bell's Palsy count	Bell's Palsy rate[b]	GBS count	GBS rate[b]	Encephalitis count	Encephalitis rate[b]	Transverse myelitis count	Transverse myelitis rate[b]	Seizure count	Seizure rate[b]	Anaesthesia/ paraesthesia count	Anaesthesia/ paraesthesia rate[b]	Cellulitis count	Cellulitis rate[b]	Hospitalization count	Hospitalization rate[b]	Death count	Death rate[b]
1	1.95	2	3.89	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	3.89	0	0.00
0	0.00	2	34.16	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
3	0.95	35	11.11	1	0.32	0	0.00	0	0.00	0	0.00	0	0.00	2	0.63	0	0.00	5	1.59	0	0.00
1	2.40	2	4.80	1	2.40	0	0.00	0	0.00	0	0.00	0	0.00	2	4.80	1	2.40	4	9.59	0	0.00
2	0.65	13	4.25	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	11	3.60	1	0.33	3	0.98	0	0.00
3	1.21	11	4.45	1	0.40	0	0.00	0	0.00	0	0.00	0	0.00	4	1.62	0	0.00	3	1.21	0	0.00
0	0.00	9	14.36	2	3.19	0	0.00	0	0.00	0	0.00	1	1.60	2	3.19	0	0.00	1	1.60	0	0.00
3	14.54	41	198.71	1	4.85	0	0.00	0	0.00	0	0.00	0	0.00	1	4.85	13	63.01	1	4.85	1	4.85
3	14.35	25	119.60	2	9.57	0	0.00	0	0.00	1	4.78	1	4.78	10	47.84	9	43.06	1	4.78	2	9.57
2	8.54	16	68.31	1	4.27	0	0.00	0	0.00	0	0.00	0	0.00	3	12.81	2	8.54	3	12.81	0	0.00
1	5.54	10	55.43	1	5.54	0	0.00	0	0.00	0	0.00	0	0.00	1	5.54	0	0.00	2	11.09	0	0.00
3	5.00	17	28.35	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	7	11.67	2	3.33	6	10.00	0	0.00

Moderna mRNA-1273	3000489	26	144.12	5	27.72	2	11.09	1	5.54	10	55.43	1	5.54	0	0.00	0	0.00	0	0.00	0
	3001176	66	110.05	15	25.01	5	8.34	3	5.00	17	28.35	0	0.00	0	0.00	0	0.00	0	0.00	0
	3001530	44	124.27	6	16.95	3	8.47	1	2.82	17	48.01	0	0.00	0	0.00	0	0.00	0	0.00	0
	3001652	56	77.86	18	25.03	10	13.90	6	8.34	20	27.81	1	1.39	0	0.00	0	0.00	0	0.00	0
	3001654	15	153.58	2	20.48	0	0.00	0	0.00	4	40.95	0	0.00	0	0.00	0	0.00	0	0.00	1
	3001657	82	94.58	19	21.92	5	5.77	2	2.31	30	34.60	3	3.46	1	1.15	0	0.00	0	0.00	1
	3001658	8	31.45	2	7.86	1	3.93	1	3.93	4	15.73	0	0.00	0	0.00	0	0.00	0	0.00	0
	3001945	1	86.13	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
	3002179	63	74.15	14	16.48	3	3.53	2	2.35	19	22.36	1	1.18	0	0.00	0	0.00	0	0.00	0
	3002182	1	19.54	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
	3002187	26	118.78	4	18.27	2	9.14	2	9.14	10	45.68	0	0.00	0	0.00	0	0.00	0	0.00	0
	3002331	85	71.14	20	16.74	7	5.86	4	3.35	35	29.29	2	1.67	0	0.00	0	0.00	0	0.00	0
	3002538	76	52.02	12	8.21	3	2.05	1	0.68	27	18.48	1	0.68	0	0.00	0	0.00	0	0.00	1
	3002914	33	59.27	5	8.98	1	1.80	1	1.80	11	19.76	0	0.00	0	0.00	0	0.00	0	0.00	0
	3003184	4	30.45	1	7.61	0	0.00	0	0.00	1	7.61	0	0.00	0	0.00	0	0.00	0	0.00	0
	Unknown	4	NA	2	NA	1	NA	0	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0

1	5.54	10	55.43	1	5.54	0	0.00	0	0.00	0	0.00	0	0.00	1	5.54	0	0.00	2	11.09	0	0.00
3	5.00	17	28.35	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	7	11.67	2	3.33	6	10.00	0	0.00
1	2.82	17	48.01	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	6	16.95	0	0.00	1	2.82	0	0.00
6	8.34	20	27.81	1	1.39	0	0.00	0	0.00	0	0.00	0	0.00	6	8.34	4	5.56	5	6.95	0	0.00
0	0.00	4	40.95	0	0.00	0	0.00	0	0.00	0	0.00	1	10.24	2	20.48	1	10.24	0	0.00	0	0.00
2	2.31	30	34.60	3	3.46	1	1.15	0	0.00	0	0.00	1	1.15	6	6.92	0	0.00	8	9.23	1	1.15
1	3.93	4	15.73	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.93	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	86.13	0	0.00	0	0.00	0	0.00
2	2.35	19	22.36	1	1.18	0	0.00	0	0.00	0	0.00	0	0.00	13	15.30	3	3.53	6	7.06	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2	9.14	10	45.68	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	22.84	2	9.14	0	0.00	0	0.00
4	3.35	35	29.29	2	1.67	0	0.00	0	0.00	0	0.00	0	0.00	14	11.72	4	3.35	5	4.18	1	0.84
1	0.68	27	18.48	1	0.68	0	0.00	0	0.00	0	0.00	1	0.68	13	8.90	2	1.37	4	2.74	0	0.00
1	1.80	11	19.76	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	8.98	0	0.00	4	7.18	0	0.00
0	0.00	1	7.61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	7.61	1	7.61	0	0.00	0	0.00
0	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	1	NA	0	NA	1	NA	0	NA

	3003184	4	30.45	1	7.61	0	0.00	0	0.00	1	7.61	0	0.00	0	0.00	0	0.00	0	0.00	0
	Unknown	4	NA	2	NA	1	NA	0	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0
	016E21A-CC01	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
	016E21A-CC02	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
	Moderna mRNA-1273 total	**1062**	**57.12**	**224**	**12.05**	**77**	**4.14**	**42**	**2.26**	**362**	**19.47**	**18**	**0.97**	**1**	**0.05**	**0**	**0.00**	**1**	**0.05**	**5**
	Unknown	11	NA	3	NA	1	NA	0	NA	4	NA	0	NA	0	NA	0	NA	0	NA	0
	EK4175	9	191.20	4	84.98	2	42.49	2	42.49	2	42.49	0	0.00	0	0.00	0	0.00	0	0.00	0
	EK4241	34	148.52	5	21.84	3	13.11	2	8.74	14	61.16	1	4.37	0	0.00	0	0.00	0	0.00	0
	EK4245	34	133.40	4	15.69	2	7.85	2	7.85	15	58.85	0	0.00	0	0.00	0	0.00	0	0.00	0
	EL0140	25	141.45	6	33.95	5	28.29	2	11.32	9	50.92	0	0.00	0	0.00	0	0.00	0	0.00	0
COVID-19 mRNA	EL0203	58	195.21	11	37.02	6	20.19	4	13.46	32	107.70	2	6.73	0	0.00	0	0.00	1	3.37	0
	EL1404	3	42.58	1	14.19	1	14.19	1	14.19	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
	EL1406	40	151.07	8	30.21	6	22.66	2	7.55	21	79.31	0	0.00	0	0.00	0	0.00	1	3.78	0
	EN1195	31	47.74	3	4.62	3	4.62	2	3.08	10	15.40	0	0.00	0	0.00	0	0.00	0	0.00	0

0	0.00	1	7.61	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	7.61	1	7.61	0	0.00	0	0.00
0	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	1	NA	0	NA	1	NA	0	NA
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
42	**2.26**	**362**	**19.47**	**18**	**0.97**	**1**	**0.05**	**0**	**0.00**	**1**	**0.05**	**5**	**0.27**	**116**	**6.24**	**45**	**2.42**	**66**	**3.55**	**5**	**0.27**
0	NA	4	NA	0	NA	0	NA	0	NA	0	NA	0	NA	2	NA	0	NA	0	NA	1	NA
2	42.49	2	42.49	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	21.24	2	42.49	0	0.00	0	0.00
2	8.74	14	61.16	1	4.37	0	0.00	0	0.00	0	0.00	0	0.00	1	4.37	0	0.00	1	4.37	0	0.00
2	7.85	15	58.85	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	19.62	0	0.00	0	0.00	0	0.00
2	11.32	9	50.92	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	4	22.63	0	0.00	0	0.00	0	0.00
4	13.46	32	107.70	2	6.73	0	0.00	0	0.00	1	3.37	0	0.00	6	20.19	0	0.00	3	10.10	0	0.00
1	14.19	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	14.19	0	0.00	0	0.00	0	0.00
2	7.55	21	79.31	0	0.00	0	0.00	0	0.00	1	3.78	0	0.00	7	26.44	1	3.78	1	3.78	0	0.00
2	3.08	10	15.40	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	3.08	0	0.00	0	0.00	0	0.00

	EN1198	45	64.87	14	20.18	8	11.53	4	5.77	17	24.51	0	0.00	0	0.00	0	0.00	0	0.00	0
	EP6017	71	126.48	25	44.53	23	40.97	13	23.16	25	44.53	0	0.00	0	0.00	0	0.00	0	0.00	0
	EP6775	85	86.16	26	26.35	15	15.20	8	8.11	35	35.48	0	0.00	0	0.00	0	0.00	0	0.00	3
	ER1742	137	61.64	45	20.25	23	10.35	13	5.85	52	23.40	0	0.00	0	0.00	0	0.00	0	0.00	2
	EW0193	173	58.25	35	11.78	19	6.40	10	3.37	59	19.87	4	1.35	0	0.00	0	0.00	1	0.34	1
	EW0199	131	50.12	30	11.48	23	8.80	14	5.36	52	19.90	1	0.38	1	0.38	0	0.00	0	0.00	0
	EW0216	111	40.13	17	6.15	9	3.25	5	1.81	44	15.91	0	0.00	0	0.00	1	0.36	0	0.00	1
	EW0221	104	31.54	18	5.46	9	2.73	3	0.91	27	8.19	1	0.30	0	0.00	0	0.00	0	0.00	2
	EW3344	82	48.44	18	10.63	13	7.68	8	4.73	35	20.68	1	0.59	0	0.00	0	0.00	0	0.00	1
	EX0438	122	62.55	31	15.89	19	9.74	11	5.64	45	23.07	4	2.05	0	0.00	0	0.00	0	0.00	1
Pfizer mRNA BNT162b2	EX0904	79	66.26	24	20.13	11	9.23	7	5.87	27	22.64	3	2.52	0	0.00	1	0.84	0	0.00	0
	EX2294	36	65.33	12	21.78	6	10.89	5	9.07	13	23.59	0	0.00	0	0.00	0	0.00	0	0.00	1
	EY0578	85	25.59	17	5.12	7	2.11	5	1.51	28	8.43	3	0.90	0	0.00	0	0.00	0	0.00	1
	EY0579	15	31.16	0	0.00	0	0.00	0	0.00	8	16.62	0	0.00	0	0.00	0	0.00	0	0.00	0
	EY0583	17	28.00	3	4.94	2	3.29	1	1.65	5	8.24	0	0.00	0	0.00	0	0.00	0	0.00	0
	EY0585	8	13.93	1	1.74	1	1.74	1	1.74	2	3.48	0	0.00	0	0.00	0	0.00	0	0.00	0

4	5.77	17	24.51	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	4.32	0	0.00	5	7.21	1	1.44
13	23.16	25	44.53	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	13	23.16	0	0.00	3	5.34	1	1.78
8	8.11	35	35.48	0	0.00	0	0.00	0	0.00	0	0.00	3	3.04	10	10.14	0	0.00	9	9.12	0	0.00
13	5.85	52	23.40	0	0.00	0	0.00	0	0.00	0	0.00	2	0.90	22	9.90	1	0.45	22	9.90	2	0.90
10	3.37	59	19.87	4	1.35	0	0.00	0	0.00	1	0.34	1	0.34	29	9.76	0	0.00	9	3.03	1	0.34
14	5.36	52	19.90	1	0.38	1	0.38	0	0.00	0	0.00	0	0.00	18	6.89	0	0.00	6	2.30	1	0.38
5	1.81	44	15.91	0	0.00	0	0.00	1	0.36	0	0.00	1	0.36	24	8.68	1	0.36	5	1.81	0	0.00
3	0.91	27	8.19	1	0.30	0	0.00	0	0.00	0	0.00	2	0.61	22	6.67	0	0.00	6	1.82	0	0.00
8	4.73	35	20.68	1	0.59	0	0.00	0	0.00	0	0.00	1	0.59	8	4.73	0	0.00	3	1.77	0	0.00
11	5.64	45	23.07	4	2.05	0	0.00	0	0.00	0	0.00	1	0.51	14	7.18	0	0.00	6	3.08	0	0.00
7	5.87	27	22.64	3	2.52	0	0.00	1	0.84	0	0.00	0	0.00	7	5.87	1	0.84	7	5.87	2	1.68
5	9.07	13	23.59	0	0.00	0	0.00	0	0.00	0	0.00	1	1.81	6	10.89	0	0.00	4	7.26	0	0.00
5	1.51	28	8.43	3	0.90	0	0.00	0	0.00	0	0.00	1	0.30	7	2.11	0	0.00	7	2.11	0	0.00
0	0.00	8	16.62	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	2.08	0	0.00	0	0.00	0	0.00
1	1.65	5	8.24	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	8.24	0	0.00	1	1.65	0	0.00
1	1.74	2	3.48	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	1.74	0	0.00	0	0.00	0	0.00

EY0583	17	28.00	3	4.94	2	3.29	1	1.65	5	8.24	0	0.00	0	0.00	0	0.00	0	0.00	0
EY0585	8	13.93	1	1.74	1	1.74	1	1.74	2	3.48	0	0.00	0	0.00	0	0.00	0	0.00	0
EY0586	8	11.81	2	2.95	1	1.48	1	1.48	3	4.43	1	1.48	0	0.00	0	0.00	0	0.00	0
EY4825	71	51.08	9	6.47	3	2.16	2	1.44	27	19.42	1	0.72	0	0.00	0	0.00	0	0.00	1
FA8721	126	45.58	24	8.68	13	4.70	7	2.53	43	15.56	3	1.09	0	0.00	0	0.00	0	0.00	2
FA9091	71	17.12	16	3.86	10	2.41	6	1.45	16	3.86	0	0.00	0	0.00	0	0.00	0	0.00	1
FA9093	59	22.06	12	4.49	5	1.87	3	1.12	20	7.48	1	0.37	2	0.75	0	0.00	0	0.00	1
FA9094	13	14.91	5	5.73	3	3.44	2	2.29	1	1.15	0	0.00	0	0.00	0	0.00	0	0.00	0
FA9099	39	8.62	16	3.54	8	1.77	3	0.66	7	1.55	2	0.44	0	0.00	0	0.00	0	0.00	0
FD0810	14	8.12	5	2.90	1	0.58	0	0.00	6	3.48	0	0.00	0	0.00	0	0.00	0	0.00	0
FD7204	20	9.12	6	2.74	3	1.37	3	1.37	3	1.37	1	0.46	0	0.00	0	0.00	0	0.00	2
FD7206	25	8.76	5	1.75	1	0.35	1	0.35	8	2.80	0	0.00	0	0.00	0	0.00	1	0.35	1
FD7208	7	22.64	3	9.70	2	6.47	1	3.23	3	9.70	0	0.00	0	0.00	0	0.00	0	0.00	0
FF2595	8	10.79	4	5.39	2	2.70	1	1.35	3	4.05	0	0.00	0	0.00	0	0.00	0	0.00	1
FF2602	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
Pfizer mRNA	**2007**	**37.45**	**468**	**8.73**	**269**	**5.02**	**155**	**2.89**	**721**	**13.46**	**29**	**0.54**	**3**	**0.06**	**2**	**0.04**	**4**	**0.07**	**22**

1	1.65	5	8.24	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	5	8.24	0	0.00	1	1.65	0	0.00
1	1.74	2	3.48	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	1.74	0	0.00	0	0.00	0	0.00
1	1.48	3	4.43	1	1.48	0	0.00	0	0.00	0	0.00	0	0.00	1	1.48	0	0.00	0	0.00	0	0.00
2	1.44	27	19.42	1	0.72	0	0.00	0	0.00	0	0.00	1	0.72	10	7.19	0	0.00	4	2.88	0	0.00
7	2.53	43	15.56	3	1.09	0	0.00	0	0.00	0	0.00	2	0.72	19	6.87	0	0.00	4	1.45	0	0.00
6	1.45	16	3.86	0	0.00	0	0.00	0	0.00	0	0.00	1	0.24	11	2.65	0	0.00	4	0.96	0	0.00
3	1.12	20	7.48	1	0.37	2	0.75	0	0.00	0	0.00	1	0.37	6	2.24	0	0.00	5	1.87	0	0.00
2	2.29	1	1.15	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	2.29	0	0.00	1	1.15	0	0.00
3	0.66	7	1.55	2	0.44	0	0.00	0	0.00	0	0.00	0	0.00	5	1.11	0	0.00	6	1.33	0	0.00
0	0.00	6	3.48	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	3	1.74	0	0.00	4	2.32	0	0.00
3	1.37	3	1.37	1	0.46	0	0.00	0	0.00	0	0.00	2	0.91	4	1.82	0	0.00	0	0.00	0	0.00
1	0.35	8	2.80	0	0.00	0	0.00	0	0.00	1	0.35	1	0.35	4	1.40	0	0.00	2	0.70	0	0.00
1	3.23	3	9.70	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	3.23	0	0.00
1	1.35	3	4.05	0	0.00	0	0.00	0	0.00	0	0.00	1	1.35	0	0.00	0	0.00	0	0.00	1	1.35
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
155	**2.89**	**721**	**13.46**	**29**	**0.54**	**3**	**0.06**	**2**	**0.04**	**4**	**0.07**	**22**	**0.41**	**284**	**5.30**	**6**	**0.11**	**129**	**2.41**	**10**	**0.19**

		FF2602	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	
		Pfizer mRNA BNT162b2 total	**2007**	**37.45**	**468**	**8.73**	**269**	**5.02**	**155**	**2.89**	**721**	**13.46**	**29**	**0.54**	**3**	**0.06**	**2**	**0.04**	**4**	**0.07**	**22**	
	COVID-19 mRNA total	**COVID-19 mRNA total**	**3069**	**42.52**	**692**	**9.59**	**346**	**4.79**	**197**	**2.73**	**1083**	**15.00**	**47**	**0.65**	**4**	**0.06**	**2**	**0.03**	**5**	**0.07**	**27**	
		Unknown	2	NA	1	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	
		ABX3120	19	24.75	6	7.82	1	1.30	1	1.30	5	6.51	0	0.00	0	0.00	0	0.00	0	0.00	0	
		CTMAV532	48	120.09	8	20.02	2	5.00	2	5.00	10	25.02	1	2.50	0	0.00	0	0.00	0	0.00	0	
		NA0079	177	87.47	35	17.30	3	1.48	1	0.49	50	24.71	1	0.49	3	1.48	0	0.00	0	0.00	1	
		ABX3120-CC01	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	
	AstraZeneca ChAdOx1-S	ABX3120-CC02	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	
		MT0055	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	
		MT0056	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	
COVID-19 Non-replicating		NH0240	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	
		AstraZeneca	**246**	**76.23**	**50**	**15.49**	**6**	**1.86**	**4**	**1.24**	**65**	**20.14**	**2**	**0.62**	**3**	**0.93**	**0**	**0.00**	**0**	**0.00**	**1**	

0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
155	**2.89**	**721**	**13.46**	**29**	**0.54**	**3**	**0.06**	**2**	**0.04**	**4**	**0.07**	**22**	**0.41**	**284**	**5.30**	**6**	**0.11**	**129**	**2.41**	**10**	**0.19**
197	**2.73**	**1083**	**15.00**	**47**	**0.65**	**4**	**0.06**	**2**	**0.03**	**5**	**0.07**	**27**	**0.37**	**400**	**5.54**	**51**	**0.71**	**195**	**2.70**	**15**	**0.21**
0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	0	NA	1	NA	0	NA
1	1.30	5	6.51	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	1.30	0	0.00	4	5.21	0	0.00
2	5.00	10	25.02	1	2.50	0	0.00	0	0.00	0	0.00	0	0.00	10	25.02	1	2.50	2	5.00	0	0.00
1	0.49	50	24.71	1	0.49	3	1.48	0	0.00	0	0.00	1	0.49	40	19.77	5	2.47	20	9.88	1	0.49
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
4	**1.24**	**65**	**20.14**	**2**	**0.62**	**3**	**0.93**	**0**	**0.00**	**0**	**0.00**	**1**	**0.31**	**51**	**15.80**	**6**	**1.86**	**27**	**8.37**	**1**	**0.31**

COVID-19 Non-replicating Viral Vector		NH0240	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
		AstraZeneca ChAdOx1-S total	**246**	**76.23**	**50**	**15.49**	**6**	**1.86**	**4**	**1.24**	**65**	**20.14**	**2**	**0.62**	**3**	**0.93**	**0**	**0.00**	**0**	**0.00**	**1**
	COVISHIELD	4120Z003	45	108.69	10	24.15	6	14.49	2	4.83	8	19.32	1	2.42	0	0.00	0	0.00	0	0.00	0
		4120Z029	21	88.19	7	29.40	2	8.40	2	8.40	7	29.40	0	0.00	0	0.00	1	4.20	0	0.00	0
		COVISHIELD total	**66**	**99.22**	**17**	**25.56**	**8**	**12.03**	**4**	**6.01**	**15**	**22.55**	**1**	**1.50**	**0**	**0.00**	**1**	**1.50**	**0**	**0.00**	**0**
	Janssen AD26.COV2.S	**Janssen AD26.COV2.S total**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**
	COVID-19 Non-replicating Viral Vector total	**COVID-19 Non-replicating Viral Vector total**	**312**	**79.98**	**67**	**17.17**	**14**	**3.59**	**8**	**2.05**	**80**	**20.51**	**3**	**0.77**	**3**	**0.77**	**1**	**0.26**	**0**	**0.00**	**1**
	SinoPharm-Beijing BBIBP-CorV / Covilo	**SinoPharm-Beijing BBIBP-CorV / Covilo total**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**
Unknown	Sinovac CoronaVac	**Sinovac CoronaVac**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**

0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
4	**1.24**	**65**	**20.14**	**2**	**0.62**	**3**	**0.93**	**0**	**0.00**	**0**	**0.00**	**1**	**0.31**	**51**	**15.80**	**6**	**1.86**	**27**	**8.37**	**1**	**0.31**
2	4.83	8	19.32	1	2.42	0	0.00	0	0.00	0	0.00	0	0.00	8	19.32	1	2.42	2	4.83	0	0.00
2	8.40	7	29.40	0	0.00	0	0.00	1	4.20	0	0.00	0	0.00	2	8.40	0	0.00	4	16.80	0	0.00
4	**6.01**	**15**	**22.55**	**1**	**1.50**	**0**	**0.00**	**1**	**1.50**	**0**	**0.00**	**0**	**0.00**	**10**	**15.03**	**1**	**1.50**	**6**	**9.02**	**0**	**0.00**
0	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
8	**2.05**	**80**	**20.51**	**3**	**0.77**	**3**	**0.77**	**1**	**0.26**	**0**	**0.00**	**1**	**0.26**	**61**	**15.64**	**7**	**1.79**	**33**	**8.46**	**1**	**0.26**
0	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**
0	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**	**0**	**0.00**

	Janssen AD26.COV2.S	Janssen AD26.COV2.S total	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
	COVID-19 Non-replicating Viral Vector total	COVID-19 Non-replicating Viral Vector total	312	79.98	67	17.17	14	3.59	8	2.05	80	20.51	3	0.77	3	0.77	1	0.26	0	0.00	1
	SinoPharm-Beijing BBIBP-CorV / Covilo	SinoPharm-Beijing BBIBP-CorV / Covilo total	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
Unknown	Sinovac CoronaVac	Sinovac CoronaVac total	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0
	Unknown total	Unknown total	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0

Abbreviations:
GBS = Guillain Barre Syndrome
Notes:
[a] Excludes reports that have been flagged as being entered in error or not meeting the reporting criteria. The data are dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
[b] Rates for COVID-19 AEFI reports, events, and outcomes are per 100,000 doses administered. If 'NA' is displayed, the doses administered for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
[c] Serious AEFI defined as any of the following events: anaphylaxis, Bell's Palsy, cellulitis, seizure, encephalitis, transverse myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, pe
[d] Anaphylaxis reports that meet the Brighton Collaboration's diagnostic certainty levels 1, 2, or 3 as defined in the anaphylaxis case definition.

0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
8	2.05	80	20.51	3	0.77	3	0.77	1	0.26	0	0.00	1	0.26	61	15.64	7	1.79	33	8.46	1	0.26
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00

e dynamic and may change over time as records are added/updated leading to differences in event counts from one report to the next.
doses administered for that lot number were not available at the time of the report or the lot number was not specified on the AEFI report.
se myelitis, GBS, intussusception, meningitis, ORS, paralysis, or thrombocytopenia; OR any of the following outcomes/recommendations: hospitalization, permanent disability/incapacity, death, or recommendation of no further immunizations.
aphylaxis case definition.

References

1. Wollersheim S. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Presentation - FDA Review of Efficacy and Safety of Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Request; 2020 Dec 10. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement
2. Zhang R. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation - FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA; 2020 Dec 17. Available from: https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-17-2020-meeting-announcement
3. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - United States, December 14-23, 2020. MMWR Morb Mortal Wkly Rep. 2021;70:46-51. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
4. CDC. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. Available from: https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly COVID-19 AEFI Report
Date: Thursday, September 16, 2021 5:10:05 PM
Attachments: COVID19_AEFI_Weekly_Report_2021-09-16.docx
COVID19_AEFI_Weekly_Report_2021-09-16.pdf

Hello all,

Apologies for the delay. Please find attached this week's COVID-19 AEFI report for posting on the website.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to September 11, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including September 11, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

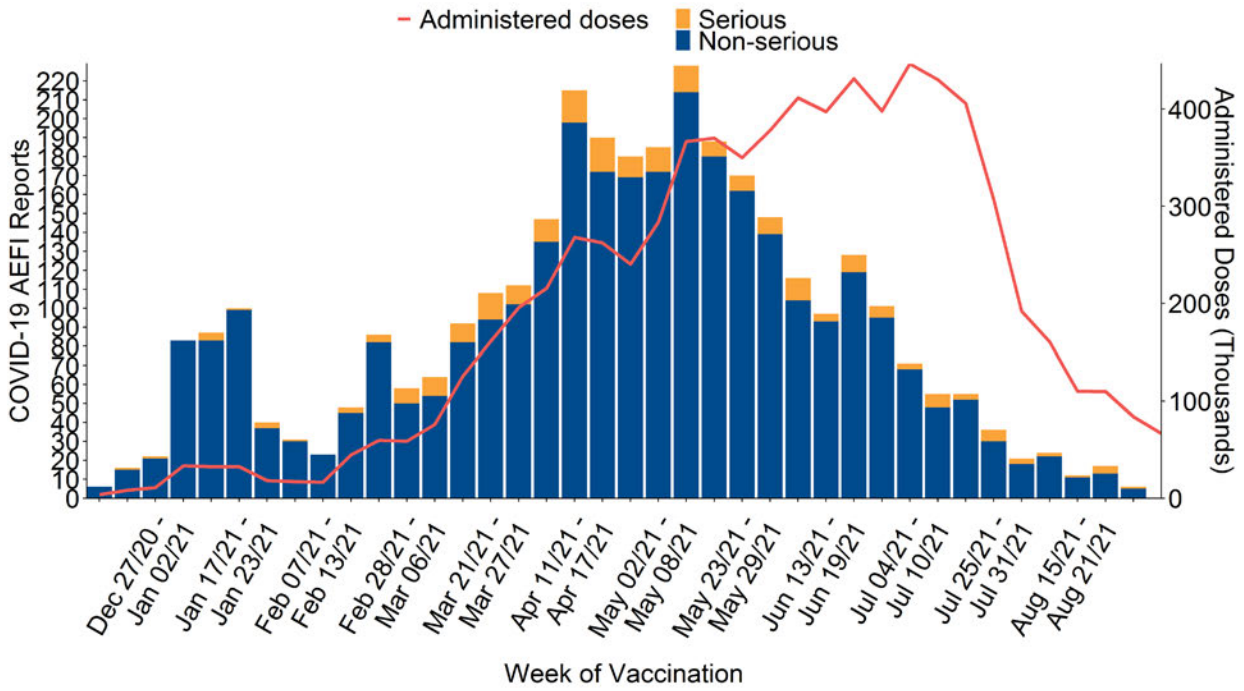
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of September 11, 2021, there have been 7,579,179 COVID-19 vaccine doses administered in BC and 3,366 COVID-19 AEFI reports (44.4 reports per 100,000 doses administered)
- 241 reports (7.2%) met the serious definition, for a rate of 3.2 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Sep. 11, 2021 **(N=3,366)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including September 11, 2021, a total of 7,579,179 doses have been administered. During this period, there have been 3,366 AEFI reports following a COVID-19 vaccine, for a reporting rate of 44.4 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 11, 2021 **(N=3,366)**

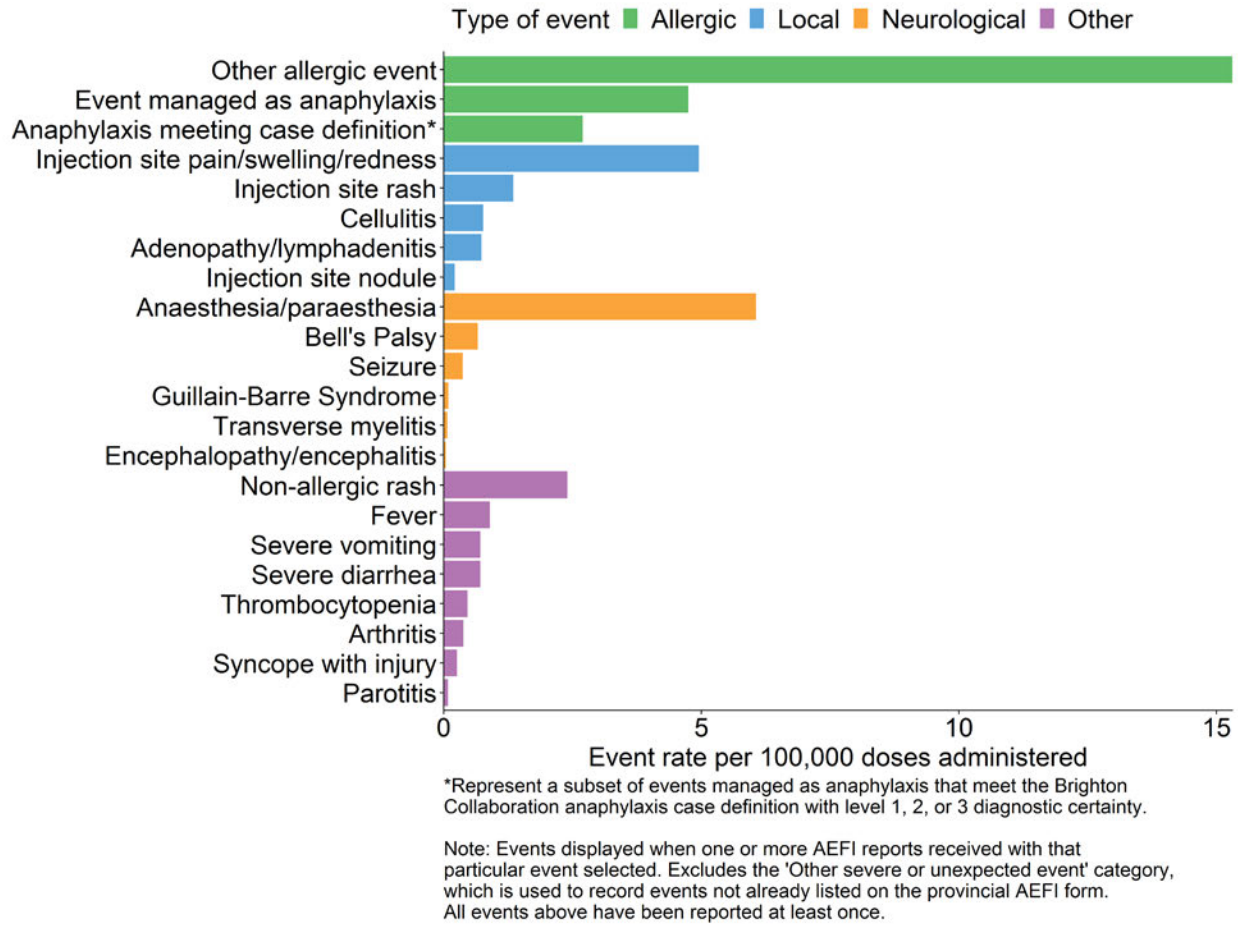
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3366**	**245**	**66**	**1059**	**1996**
Non-serious reports	3125	217	60	987	1861
Serious reports	241	28	6	72	135
Proportion serious	7.2%	11.4%	9.1%	6.8%	6.8%
Dose 1 reports	2739	221	65	842	1611
Dose 2 reports	626	24	1	217	384
Total doses administered	**7,579,179**	**322,651**	**66,521**	**1,849,456**	**5,340,551**
Dose 1 administered	4,124,170	221,717	58,616	964,167	2,879,670
Dose 2 administered	3,455,009	100,934	7,905	885,289	2,460,881
Total reporting rate	**44.4**	**75.9**	**99.2**	**57.3**	**37.4**
Serious rate	3.2	8.7	9.0	3.9	2.5
Dose 1 rate	66.4	99.7	110.9	87.3	55.9
Dose 2 rate	18.1	23.8	12.7	24.5	15.6

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,366 AEFI reports received up to September 11, 2021 contained a total of 4,257 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 11, 2021 **(N=4,257)**



Event Descriptions

Three hundred sixty reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 205 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

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Ninety-nine reports contained a diagnosed neurological event. Fifty individuals experienced Bell’s Palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional two individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging and the other’s workup was inconsistent with transverse myelitis. Twenty-eight individuals reported seizures, including 13

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Serious events:

Two hundred forty-one reports (7.2%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 226 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis, 106 for circulatory system events (including 24 for stroke, 19 for pulmonary embolism, 15 for myocardial infarction, 46 for myopericarditis, and two for an arrhythmia), 21 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and seven Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). Two hospitalizations occurred for rhabdomyolysis, one of which was also suspected of having myocarditis. One hospitalization each occurred for a pregnancy related complication, and capillary leak syndrome. Eighteen hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, of which four were for thrombosis with thrombocytopenia syndrome (described further below). The remaining reports were for

individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Fifteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

'Other serious' events:

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **Serious events** section. Amongst these events, 112 were for various thrombotic/ thromboembolic conditions. These included 25 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 15 myocardial infarctions, 28 pulmonary emboli, 36 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the

week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 92 reports of pericarditis/myocarditis. Forty-four individuals were diagnosed with pericarditis alone, twenty with myocarditis alone, and 27 with myopericarditis. Ages ranged from 14 to 95 with a median of 40.5 years, and 59 were male. Thirty-two had received Moderna vaccine, 53 had Pfizer vaccine, and six had AstraZeneca/COVISHIELD. Forty-three of these events occurred after a second dose (21 Pfizer and 21 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. Nineteen of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-one (out of 44) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Eighteen (out of 27) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis.[21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on September 15, 2021. Only AEFIs reported and doses administered up to September 11, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to September 11, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including September 11, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

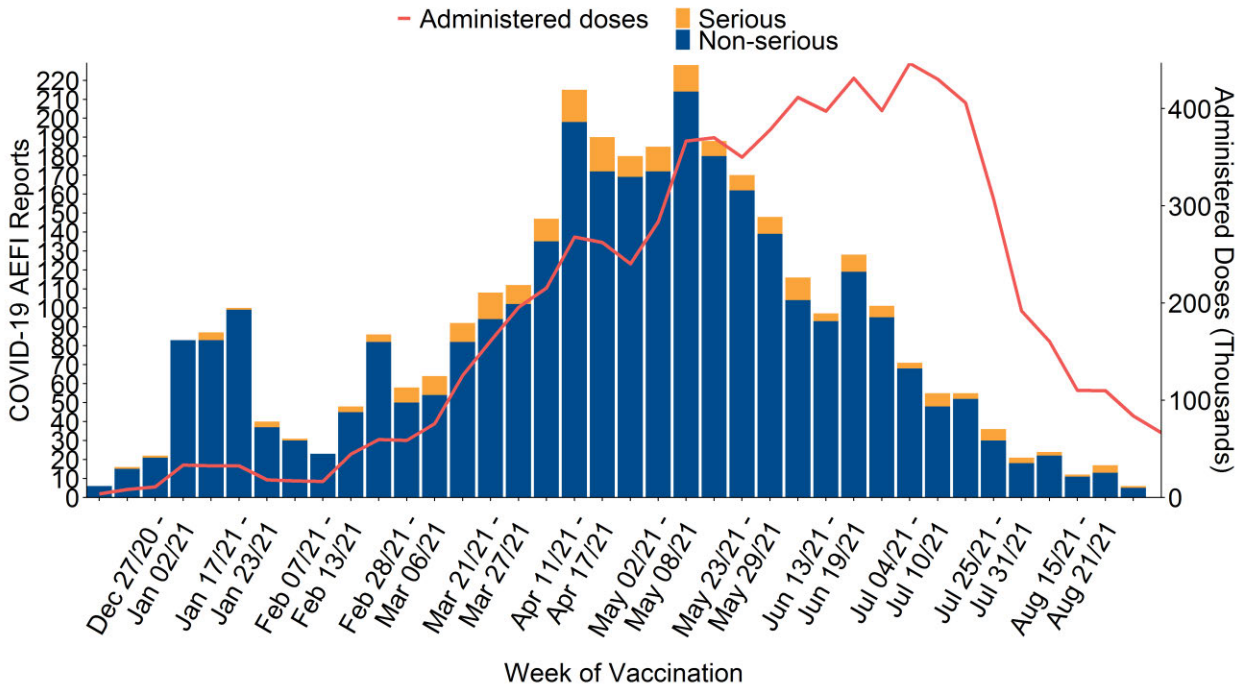
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of September 11, 2021, there have been 7,579,179 COVID-19 vaccine doses administered in BC and 3,366 COVID-19 AEFI reports (44.4 reports per 100,000 doses administered)
- 241 reports (7.2%) met the serious definition, for a rate of 3.2 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Sep. 11, 2021 **(N=3,366)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including September 11, 2021, a total of 7,579,179 doses have been administered. During this period, there have been 3,366 AEFI reports following a COVID-19 vaccine, for a reporting rate of 44.4 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 11, 2021 **(N=3,366)**

		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3366**	**245**	**66**	**1059**	**1996**
Non-serious reports	3125	217	60	987	1861
Serious reports	241	28	6	72	135
Proportion serious	7.2%	11.4%	9.1%	6.8%	6.8%
Dose 1 reports	2739	221	65	842	1611
Dose 2 reports	626	24	1	217	384
Total doses administered	**7,579,179**	**322,651**	**66,521**	**1,849,456**	**5,340,551**
Dose 1 administered	4,124,170	221,717	58,616	964,167	2,879,670
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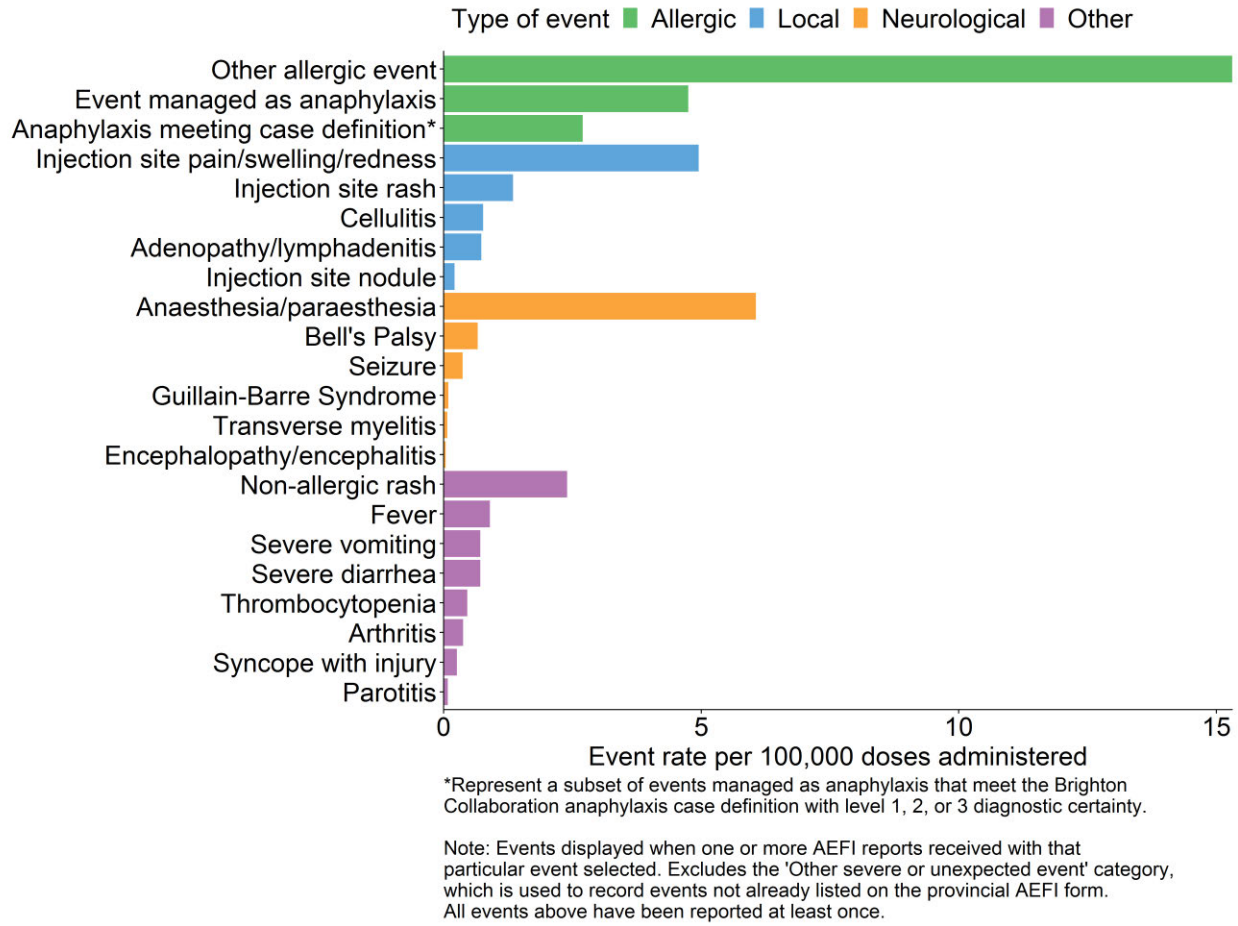

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- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
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One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the

week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 92 reports of pericarditis/myocarditis. Forty-four individuals were diagnosed with pericarditis alone, twenty with myocarditis alone, and 27 with myopericarditis. Ages ranged from 14 to 95 with a median of 40.5 years, and 59 were male. Thirty-two had received Moderna vaccine, 53 had Pfizer vaccine, and six had AstraZeneca/COVISHIELD. Forty-three of these events occurred after a second dose (21 Pfizer and 21 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. Nineteen of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-one (out of 44) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Eighteen (out of 27) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis.[21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on September 15, 2021. Only AEFIs reported and doses administered up to September 11, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Weekly COVID-19 AEFI Report
Date: Thursday, September 23, 2021 8:58:29 AM
Attachments: COVID19_AEFI_Weekly_Report_2021-09-23.docx
COVID19_AEFI_Weekly_Report_2021-09-23.pdf

Hello all,

Please find attached this week's COVID-19 AEFI report for posting on the website.

Thank you for all your hard work!

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

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Fax (604)707-2515

I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to September 18, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including September 18, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

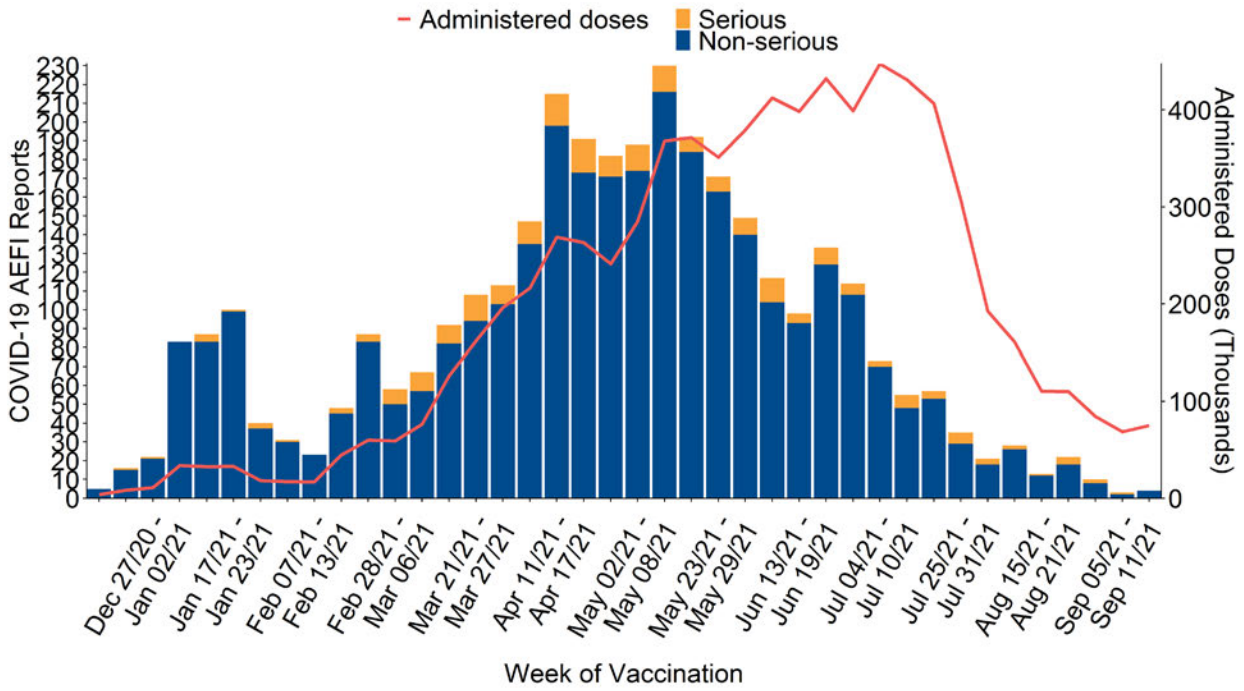
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of September 18, 2021, there have been 7,679,036 COVID-19 vaccine doses administered in BC and 3,428 COVID-19 AEFI reports (44.6 reports per 100,000 doses administered)
- 247 reports (7.2%) met the serious definition, for a rate of 3.2 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Sep. 18, 2021 **(N=3,428)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including September 18, 2021, a total of 7,679,036 doses have been administered. During this period, there have been 3,428 AEFI reports following a COVID-19 vaccine, for a reporting rate of 44.6 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 18, 2021 **(N=3,428)**

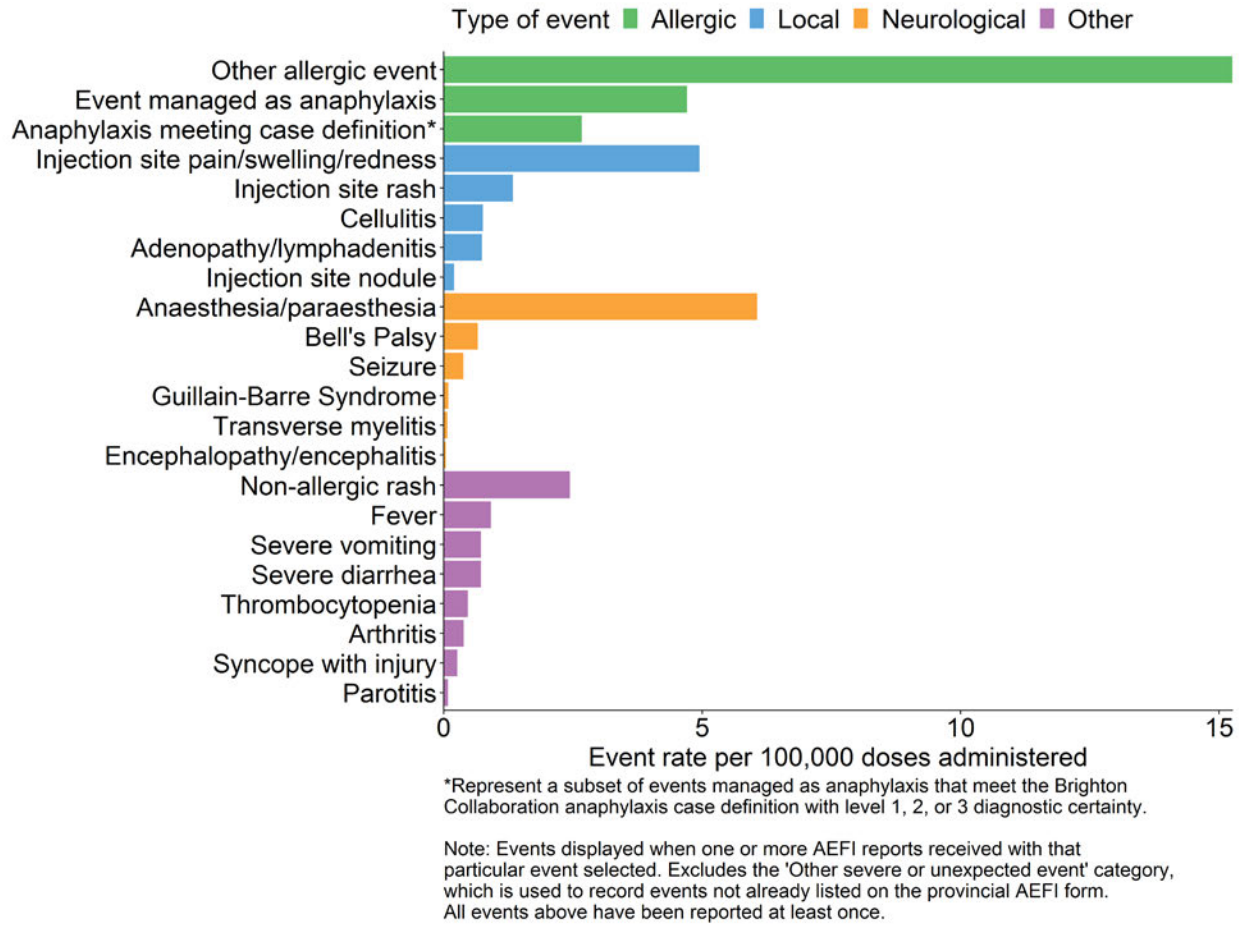
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3428**	**246**	**66**	**1084**	**2032**
Non-serious reports	3181	218	60	1010	1893
Serious reports	247	28	6	74	139
Proportion serious	7.2%	11.4%	9.1%	6.8%	6.8%
Dose 1 reports	2781	222	65	862	1632
Dose 2 reports	645	24	1	222	398
Total doses administered	**7,679,036**	**323,979**	**67,434**	**1,883,353**	**5,404,270**
Dose 1 administered	4,175,758	222,561	59,116	979,744	2,914,337
Dose 2 administered	3,503,278	101,418	8,318	903,609	2,489,933
Total reporting rate	**44.6**	**75.9**	**97.9**	**57.6**	**37.6**
Serious rate	3.2	8.6	8.9	3.9	2.6
Dose 1 rate	66.6	99.7	110.0	88.0	56.0
Dose 2 rate	18.4	23.7	12.0	24.6	16.0

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,428 AEFI reports received up to September 18, 2021 contained a total of 4,332 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 18, 2021 **(N=4,332)**



Event Descriptions

Three hundred sixty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 205 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-eight reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, a reaction described by “others”, rather than cellulitis.[15]

Ninety-nine reports contained a diagnosed neurological event. Fifty-one individuals experienced Bell’s palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional two individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging and the other’s workup was inconsistent with transverse myelitis. Twenty-nine individuals were reported with

seizures, including 13 with a history of a seizure disorder. Three individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy attributed to a workplace toxin exposure and was hospitalized; this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt. There were seven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 36 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both, the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were eleven reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.7,8

Serious events:

Two hundred forty-seven reports (7.2%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 231 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis, 107 for circulatory system events (including 24 for stroke, 19 for pulmonary embolism, 15 for myocardial infarction, 47 for myopericarditis, and two for an arrhythmia), 21 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and seven Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). Two hospitalizations occurred for rhabdomyolysis, one of which was also suspected of having myocarditis. One hospitalization each occurred for a pregnancy related complication, and capillary leak syndrome. Nineteen hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, of which four were for thrombosis with

thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.

'Other serious' events:

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 113 were for various thrombotic/ thromboembolic conditions. These included 25 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 15 myocardial infarctions, 29 pulmonary emboli, 36 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days

after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 97 reports of pericarditis/myocarditis. Forty-nine individuals were diagnosed with pericarditis alone, twenty with myocarditis alone, and 28 with myopericarditis. Ages ranged from 14 to 95 with a median of 40.4 years, and 63 were male. Thirty-six had received Moderna vaccine, 55 received Pfizer vaccine, and six received AstraZeneca/COVISHIELD. Forty-six of these events occurred after a second dose (22 Pfizer and 23 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. Eighteen (out of 20) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-three (out of 49) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Eighteen (out of 28) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis.[21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Table 2: Number of Myocarditis/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 – Sep. 18, 2021 **(N=91)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna mRNA-1273	**N (% Total)**	**0**	**9 (9.9%)**	**6 (6.6%)**	**8 (8.8%)**	**13 (14.3%)**	**36 (39.6%)**
Dose 1	N (% Total)	0	2 (2.2%)	2 (2.2%)	4 (4.4%)	5 (5.5%)	13 (14.3%)
Dose 2	N (% Total)	0	7 (7.7%)	4 (4.4%)	4 (4.4%)	8 (8.8%)	23 (25.3%)
Pfizer mRNA BNT162b2	**N (% Total)**	**9 (9.9%)**	**10 (11%)**	**3 (3.3%)**	**9 (9.9%)**	**24 (26.4%)**	**55 (60.4%)**
Dose 1	N (% Total)	5 (5.5%)	3 (3.3%)	1 (1.1%)	7 (7.7%)	17 (18.7%)	33 (36.3%)
Dose 2	N (% Total)	4 (4.4%)	7 (7.7%)	2 (2.2%)	2 (2.2%)	7 (7.7%)	22 (24.2%)
Total	**N (% Total)**	**9 (9.9%)**	**19 (20.9%)**	**9 (9.9%)**	**17 (18.7%)**	**37 (40.7%)**	**91 (100%)**

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on September 22, 2021. Only AEFIs reported and doses administered up to September 18, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to September 18, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including September 18, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

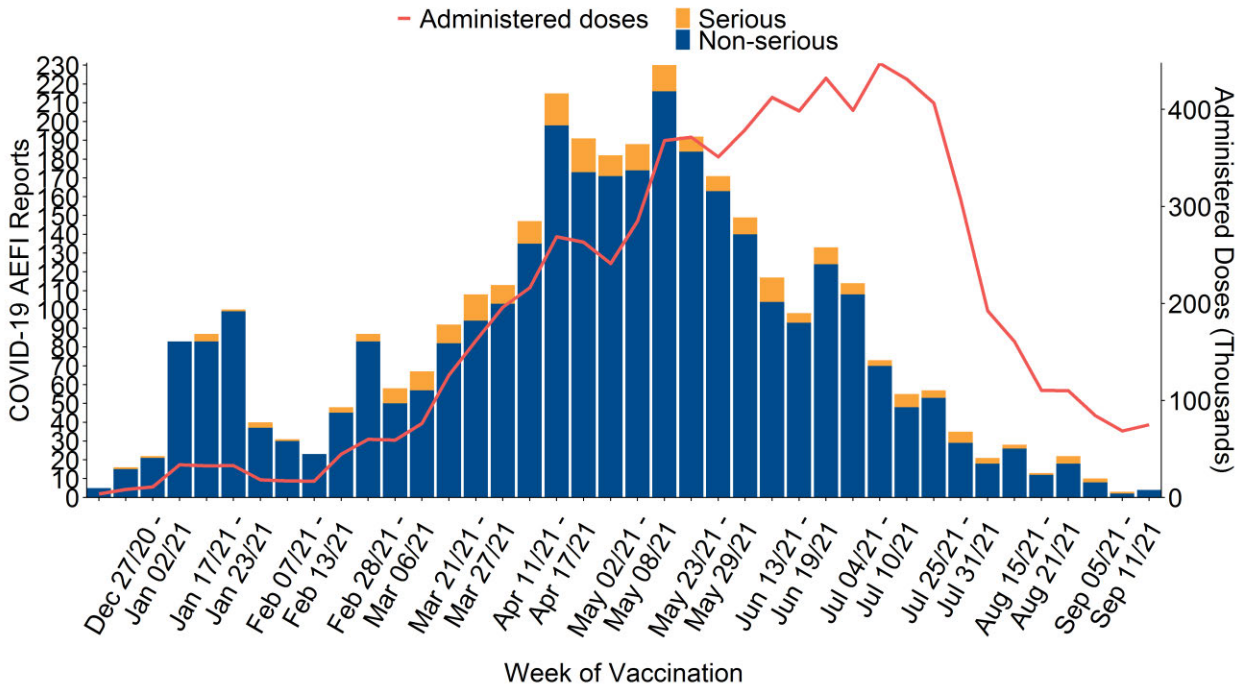
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of September 18, 2021, there have been 7,679,036 COVID-19 vaccine doses administered in BC and 3,428 COVID-19 AEFI reports (44.6 reports per 100,000 doses administered)
- 247 reports (7.2%) met the serious definition, for a rate of 3.2 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Sep. 18, 2021 **(N=3,428)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including September 18, 2021, a total of 7,679,036 doses have been administered. During this period, there have been 3,428 AEFI reports following a COVID-19 vaccine, for a reporting rate of 44.6 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 18, 2021 **(N=3,428)**

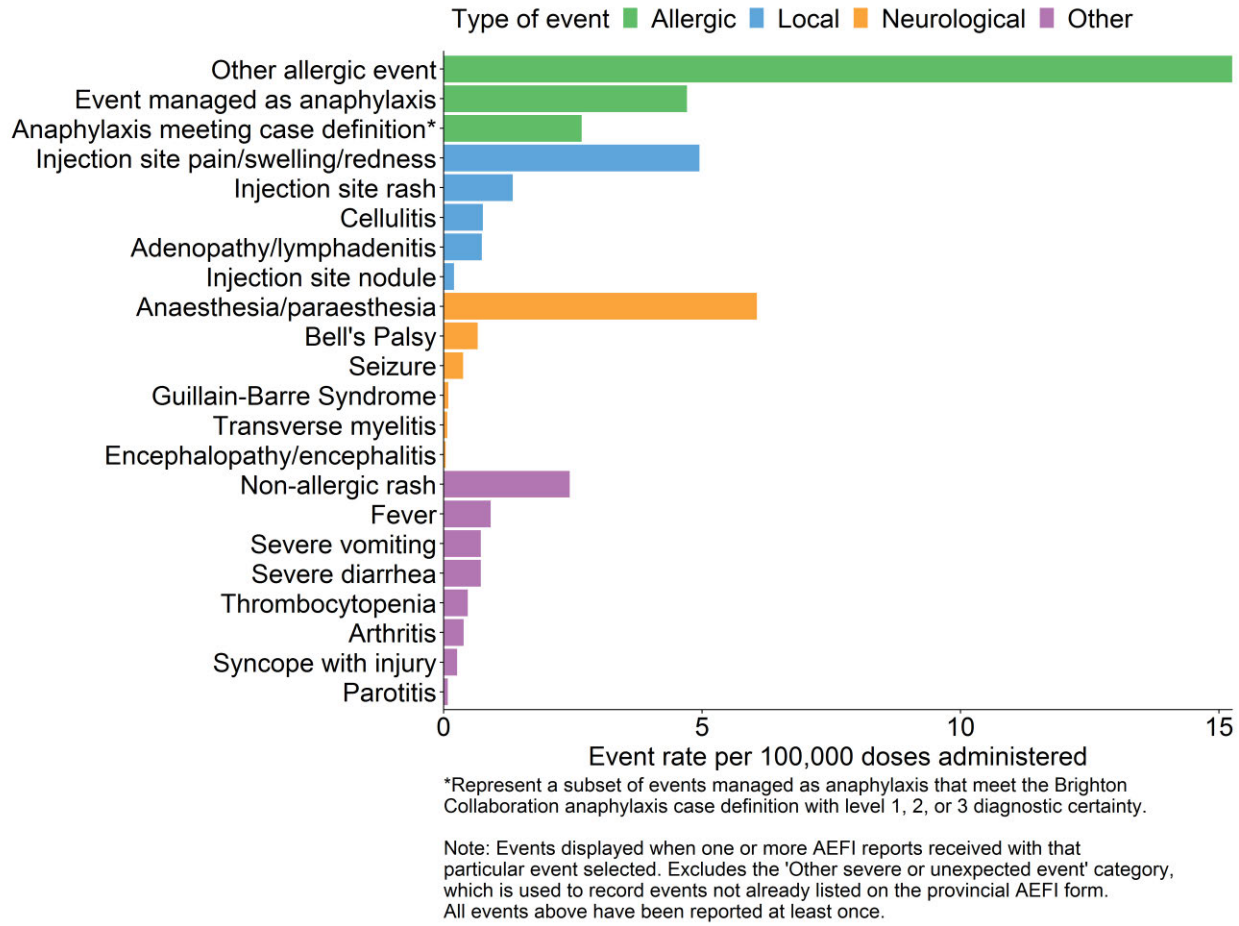
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3428**	**246**	**66**	**1084**	**2032**
Non-serious reports	3181	218	60	1010	1893
Serious reports	247	28	6	74	139
Proportion serious	7.2%	11.4%	9.1%	6.8%	6.8%
Dose 1 reports	2781	222	65	862	1632
Dose 2 reports	645	24	1	222	398
Total doses administered	**7,679,036**	**323,979**	**67,434**	**1,883,353**	**5,404,270**
Dose 1 administered	4,175,758	222,561	59,116	979,744	2,914,337
Dose 2 administered	3,503,278	101,418	8,318	903,609	2,489,933
Total reporting rate	**44.6**	**75.9**	**97.9**	**57.6**	**37.6**
Serious rate	3.2	8.6	8.9	3.9	2.6
Dose 1 rate	66.6	99.7	110.0	88.0	56.0
Dose 2 rate	18.4	23.7	12.0	24.6	16.0

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,428 AEFI reports received up to September 18, 2021 contained a total of 4,332 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 18, 2021 **(N=4,332)**



Event Descriptions

Three hundred sixty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 205 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-eight reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, a reaction described by “others”, rather than cellulitis.[15]

Ninety-nine reports contained a diagnosed neurological event. Fifty-one individuals experienced Bell’s palsy within 30 days following COVID-19 vaccination. Three individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional two individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging and the other’s workup was inconsistent with transverse myelitis. Twenty-nine individuals were reported with

seizures, including 13 with a history of a seizure disorder. Three individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy attributed to a workplace toxin exposure and was hospitalized; this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt. There were seven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 36 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both, the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were eleven reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.7,8

Serious events:
Two hundred forty-seven reports (7.2%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 231 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis, 107 for circulatory system events (including 24 for stroke, 19 for pulmonary embolism, 15 for myocardial infarction, 47 for myopericarditis, and two for an arrhythmia), 21 for a neurological diagnosis (including three for transverse myelitis, six for seizure, two intracerebral hemorrhage with one associated encephalopathy, another separate encephalopathy, one encephalitis, one meningitis, and seven Guillain-Barre Syndrome), and 3 for a respiratory condition (one respiratory distress, and two for exacerbation of idiopathic pulmonary fibrosis). Two hospitalizations occurred for rhabdomyolysis, one of which was also suspected of having myocarditis. One hospitalization each occurred for a pregnancy related complication, and capillary leak syndrome. Nineteen hospitalizations were for thrombocytopenia alone or associated with a concurrent condition, of which four were for thrombosis with

thrombocytopenia syndrome (described further below). The remaining reports were for individuals who were hospitalized for monitoring of allergic, neurological, or cardiac symptoms but without a medically diagnosed event.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.

'Other serious' events:

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 113 were for various thrombotic/ thromboembolic conditions. These included 25 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 15 myocardial infarctions, 29 pulmonary emboli, 36 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of which were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days

after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 97 reports of pericarditis/myocarditis. Forty-nine individuals were diagnosed with pericarditis alone, twenty with myocarditis alone, and 28 with myopericarditis. Ages ranged from 14 to 95 with a median of 40.4 years, and 63 were male. Thirty-six had received Moderna vaccine, 55 received Pfizer vaccine, and six received AstraZeneca/COVISHIELD. Forty-six of these events occurred after a second dose (22 Pfizer and 23 Moderna). Some had alternate explanations including rheumatic diseases or a genetic syndrome associated with cardiac disorders. Eighteen (out of 20) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-three (out of 49) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Eighteen (out of 28) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for either myocarditis or pericarditis.[21] These conditions are being investigated as a possible safety signal after mRNA vaccines, with an association seen in several countries including the US and UK as well as in Ontario, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Table 2: Number of Myocarditis/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 – Sep. 18, 2021 **(N=91)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna mRNA-1273	**N (% Total)**	**0**	**9 (9.9%)**	**6 (6.6%)**	**8 (8.8%)**	**13 (14.3%)**	**36 (39.6%)**
Dose 1	N (% Total)	0	2 (2.2%)	2 (2.2%)	4 (4.4%)	5 (5.5%)	13 (14.3%)
Dose 2	N (% Total)	0	7 (7.7%)	4 (4.4%)	4 (4.4%)	8 (8.8%)	23 (25.3%)
Pfizer mRNA BNT162b2	**N (% Total)**	**9 (9.9%)**	**10 (11%)**	**3 (3.3%)**	**9 (9.9%)**	**24 (26.4%)**	**55 (60.4%)**
Dose 1	N (% Total)	5 (5.5%)	3 (3.3%)	1 (1.1%)	7 (7.7%)	17 (18.7%)	33 (36.3%)
Dose 2	N (% Total)	4 (4.4%)	7 (7.7%)	2 (2.2%)	2 (2.2%)	7 (7.7%)	22 (24.2%)
Total	**N (% Total)**	**9 (9.9%)**	**19 (20.9%)**	**9 (9.9%)**	**17 (18.7%)**	**37 (40.7%)**	**91 (100%)**

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on September 22, 2021. Only AEFIs reported and doses administered up to September 18, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Minhas, Sableen
To: Dalati, Hadi [BCCDC]; Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: Weekly COVID-19 AEFI Report
Date: Thursday, September 23, 2021 9:13:13 AM

Thank you Hadi!

Sableen Minhas
Communications Specialist
BC Centre for Disease Control
Provincial Health Services Authority

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, September 23, 2021 8:58 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Weekly COVID-19 AEFI Report

Hello all,

Please find attached this week's COVID-19 AEFI report for posting on the website.

Thank you for all your hard work!

Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515

I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaɁ/Selilwitulh (TsleilWaututh) Nations.

From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Fortnightly COVID-19 AEFI Report
Date: Thursday, October 07, 2021 12:05:00 PM
Attachments: COVID19_AEFI_Fortnightly_Report_2021-10-07.docx
COVID19_AEFI_Fortnightly_Report_2021-10-07.pdf

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting on the website.

Thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

Tel (604)707-2537

Fax (604)707-2515

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to October 2, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including October 2, 2021. Please refer to the BCCDC website for reporting guidelines and to the Data Notes section at the end of this report for additional information on the source data.[1] Events can be reported even when there is no certainty of a causal association.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

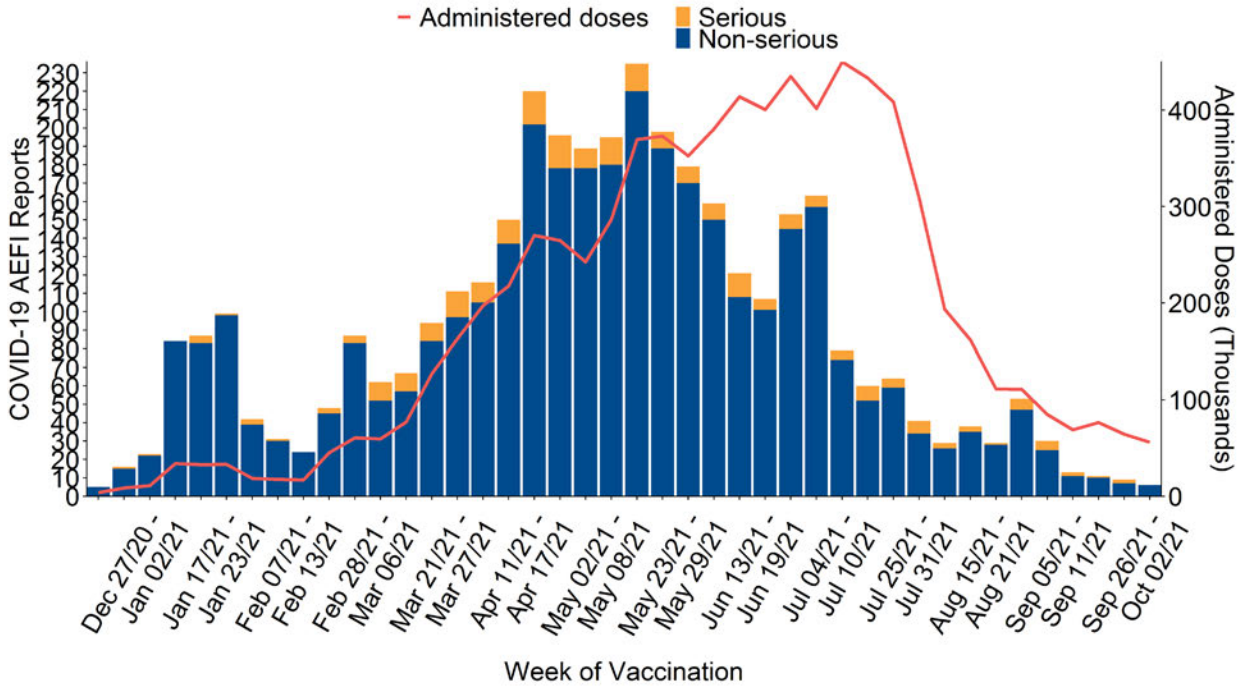
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of October 2, 2021, there have been 7,842,664 COVID-19 vaccine doses administered in BC and 3,723 COVID-19 AEFI reports (47.5 reports per 100,000 doses administered)
- 271 reports (7.3%) met the serious definition, for a rate of 3.5 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Oct. 2, 2021 **(N=3,723)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including October 2, 2021, a total of 7,842,664 doses have been administered. During this period, there have been 3,723 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.5 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Oct. 2, 2021 **(N=3,723)**

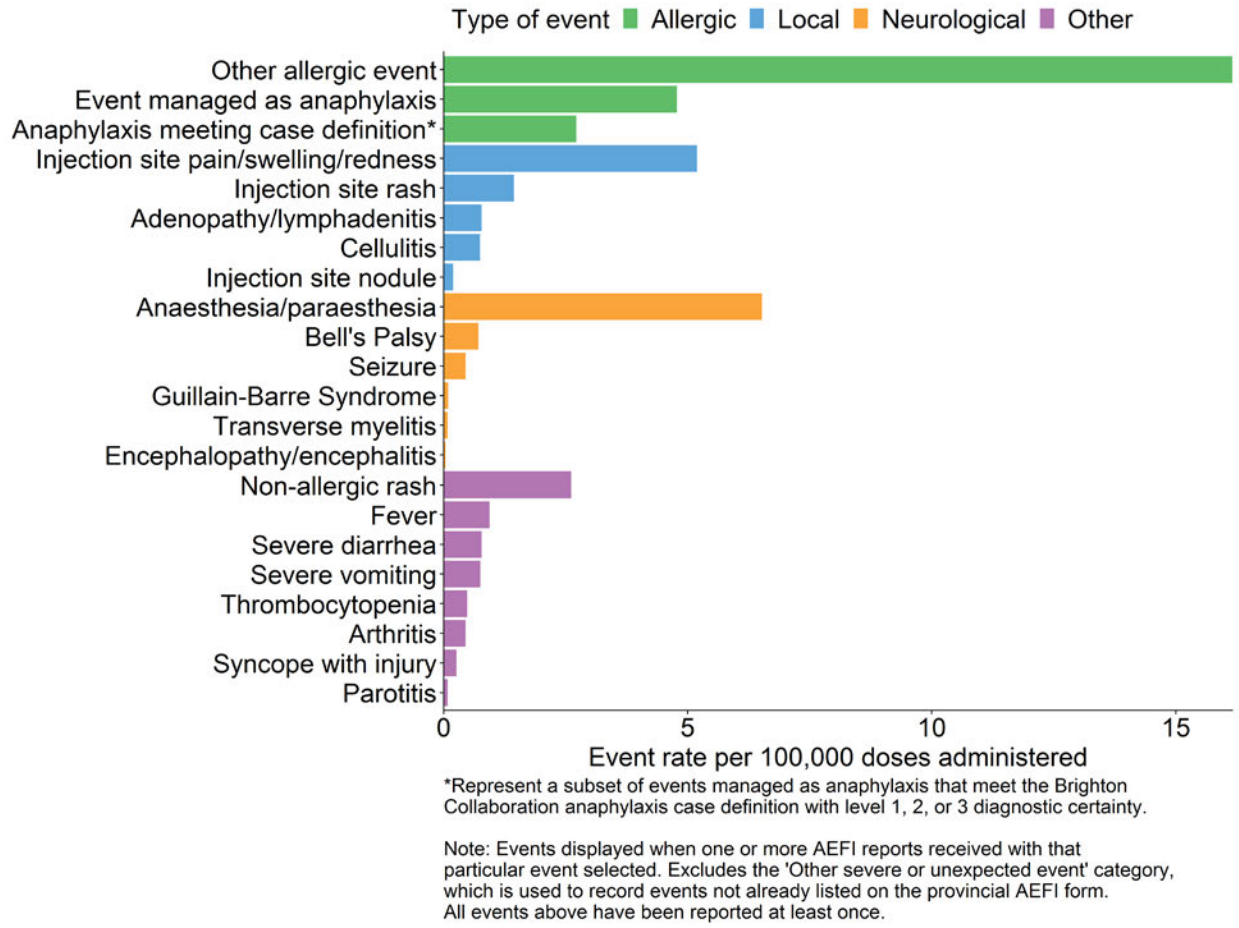
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**Moderna Spikevax**	**Pfizer Comirnaty**
Total reports	**3723**	**255**	**66**	**1217**	**2185**
Non-serious reports	3452	226	60	1135	2031
Serious reports	271	29	6	82	154
Proportion serious	7.3%	11.4%	9.1%	6.7%	7%
Dose 1 reports	2980	230	65	950	1735
Dose 2 reports	739	24	1	266	448
Total doses administered	**7,842,664**	**326,891**	**69,803**	**1,934,524**	**5,511,446**
Dose 1 administered	4,238,687	224,278	60,384	997,865	2,956,160
Dose 2 administered	3,603,977	102,613	9,419	936,659	2,555,286
Total reporting rate	**47.5**	**78.0**	**94.6**	**62.9**	**39.6**
Serious rate	3.5	8.9	8.6	4.2	2.8
Dose 1 rate	70.3	102.6	107.6	95.2	58.7
Dose 2 rate	20.5	23.4	10.6	28.4	17.5

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,723 AEFI reports received up to October 2, 2021 contained a total of 4,718 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Oct. 2, 2021 **(N=4,718)**



Event Descriptions

Three hundred seventy-five reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 213 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-eight reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, a reaction described by “others”, rather than cellulitis.[15] None of these reports were confirmed by microbial testing.

Two hundred seventy-one reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 255 individuals were admitted to hospital, including 3.6% of cases reported as anaphylaxis.

One-hundred-and-twelve reports contained a diagnosed neurological event. Fifty-six individuals

experienced Bell's palsy within 30 days following COVID-19 vaccination. Four individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional two individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging and the other's workup was inconsistent with transverse myelitis. Thirty-five individuals were reported with seizures (28.6% of which were hospitalized), including 13 with a history of a seizure disorder. Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy attributed to a workplace toxin exposure and was hospitalized; this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt. There were seven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 38 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were thirteen reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8] Collectively, thrombocytopenia cases lead to 20 hospitalizations (52.6% of cases).

Additionally, 2 cases were hospitalized for arrhythmias, 1 for respiratory distress, two for exacerbation of idiopathic pulmonary fibrosis, 1 for a pregnancy related complication, and 2 for rhabdomyolysis.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 118 were for various thrombotic/ thromboembolic conditions. These included 27 strokes (96.3% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 15 myocardial infarctions (all hospitalized), 31 pulmonary emboli (67.7% hospitalized), 37 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of whom were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that

progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 105 reports of pericarditis/myocarditis. Fifty-four individuals were diagnosed with pericarditis alone, 27 with myocarditis alone, and 31 with myopericarditis. Ages ranged from 14 to 95 with a median of 38.8 years, and 74 were male. Forty had received Moderna Spikevax vaccine, 65 received Pfizer Comirnaty vaccine, and seven received AstraZeneca/COVISHIELD. Fifty-two of these events occurred after a second dose (27 Pfizer Comirnaty and 24 Moderna Spikevax). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Twenty-four (out of 27) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-six (out of 54) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty (out of 31) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis or pericarditis.[21] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Table 2: Number of Myocarditis/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 – Oct. 2, 2021 **(N=105)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0**	**10 (9.5%)**	**7 (6.7%)**	**10 (9.5%)**	**13 (12.4%)**	**40 (38.1%)**
Dose 1	N (% Total)	0	2 (1.9%)	3 (2.9%)	5 (4.8%)	6 (5.7%)	16 (15.2%)
Dose 2	N (% Total)	0	8 (7.6%)	4 (3.8%)	5 (4.8%)	7 (6.7%)	24 (22.9%)
Pfizer Comirnaty	**N (% Total)**	**12 (11.4%)**	**12 (11.4%)**	**3 (2.9%)**	**12 (11.4%)**	**26 (24.8%)**	**65 (61.9%)**
Dose 1	N (% Total)	6 (5.7%)	3 (2.9%)	1 (1%)	10 (9.5%)	18 (17.1%)	38 (36.2%)
Dose 2	N (% Total)	6 (5.7%)	9 (8.6%)	2 (1.9%)	2 (1.9%)	8 (7.6%)	27 (25.7%)
Total	**N (% Total)**	**12 (11.4%)**	**22 (21%)**	**10 (9.6%)**	**22 (21%)**	**39 (37.1%)**	**105 (100%)**

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on October 6, 2021. Only AEFIs reported and doses administered up to October 2, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to October 2, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including October 2, 2021. Please refer to the BCCDC website for reporting guidelines and to the Data Notes section at the end of this report for additional information on the source data.[1] Events can be reported even when there is no certainty of a causal association.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

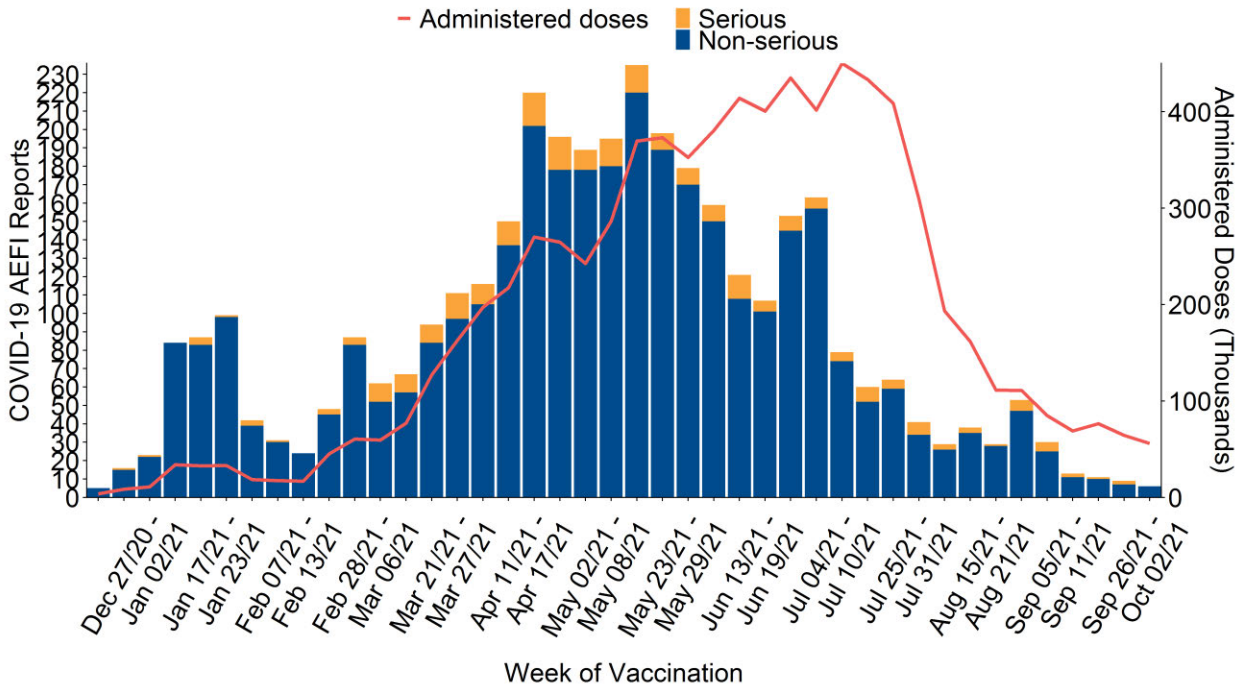
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of October 2, 2021, there have been 7,842,664 COVID-19 vaccine doses administered in BC and 3,723 COVID-19 AEFI reports (47.5 reports per 100,000 doses administered)
- 271 reports (7.3%) met the serious definition, for a rate of 3.5 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Oct. 2, 2021 **(N=3,723)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including October 2, 2021, a total of 7,842,664 doses have been administered. During this period, there have been 3,723 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.5 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Oct. 2, 2021 **(N=3,723)**

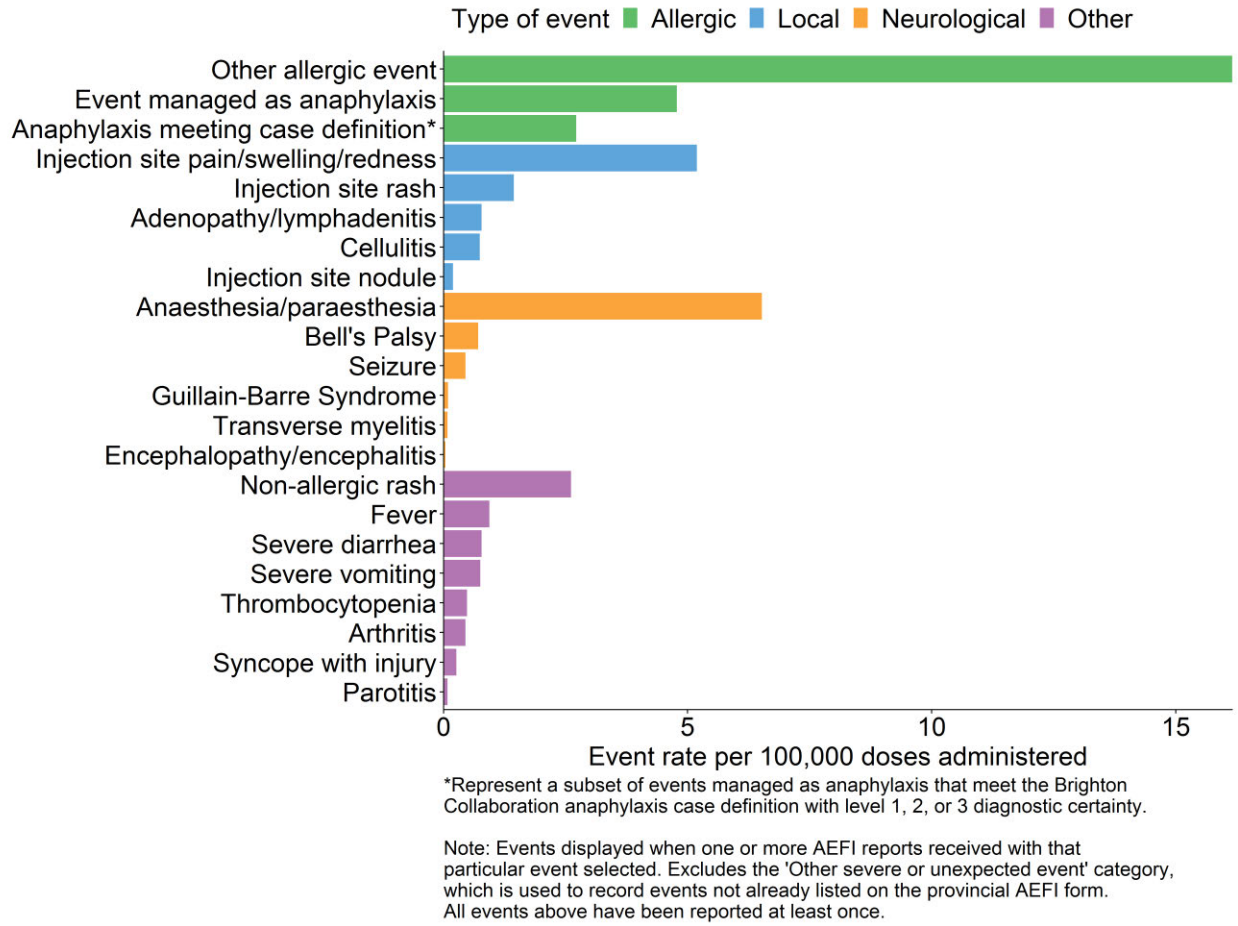
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**Moderna Spikevax**	**Pfizer Comirnaty**
Total reports	**3723**	**255**	**66**	**1217**	**2185**
Non-serious reports	3452	226	60	1135	2031
Serious reports	271	29	6	82	154
Proportion serious	7.3%	11.4%	9.1%	6.7%	7%
Dose 1 reports	2980	230	65	950	1735
Dose 2 reports	739	24	1	266	448
Total doses administered	**7,842,664**	**326,891**	**69,803**	**1,934,524**	**5,511,446**
Dose 1 administered	4,238,687	224,278	60,384	997,865	2,956,160
Dose 2 administered	3,603,977	102,613	9,419	936,659	2,555,286
Total reporting rate	**47.5**	**78.0**	**94.6**	**62.9**	**39.6**
Serious rate	3.5	8.9	8.6	4.2	2.8
Dose 1 rate	70.3	102.6	107.6	95.2	58.7
Dose 2 rate	20.5	23.4	10.6	28.4	17.5

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,723 AEFI reports received up to October 2, 2021 contained a total of 4,718 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Oct. 2, 2021 **(N=4,718)**



Event Descriptions

Three hundred seventy-five reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 213 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-eight reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, a reaction described by “others”, rather than cellulitis.[15] None of these reports were confirmed by microbial testing.

Two hundred seventy-one reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 255 individuals were admitted to hospital, including 3.6% of cases reported as anaphylaxis.

One-hundred-and-twelve reports contained a diagnosed neurological event. Fifty-six individuals

experienced Bell's palsy within 30 days following COVID-19 vaccination. Four individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional two individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging and the other's workup was inconsistent with transverse myelitis. Thirty-five individuals were reported with seizures (28.6% of which were hospitalized), including 13 with a history of a seizure disorder. Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy attributed to a workplace toxin exposure and was hospitalized; this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt. There were seven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 38 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were thirteen reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8] Collectively, thrombocytopenia cases lead to 20 hospitalizations (52.6% of cases).

Additionally, 2 cases were hospitalized for arrhythmias, 1 for respiratory distress, two for exacerbation of idiopathic pulmonary fibrosis, 1 for a pregnancy related complication, and 2 for rhabdomyolysis.

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 118 were for various thrombotic/ thromboembolic conditions. These included 27 strokes (96.3% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 15 myocardial infarctions (all hospitalized), 31 pulmonary emboli (67.7% hospitalized), 37 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of whom were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that

progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 105 reports of pericarditis/myocarditis. Fifty-four individuals were diagnosed with pericarditis alone, 27 with myocarditis alone, and 31 with myopericarditis. Ages ranged from 14 to 95 with a median of 38.8 years, and 74 were male. Forty had received Moderna Spikevax vaccine, 65 received Pfizer Comirnaty vaccine, and seven received AstraZeneca/COVISHIELD. Fifty-two of these events occurred after a second dose (27 Pfizer Comirnaty and 24 Moderna Spikevax). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Twenty-four (out of 27) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-six (out of 54) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty (out of 31) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis or pericarditis.[21] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Table 2: Number of Myocarditis/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 – Oct. 2, 2021 **(N=105)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	N (% Total)	**0**	**10 (9.5%)**	**7 (6.7%)**	**10 (9.5%)**	**13 (12.4%)**	**40 (38.1%)**
Dose 1	N (% Total)	0	2 (1.9%)	3 (2.9%)	5 (4.8%)	6 (5.7%)	16 (15.2%)
Dose 2	N (% Total)	0	8 (7.6%)	4 (3.8%)	5 (4.8%)	7 (6.7%)	24 (22.9%)
Pfizer Comirnaty	N (% Total)	**12 (11.4%)**	**12 (11.4%)**	**3 (2.9%)**	**12 (11.4%)**	**26 (24.8%)**	**65 (61.9%)**
Dose 1	N (% Total)	6 (5.7%)	3 (2.9%)	1 (1%)	10 (9.5%)	18 (17.1%)	38 (36.2%)
Dose 2	N (% Total)	6 (5.7%)	9 (8.6%)	2 (1.9%)	2 (1.9%)	8 (7.6%)	27 (25.7%)
Total	N (% Total)	**12 (11.4%)**	**22 (21%)**	**10 (9.6%)**	**22 (21%)**	**39 (37.1%)**	**105 (100%)**

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on October 6, 2021. Only AEFIs reported and doses administered up to October 2, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Fortnightly COVID-19 AEFI Report
Date: Thursday, October 21, 2021 2:12:05 PM
Attachments: COVID19_AEFI_FORTNIGHTLY_Report_2021-10-21.docx
COVID19_AEFI_FORTNIGHTLY_Report_2021-10-21.pdf

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting on the website.

Thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to October 16, 2021

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Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

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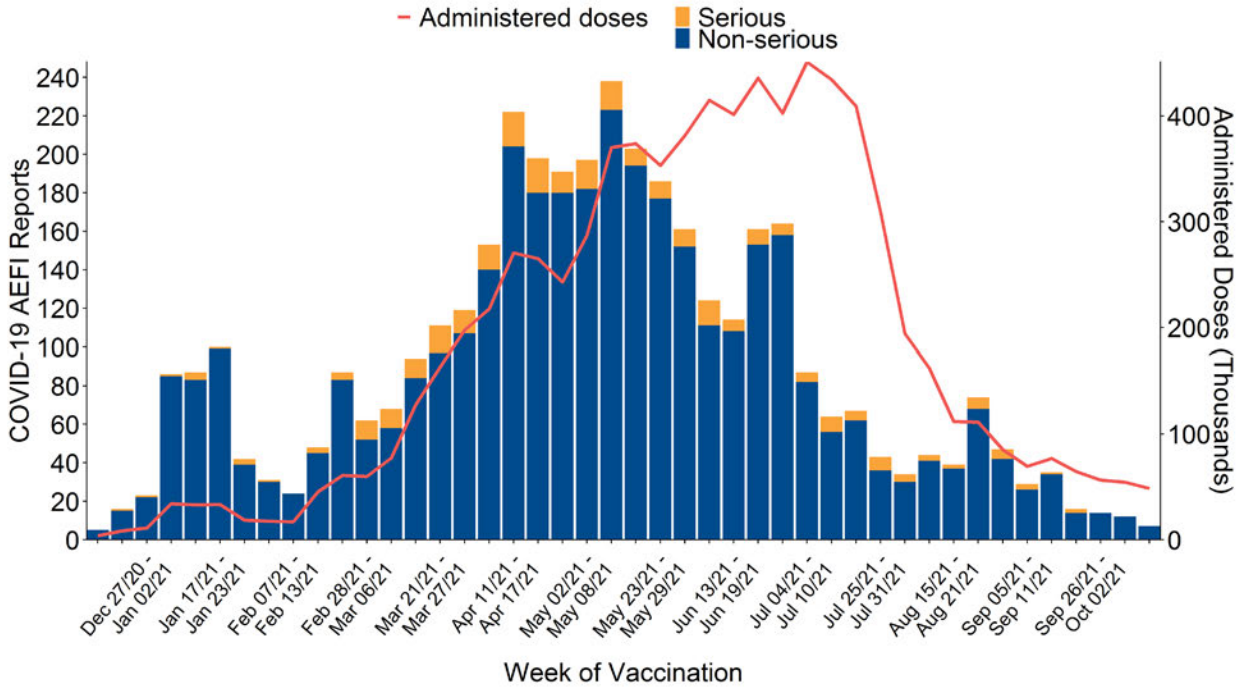
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of October 16, 2021, there have been 7,963,048 COVID-19 vaccine doses administered in BC and 3,927 COVID-19 AEFI reports (49.3 reports per 100,000 doses administered)
- 276 reports (7%) met the serious definition, for a rate of 3.5 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Oct. 16, 2021 **(N=3,927)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including October 16, 2021, a total of 7,963,048 doses have been administered. During this period, there have been 3,927 AEFI reports following a COVID-19 vaccine, for a reporting rate of 49.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Oct. 16, 2021 **(N=3,927)**

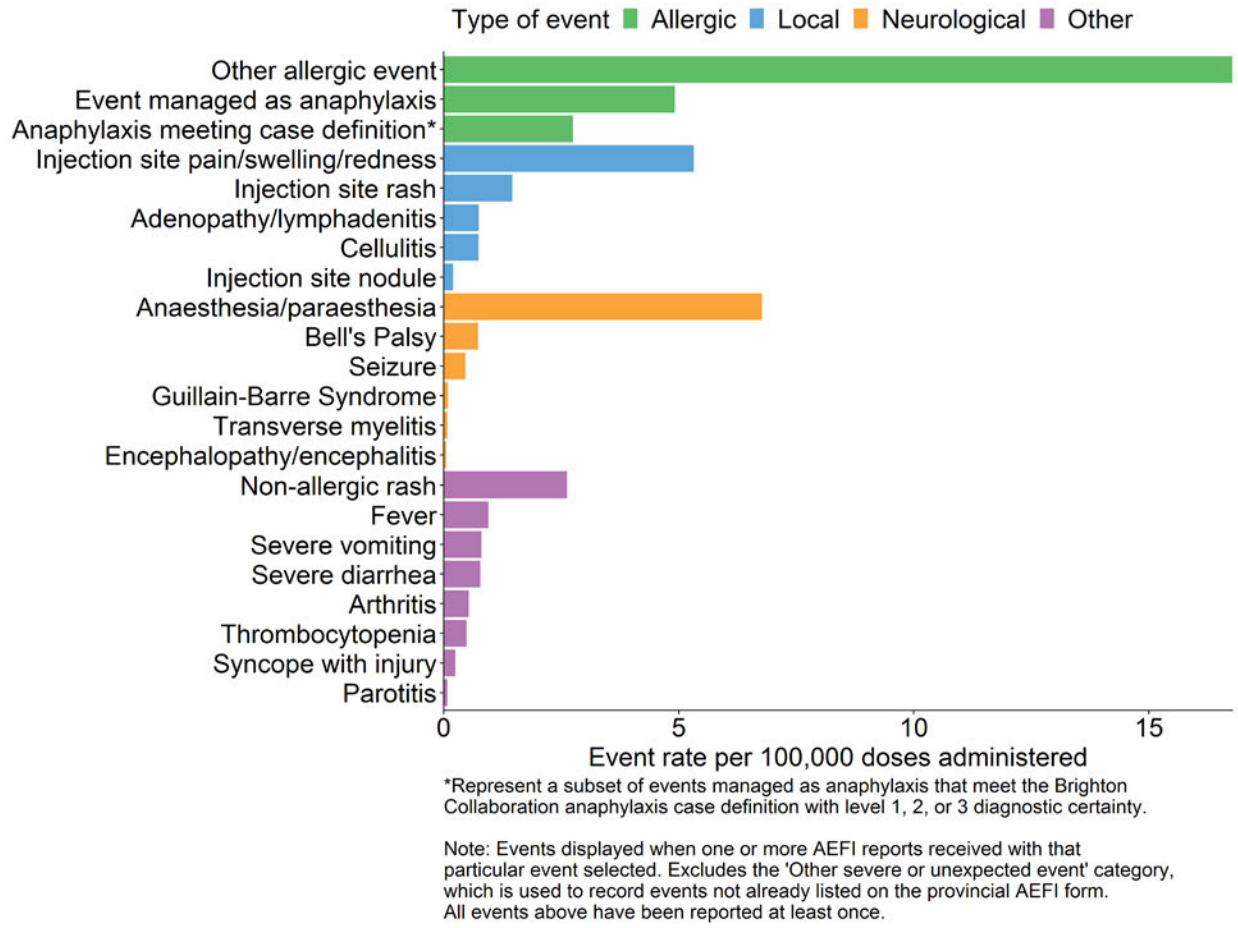
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3927**	**257**	**67**	**1297**	**2306**
Non-serious reports	3651	228	61	1213	2149
Serious reports	276	29	6	84	157
Proportion serious	7%	11.3%	9%	6.5%	6.8%
Dose 1 reports	3145	233	66	1009	1837
Dose 2 reports	773	24	1	281	467
Total doses administered	**7,963,048**	**328,542**	**71,329**	**1,973,336**	**5,589,841**
Dose 1 administered	4,280,720	225,294	61,220	1,010,842	2,983,364
Dose 2 administered	3,682,328	103,248	10,109	962,494	2,606,477
Total reporting rate	**49.3**	**78.2**	**93.9**	**65.7**	**41.3**
Serious rate	3.5	8.8	8.4	4.3	2.8
Dose 1 rate	73.5	103.4	107.8	99.8	61.6
Dose 2 rate	21.0	23.2	9.9	29.2	17.9

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,927 AEFI reports received up to October 16, 2021 contained a total of 4,976 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Oct. 16, 2021 **(N=4,976)**



Event Descriptions

Three hundred ninety-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 219 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-nine reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, rather than cellulitis.[15] None of these reports were confirmed by microbial testing.

Two hundred seventy-six reports (7%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 260 individuals were admitted to hospital, including 5% of cases reported as anaphylaxis.

One hundred and eighteen reports contained a diagnosed neurological event. Fifty-eight individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Four

individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional two individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging and the other's workup was inconsistent with transverse myelitis. Thirty-seven individuals were reported with seizures (21.6% of which were hospitalized), including 13 with a history of a seizure disorder. Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy attributed to a workplace toxin exposure and was hospitalized; this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt. There were seven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 35 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were thirteen reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8] Collectively, thrombocytopenia cases lead to 20 hospitalizations (52.6% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.

- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

- In six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction.

- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.

- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 119 were for various thrombotic/ thromboembolic conditions. These included 27 strokes (96.3% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 15 myocardial infarctions (all hospitalized), 31 pulmonary emboli (67.7% hospitalized), 38 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of whom were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 114 reports of pericarditis/myocarditis. Fifty-six individuals were diagnosed with pericarditis alone, 30 with myocarditis alone, and 35 with myopericarditis. Ages ranged from 14 to 95 with a median of 38.3 years, and 78 were male. Forty-three had received Moderna Spikevax vaccine, 71 received Pfizer Comirnaty vaccine, and seven received AstraZeneca/COVISHIELD. Fifty-seven of these events occurred after a second dose (30 Pfizer Comirnaty and 26 Moderna Spikevax). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Twenty-seven (out of 30) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-seven (out of 56) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-two (out of 35) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[21] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 – Oct. 16, 2021 **(N=114)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**10 (8.8%)**	**9 (7.9%)**	**10 (8.8%)**	**14 (12.3%)**	**43 (37.7%)**
Dose 1	N (% Total)	0 (0%)	2 (1.8%)	4 (3.5%)	5 (4.4%)	6 (5.3%)	17 (14.9%)
Dose 2	N (% Total)	0 (0%)	8 (7%)	5 (4.4%)	5 (4.4%)	8 (7%)	26 (22.8%)
Pfizer Comirnaty	**N (% Total)**	**14 (12.3%)**	**12 (10.5%)**	**3 (2.6%)**	**14 (12.3%)**	**28 (24.6%)**	**71 (62.3%)**
Dose 1	N (% Total)	6 (5.3%)	3 (2.6%)	1 (0.9%)	12 (10.5%)	19 (16.7%)	41 (36%)
Dose 2	N (% Total)	8 (7%)	9 (7.9%)	2 (1.8%)	2 (1.8%)	9 (7.9%)	30 (26.3%)
mRNA Vaccines	**N (% Total)**	**14 (12.3%)**	**22 (19.3%)**	**12 (10.6%)**	**24 (21.1%)**	**42 (36.9%)**	**114 (100%)**

Total = 114 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (6 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Data taken from Panorama up until 16th October, 2021

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 – Oct. 16, 2021. Stratified by sex, age groups, vaccine trade name, and dose **(N=114)**

Vaccine / Age Group	Reporting Rate† (95% CI)					
	Males			Females		
Moderna Spikevax	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	18.5 (4.5-68.2)	150.9 (74.4-281.5)	79.6 (41-143.5)	20.8 (5-76.7)	22.2 (5.4-82.1)	21.5 (6.6-59.9)
25-29	**83.5 (33.9-183)**	**118.2 (52-242.1)**	**99.8 (53.1-174.7)**	0 (0-0)	0 (0-0)	0 (0-0)
30-39	40.5 (16.4-88.8)	34.8 (12.6-83.8)	37.9 (18.7-70.6)	11.4 (2.8-42)	24.6 (7.6-68.5)	17.7 (6.4-42.7)
40+	12.7 (5.1-27.8)	13.2 (5.4-28.9)	12.9 (6.6-23.3)	6.4 (2-17.8)	12.6 (5.1-27.5)	9.5 (4.5-18.5)
All Ages	25.1 (14.8-40.4)	**39.6 (25.5-59.4)**	**32.1 (22.8-44.1)**	8.1 (3.3-17.8)	14.4 (7.1-26.9)	11.2 (6.3-18.8)
Pfizer Comirnaty	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	38.6 (17-79.1)	51.6 (24.2-100.4)	44.8 (25.2-74.8)	7.9 (1.9-29.3)	17.6 (5.4-48.9)	12.5 (4.5-30.1)
18-24	21.7 (7.9-52.1)	51.1 (24-99.3)	35.1 (18.7-61.6)	0 (0-0)	23.7 (8.6-57.2)	11.1 (4-26.8)
25-29	**8.8 (2.1-32.4)**	**10.2 (2.5-37.6)**	**9.4 (2.9-26.3)**	0 (0-0)	9.4 (2.3-34.9)	4.5 (1.1-16.4)
30-39	40.8 (21.7-71.4)	5.2 (1.3-19.2)	24.2 (13.3-41.4)	12.7 (4.6-30.5)	4.7 (1.1-17.5)	8.9 (3.6-19.6)
40+	8.6 (4.3-16.1)	5.7 (2.3-12.6)	7.3 (4.1-12.2)	12.8 (7.4-20.9)	6 (2.7-12.4)	9.6 (6-14.7)
All Ages	17.6 (12-25.2)	**14.7 (9.3-22.2)**	**16.3 (12.1-21.5)**	10.2 (6.3-15.8)	8.7 (5-14.2)	9.5 (6.6-13.3)

mRNA Vaccines	Dose 1	Dose 2	All Doses	Dose 1	Dose 2	All Doses
12-17	38.1 (16.8-78.0)	51.2 (24.0-99.5)	44.2 (24.9-74.0)	7.8 (1.9-28.9)	17.4 (5.4-48.5)	12.4 (4.5-29.8)
18-24	20.8 (8.4-45.5)	79.3 (46.7-127.9)	47.7 (29.9-72.9)	5.2 (1.3-19.3)	23.4 (9.5-51.2)	13.8 (6.1-28.3)
25-29	30.9 (13.6-63.4)	42.7 (20-83.1)	36.4 (20.5-60.9)	0 (0-0)	6.9 (1.7-25.4)	3.3 (0.8-12.1)
30-39	40.7 (23.9-65.6)	14.4 (5.8-31.5)	28.4 (17.8-43.5)	12.3 (5.0-27.0)	10.3 (3.7-24.7)	11.3 (5.6-21.2)
40+	9.8 (5.5-16.3)	8 (4.1-14.4)	8.9 (5.7-13.4)	11.2 (6.7-17.7)	7.9 (4.2-13.8)	9.6 (6.4-13.9)
All Ages	19.6 (14.3-26.4)	21.7 (15.8-29.3)	20.6 (16.5-25.5)	9.7 (6.3-14.4)	10.2 (6.5-15.2)	9.9 (7.3-13.3)

† Rates calculated per 1 million doses administered. Data taken from Panorama up until 16th October, 2021. These rates were calculated from reports of myocarditis/pericarditis without accounting for Brighton Collaboration levels.

Table 3 shows the rates for Myo/Pericarditis following either dose (or both doses combined) of Moderna Spikevax in BC are higher than those following the respective dose(s) of the Pfizer Comirnaty vaccine for males between 25 and 29 years old. The rates following a second dose (and both doses combined) of Moderna Spikevax are also higher for males of all ages combined. No significant difference in rates was observed by product for females.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on October 20, 2021. Only AEFIs reported and doses administered up to October 16, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to October 16, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including October 16, 2021. Please refer to the BCCDC website for reporting guidelines and to the Data Notes section at the end of this report for additional information on the source data.[1] Events can be reported even when there is no certainty of a casual association.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-7,22,23]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,9,22]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[10] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[11] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[12]

Definitions

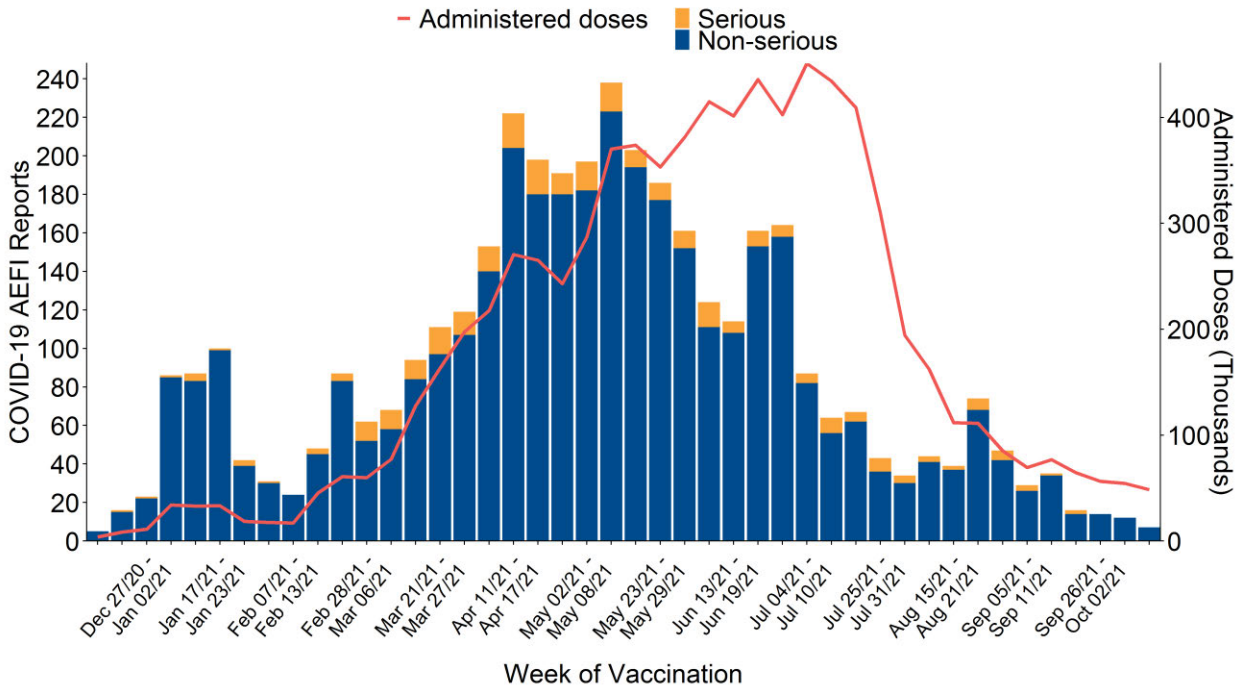
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of October 16, 2021, there have been 7,963,048 COVID-19 vaccine doses administered in BC and 3,927 COVID-19 AEFI reports (49.3 reports per 100,000 doses administered)
- 276 reports (7%) met the serious definition, for a rate of 3.5 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Oct. 16, 2021 **(N=3,927)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including October 16, 2021, a total of 7,963,048 doses have been administered. During this period, there have been 3,927 AEFI reports following a COVID-19 vaccine, for a reporting rate of 49.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Oct. 16, 2021 **(N=3,927)**

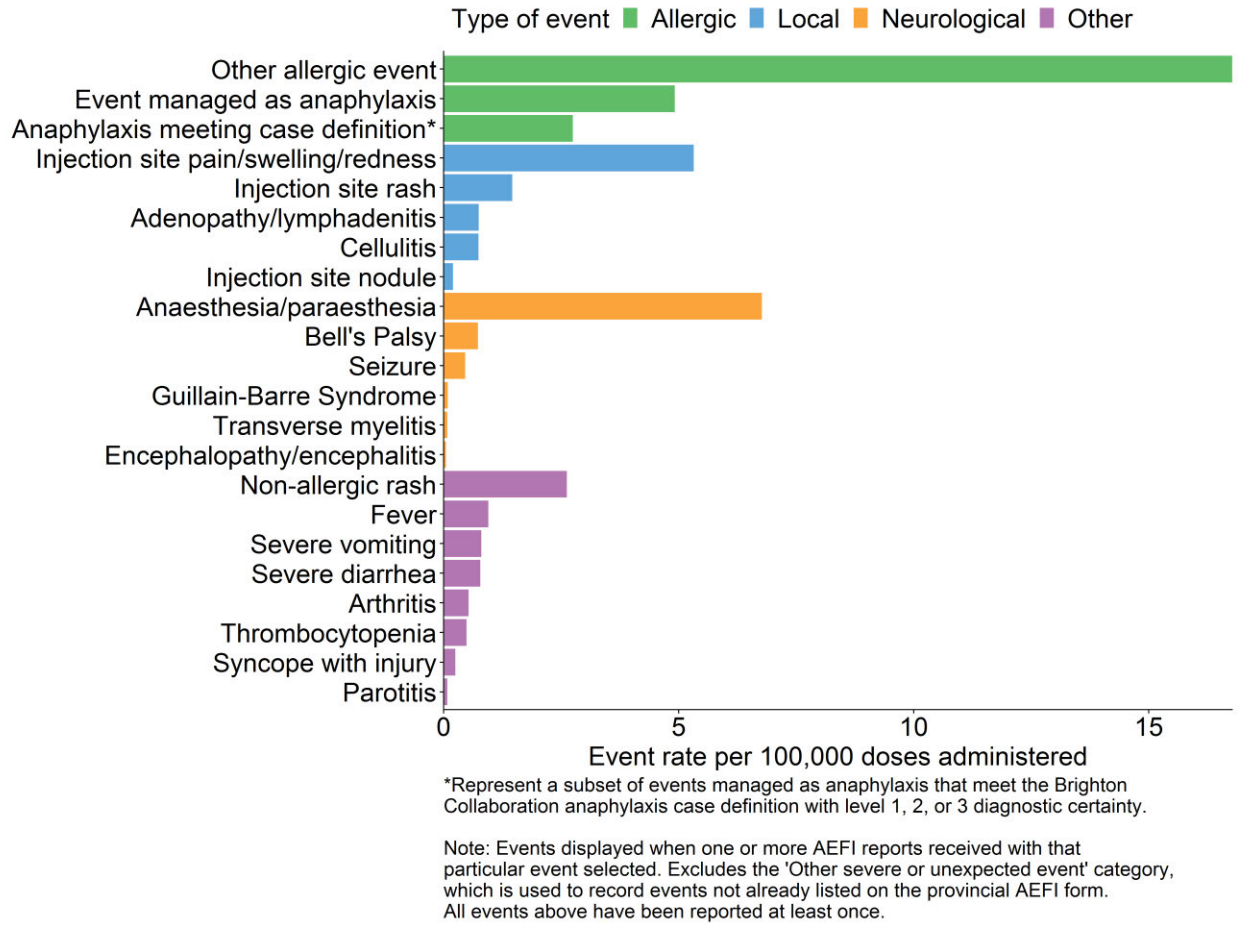
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3927**	**257**	**67**	**1297**	**2306**
Non-serious reports	3651	228	61	1213	2149
Serious reports	276	29	6	84	157
Proportion serious	7%	11.3%	9%	6.5%	6.8%
Dose 1 reports	3145	233	66	1009	1837
Dose 2 reports	773	24	1	281	467
Total doses administered	**7,963,048**	**328,542**	**71,329**	**1,973,336**	**5,589,841**
Dose 1 administered	4,280,720	225,294	61,220	1,010,842	2,983,364
Dose 2 administered	3,682,328	103,248	10,109	962,494	2,606,477
Total reporting rate	**49.3**	**78.2**	**93.9**	**65.7**	**41.3**
Serious rate	3.5	8.8	8.4	4.3	2.8
Dose 1 rate	73.5	103.4	107.8	99.8	61.6
Dose 2 rate	21.0	23.2	9.9	29.2	17.9

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 3,927 AEFI reports received up to October 16, 2021 contained a total of 4,976 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Oct. 16, 2021 **(N=4,976)**



Event Descriptions

Three hundred ninety-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 219 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[14] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Fifty-nine reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction, rather than cellulitis.[15] None of these reports were confirmed by microbial testing.

Two hundred seventy-six reports (7%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 260 individuals were admitted to hospital, including 5% of cases reported as anaphylaxis.

One hundred and eighteen reports contained a diagnosed neurological event. Fifty-eight individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Four

individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional two individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging and the other's workup was inconsistent with transverse myelitis. Thirty-seven individuals were reported with seizures (21.6% of which were hospitalized), including 13 with a history of a seizure disorder. Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy attributed to a workplace toxin exposure and was hospitalized; this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt. There were seven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[12,16,17] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[18]

There were 35 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were thirteen reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative.[7,8] Collectively, thrombocytopenia cases lead to 20 hospitalizations (52.6% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[10] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.

- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

- In six individuals, death was the outcome of cardiac arrest. Five of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction.

- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.

- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 119 were for various thrombotic/ thromboembolic conditions. These included 27 strokes (96.3% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 15 myocardial infarctions (all hospitalized), 31 pulmonary emboli (67.7% hospitalized), 38 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[8,9]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[19] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[20]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of whom were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 114 reports of pericarditis/myocarditis. Fifty-six individuals were diagnosed with pericarditis alone, 30 with myocarditis alone, and 35 with myopericarditis. Ages ranged from 14 to 95 with a median of 38.3 years, and 78 were male. Forty-three had received Moderna Spikevax vaccine, 71 received Pfizer Comirnaty vaccine, and seven received AstraZeneca/COVISHIELD. Fifty-seven of these events occurred after a second dose (30 Pfizer Comirnaty and 26 Moderna Spikevax). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Twenty-seven (out of 30) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-seven (out of 56) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-two (out of 35) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[21] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,12]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 – Oct. 16, 2021 **(N=114)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**10 (8.8%)**	**9 (7.9%)**	**10 (8.8%)**	**14 (12.3%)**	**43 (37.7%)**
Dose 1	N (% Total)	0 (0%)	2 (1.8%)	4 (3.5%)	5 (4.4%)	6 (5.3%)	17 (14.9%)
Dose 2	N (% Total)	0 (0%)	8 (7%)	5 (4.4%)	5 (4.4%)	8 (7%)	26 (22.8%)
Pfizer Comirnaty	**N (% Total)**	**14 (12.3%)**	**12 (10.5%)**	**3 (2.6%)**	**14 (12.3%)**	**28 (24.6%)**	**71 (62.3%)**
Dose 1	N (% Total)	6 (5.3%)	3 (2.6%)	1 (0.9%)	12 (10.5%)	19 (16.7%)	41 (36%)
Dose 2	N (% Total)	8 (7%)	9 (7.9%)	2 (1.8%)	2 (1.8%)	9 (7.9%)	30 (26.3%)
mRNA Vaccines	**N (% Total)**	**14 (12.3%)**	**22 (19.3%)**	**12 (10.6%)**	**24 (21.1%)**	**42 (36.9%)**	**114 (100%)**

Total = 114 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (6 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Data taken from Panorama up until 16th October, 2021

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 – Oct. 16, 2021. Stratified by sex, age groups, vaccine trade name, and dose **(N=114)**

Vaccine / Age Group	Reporting Rate† (95% CI)					
	Males			Females		
Moderna Spikevax	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	18.5 (4.5-68.2)	150.9 (74.4-281.5)	79.6 (41-143.5)	20.8 (5-76.7)	22.2 (5.4-82.1)	21.5 (6.6-59.9)
25-29	**83.5 (33.9-183)**	**118.2 (52-242.1)**	**99.8 (53.1-174.7)**	0 (0-0)	0 (0-0)	0 (0-0)
30-39	40.5 (16.4-88.8)	34.8 (12.6-83.8)	37.9 (18.7-70.6)	11.4 (2.8-42)	24.6 (7.6-68.5)	17.7 (6.4-42.7)
40+	12.7 (5.1-27.8)	13.2 (5.4-28.9)	12.9 (6.6-23.3)	6.4 (2-17.8)	12.6 (5.1-27.5)	9.5 (4.5-18.5)
All Ages	25.1 (14.8-40.4)	**39.6 (25.5-59.4)**	**32.1 (22.8-44.1)**	8.1 (3.3-17.8)	14.4 (7.1-26.9)	11.2 (6.3-18.8)
Pfizer Comirnaty	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	38.6 (17-79.1)	51.6 (24.2-100.4)	44.8 (25.2-74.8)	7.9 (1.9-29.3)	17.6 (5.4-48.9)	12.5 (4.5-30.1)
18-24	21.7 (7.9-52.1)	51.1 (24-99.3)	35.1 (18.7-61.6)	0 (0-0)	23.7 (8.6-57.2)	11.1 (4-26.8)
25-29	**8.8 (2.1-32.4)**	**10.2 (2.5-37.6)**	**9.4 (2.9-26.3)**	0 (0-0)	9.4 (2.3-34.9)	4.5 (1.1-16.4)
30-39	40.8 (21.7-71.4)	5.2 (1.3-19.2)	24.2 (13.3-41.4)	12.7 (4.6-30.5)	4.7 (1.1-17.5)	8.9 (3.6-19.6)
40+	8.6 (4.3-16.1)	5.7 (2.3-12.6)	7.3 (4.1-12.2)	12.8 (7.4-20.9)	6 (2.7-12.4)	9.6 (6-14.7)
All Ages	17.6 (12-25.2)	**14.7 (9.3-22.2)**	**16.3 (12.1-21.5)**	10.2 (6.3-15.8)	8.7 (5-14.2)	9.5 (6.6-13.3)

mRNA Vaccines	Dose 1	Dose 2	All Doses	Dose 1	Dose 2	All Doses
12-17	38.1 (16.8-78.0)	51.2 (24.0-99.5)	44.2 (24.9-74.0)	7.8 (1.9-28.9)	17.4 (5.4-48.5)	12.4 (4.5-29.8)
18-24	20.8 (8.4-45.5)	79.3 (46.7-127.9)	47.7 (29.9-72.9)	5.2 (1.3-19.3)	23.4 (9.5-51.2)	13.8 (6.1-28.3)
25-29	30.9 (13.6-63.4)	42.7 (20-83.1)	36.4 (20.5-60.9)	0 (0-0)	6.9 (1.7-25.4)	3.3 (0.8-12.1)
30-39	40.7 (23.9-65.6)	14.4 (5.8-31.5)	28.4 (17.8-43.5)	12.3 (5.0-27.0)	10.3 (3.7-24.7)	11.3 (5.6-21.2)
40+	9.8 (5.5-16.3)	8 (4.1-14.4)	8.9 (5.7-13.4)	11.2 (6.7-17.7)	7.9 (4.2-13.8)	9.6 (6.4-13.9)
All Ages	19.6 (14.3-26.4)	21.7 (15.8-29.3)	20.6 (16.5-25.5)	9.7 (6.3-14.4)	10.2 (6.5-15.2)	9.9 (7.3-13.3)

† Rates calculated per 1 million doses administered. Data taken from Panorama up until 16th October, 2021. These rates were calculated from reports of myocarditis/pericarditis without accounting for Brighton Collaboration levels.

Table 3 shows the rates for Myo/Pericarditis following either dose (or both doses combined) of Moderna Spikevax in BC are higher than those following the respective dose(s) of the Pfizer Comirnaty vaccine for males between 25 and 29 years old. The rates following a second dose (and both doses combined) of Moderna Spikevax are also higher for males of all ages combined. No significant difference in rates was observed by product for females.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on October 20, 2021. Only AEFIs reported and doses administered up to October 16, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Fortnightly COVID-19 AEFI Report
Date: Thursday, November 04, 2021 4:05:16 PM
Attachments: COVID19_AEFI_Fortnightly_Report_2021-11-04.docx
COVID19_AEFI_Fortnightly_Report_2021-11-04.pdf

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting on the website.

Thank you for all your hard work.

Best,

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to October 30, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including October 30, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

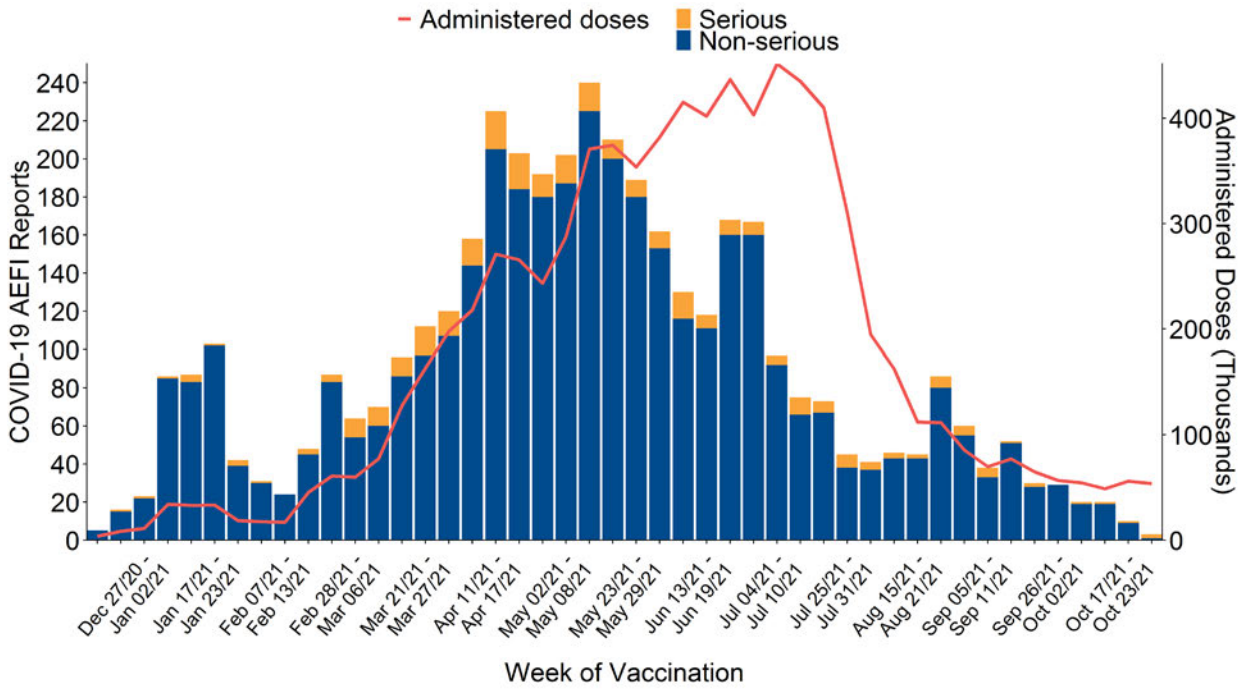
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of October 30, 2021, there have been 8,088,280 COVID-19 vaccine doses administered in BC and 4,148 COVID-19 AEFI reports (51.3 reports per 100,000 doses administered)
- 296 reports (7.1%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Oct. 30, 2021 **(N=4,148)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including October 30, 2021, a total of 8,088,280 doses have been administered. During this period, there have been 4,148 AEFI reports following a COVID-19 vaccine, for a reporting rate of 51.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Oct. 30, 2021 **(N=4,148)**

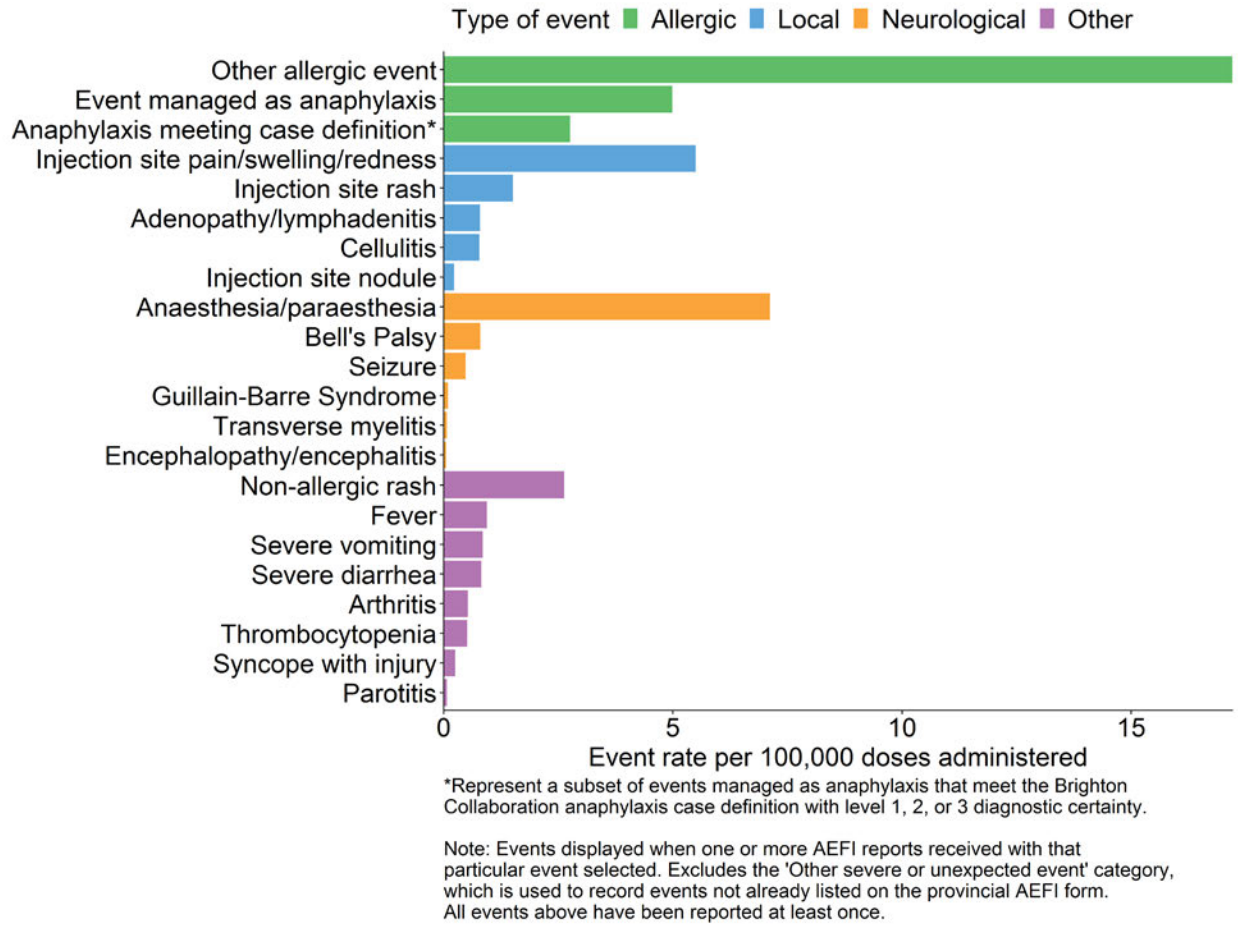
	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**
Total reports	**4148**	**265**	**67**	**1392**	**2424**
Non-serious reports	3852	234	61	1301	2256
Serious reports	296	31	6	91	168
Proportion serious	7.1%	11.7%	9%	6.5%	6.9%
Dose 1 reports	3313	241	66	1085	1921
Dose 2 reports	822	24	1	297	500
Total doses administered	**8,088,280**	**330,210**	**72,682**	**2,012,772**	**5,672,615**
Dose 1 administered	4,316,940	226,187	61,915	1,021,563	3,007,274
Dose 2 administered	3,771,340	104,023	10,767	991,209	2,665,341
Total reporting rate	**51.3**	**80.3**	**92.2**	**69.2**	**42.7**
Serious rate	3.7	9.4	8.3	4.5	3.0
Dose 1 rate	76.7	106.5	106.6	106.2	63.9
Dose 2 rate	21.8	23.1	9.3	30.0	18.8

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 4,148 AEFI reports received up to October 30, 2021 contained a total of 5,252 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Oct. 30, 2021 **(N=5,252)**



Event Descriptions

Four hundred four reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 223 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Sixty-three reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Two hundred ninety-six reports (7.1%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 279 individuals were admitted to hospital, including 4.6% of cases reported as anaphylaxis.

One hundred and twenty-seven reports contained a diagnosed neurological event. Sixty-five individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Four

individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional two individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging and the other's workup was inconsistent with transverse myelitis. Thirty-nine individuals were reported with seizures (21.6% of which were hospitalized), including 13 with a history of a seizure disorder. Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy attributed to a workplace toxin exposure and was hospitalized; this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt. There were seven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 36 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were thirteen reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases lead to 23 hospitalizations (63.9% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Fourteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.[†]

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

- In four individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.

[†] In previous reports, two records were erroneously included in the death count above. These records do not meet the reporting criteria and have been removed.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 126 were for various thrombotic/ thromboembolic conditions. These included 28 strokes (96.4% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 17 myocardial infarctions (all hospitalized), 33 pulmonary emboli (63.6% hospitalized), 40 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of whom were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 125 reports of pericarditis/myocarditis. Thirty-four individuals were diagnosed with myocarditis, 59 with pericarditis, and 39 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.3 years, and 82 were male. Forty-seven had received Moderna Spikevax vaccine, 78 received Pfizer Comirnaty vaccine, and seven received AstraZeneca Verity/Verity COVISHIELD. Sixty-two of these events occurred after a second dose (27 Moderna Spikevax and 34 Pfizer Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Thirty (out of 304) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-seven (out of 59) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-three (out of 39) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Oct. 30, 2021 **(N=125)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**11 (8.8%)**	**11 (8.8%)**	**10 (8%)**	**15 (12%)**	**47 (37.6%)**
Dose 1	N (% Total)	0 (0%)	3 (2.4%)	6 (4.8%)	5 (4%)	6 (4.8%)	20 (16%)
Dose 2	N (% Total)	0 (0%)	8 (6.4%)	5 (4%)	5 (4%)	9 (7.2%)	27 (21.6%)
Pfizer Comirnaty	**N (% Total)**	**15 (12%)**	**15 (12%)**	**4 (3.2%)**	**15 (12%)**	**29 (23.2%)**	**78 (62.4%)**
Dose 1	N (% Total)	6 (4.8%)	4 (3.2%)	1 (0.8%)	13 (10.4%)	20 (16%)	44 (35.2%)
Dose 2	N (% Total)	9 (7.2%)	11 (8.8%)	3 (2.4%)	2 (1.6%)	9 (7.2%)	34 (27.2%)
mRNA Vaccines	**N (% Total)**	**15 (12%)**	**26 (20.8%)**	**15 (12%)**	**25 (20%)**	**44 (35.2%)**	**125 (100%)**

Total = 125 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (6 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Data taken from Panorama up until 30th October, 2021

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Oct. 30, 2021. Stratified by sex, age groups, vaccine trade name, and dose **(N=125)**

Vaccine / Age Group	Reporting Rate* (95% CI)					
	Males			Females		
Moderna Spikevax	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	36.5 (11.3-101.8)	141.8 (69.9-264.5)	86.4 (46.1-151.4)	20.6 (5-76)	21.3 (5.2-78.7)	21 (6.5-58.4)
25-29	**82.2 (33.4-180.2)**	**111.3 (49-228.1)**	**96.2 (51.3-168.5)**	47.9 (14.8-133.5)	0 (0-0)	24.1 (7.5-67.1)
30-39	39.9 (16.2-87.4)	33.3 (12.1-80.1)	36.7 (18.1-68.5)	11.2 (2.7-41.4)	23.7 (7.3-66.1)	17.3 (6.3-41.7)
40+	12.6 (5.1-27.5)	12.9 (5.2-28.3)	12.7 (6.6-23)	6.3 (2-17.6)	15.5 (6.8-31.7)	10.9 (5.4-20.4)
All Ages	26.7 (16-42.4)	**38.4 (24.7-57.4)**	**32.4 (23.1-44.3)**	12.1 (5.7-23.5)	16.1 (8.3-29)	14.1 (8.4-22.4)
Pfizer Comirnaty	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	38.2 (16.8-78.2)	58.1 (28.7-108.4)	47.7 (27.5-78.3)	7.9 (1.9-29)	17 (5.3-47.3)	12.3 (4.5-29.5)
18-24	21.4 (7.8-51.4)	56.4 (27.8-105.2)	37.8 (20.8-64.6)	6.9 (1.7-25.5)	30.6 (12.4-67)	18.2 (8-37.2)
25-29	**8.7 (2.1-32)**	**9.7 (2.4-35.9)**	**9.2 (2.8-25.5)**	0 (0-0)	18.3 (5.7-50.9)	8.7 (2.7-24.3)
30-39	44.7 (24.5-76.3)	5 (1.2-18.5)	26 (14.7-43.5)	12.5 (4.6-30.2)	4.6 (1.1-17)	8.8 (3.6-19.2)
40+	8.6 (4.2-16)	5.7 (2.3-12.4)	7.2 (4.1-12.1)	13.8 (8.1-22.2)	6 (2.6-12.3)	10.1 (6.4-15.3)
All Ages	18.2 (12.4-25.8)	**15.9 (10.4-23.6)**	**17.1 (12.9-22.4)**	11.4 (7.2-17.2)	9.9 (5.9-15.7)	10.7 (7.6-14.7)

mRNA Vaccines	Dose 1	Dose 2	All Doses	Dose 1	Dose 2	All Doses
12-17	37.6 (16.6-77)	57.5 (28.4-107.3)	47.1 (27.2-77.3)	7.7 (1.9-28.6)	16.8 (5.2-46.8)	12.1 (4.4-29.1)
18-24	25.6 (11.3-52.5)	80.7 (48.4-128.1)	51.5 (33.1-77.2)	10.4 (3.2-28.9)	28.1 (12.4-57.6)	18.9 (9.3-35.2)
25-29	30.5 (13.4-62.5)	40.6 (19.1-79)	35.3 (19.9-59)	12.3 (3.8-34.4)	13.3 (4.1-37)	12.8 (5.2-28)
30-39	43.2 (25.9-68.6)	13.8 (5.6-30.3)	29.4 (18.7-44.4)	12.2 (4.9-26.7)	10 (3.6-24)	11.1 (5.5-20.7)
40+	9.7 (5.5-16.2)	7.9 (4-14.2)	8.8 (5.7-13.2)	11.9 (7.3-18.6)	8.6 (4.7-14.7)	10.3 (7-14.8)
All Ages	20.5 (15.1-27.3)	22.3 (16.3-29.8)	21.3 (17.1-26.3)	11.6 (7.8-16.6)	11.5 (7.6-16.8)	11.5 (8.7-15.1)

† Rates calculated per 1 million doses administered. Data taken from Panorama up until 30th October, 2021. These rates were calculated from reports of myocarditis/pericarditis without accounting for Brighton Collaboration levels.

Table 3 shows the rates for Myo/Pericarditis following either dose (or both doses combined) of Moderna Spikevax in BC are higher than those following the respective dose(s) of the Pfizer Comirnaty vaccine for males between 25 and 29 years old. The rates following a second dose (and both doses combined) of Moderna Spikevax are also higher for males of all ages combined. No significant difference in rates was observed by product for females.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on November 3, 2021. Only AEFIs reported and doses administered up to October 30, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to October 30, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including October 30, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

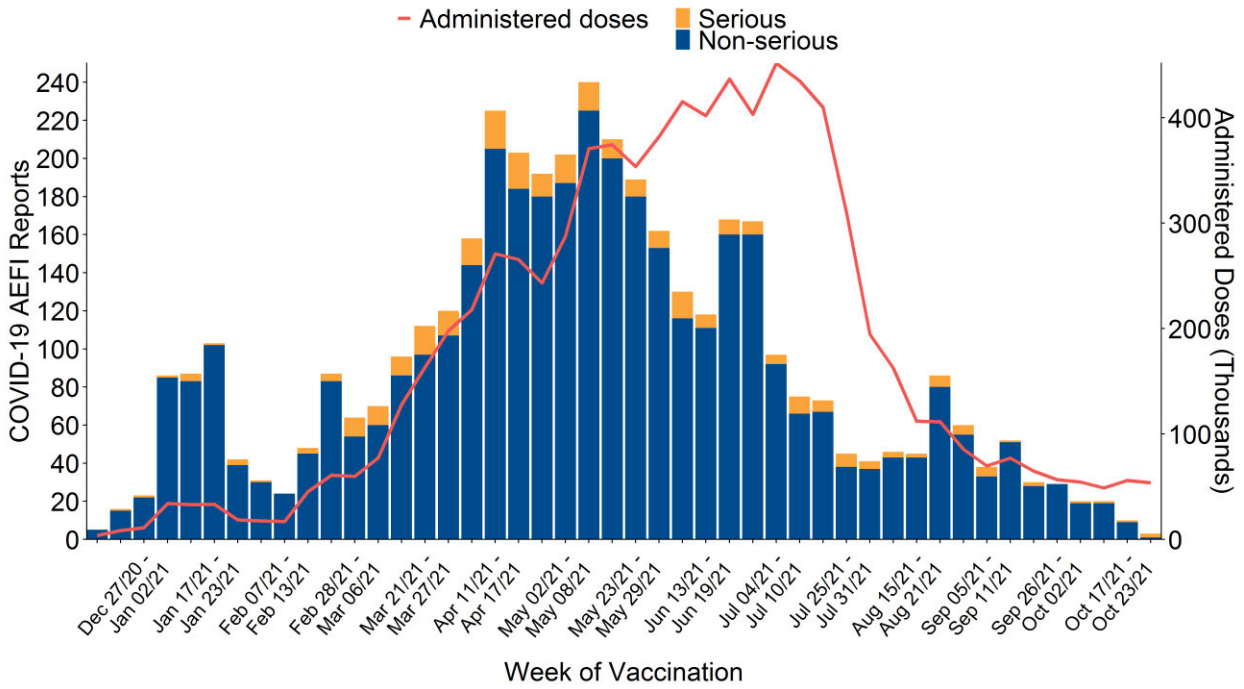
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of October 30, 2021, there have been 8,088,280 COVID-19 vaccine doses administered in BC and 4,148 COVID-19 AEFI reports (51.3 reports per 100,000 doses administered)
- 296 reports (7.1%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Oct. 30, 2021 **(N=4,148)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including October 30, 2021, a total of 8,088,280 doses have been administered. During this period, there have been 4,148 AEFI reports following a COVID-19 vaccine, for a reporting rate of 51.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Oct. 30, 2021 **(N=4,148)**

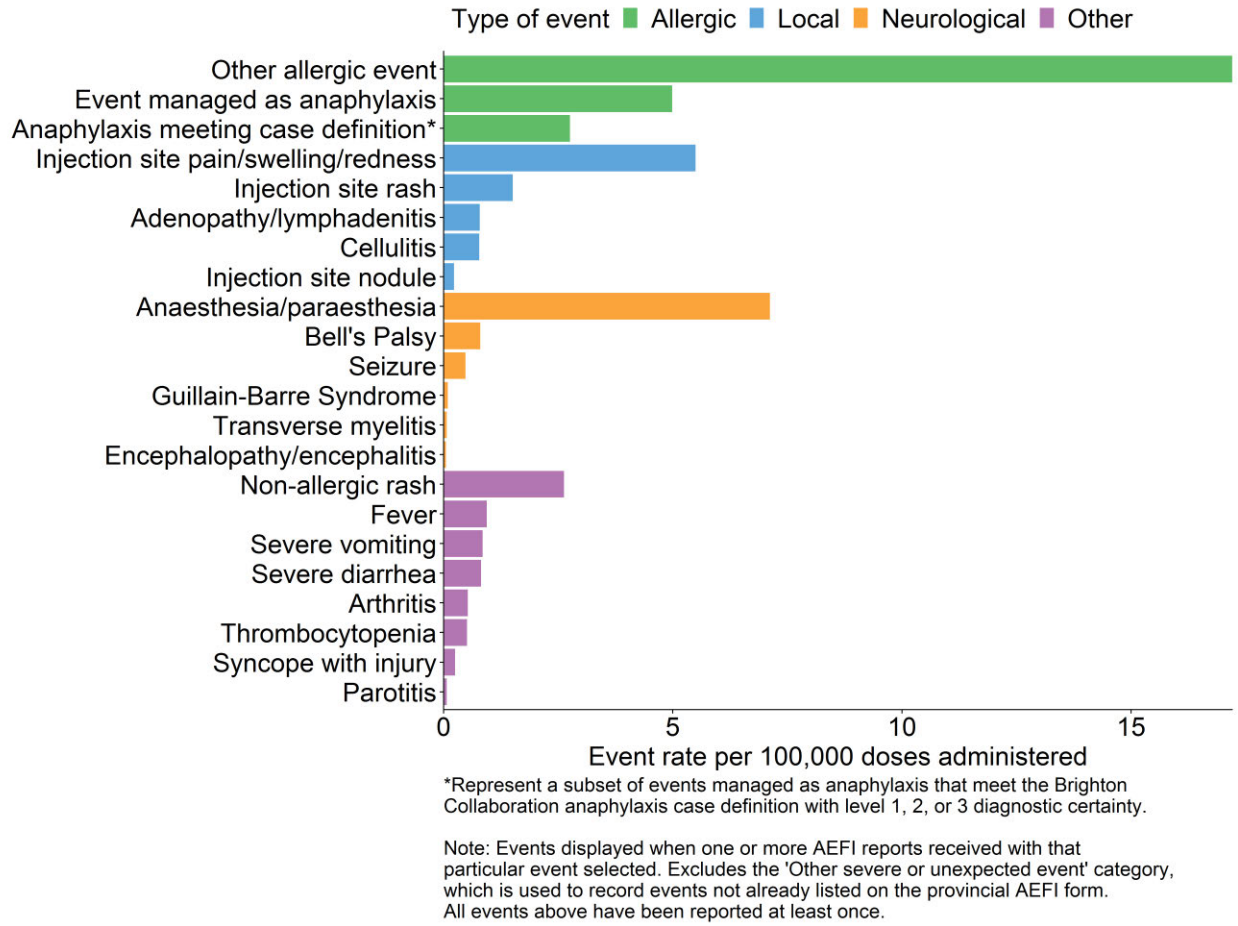
	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**
Total reports	**4148**	**265**	**67**	**1392**	**2424**
Non-serious reports	3852	234	61	1301	2256
Serious reports	296	31	6	91	168
Proportion serious	7.1%	11.7%	9%	6.5%	6.9%
Dose 1 reports	3313	241	66	1085	1921
Dose 2 reports	822	24	1	297	500
Total doses administered	**8,088,280**	**330,210**	**72,682**	**2,012,772**	**5,672,615**
Dose 1 administered	4,316,940	226,187	61,915	1,021,563	3,007,274
Dose 2 administered	3,771,340	104,023	10,767	991,209	2,665,341
Total reporting rate	**51.3**	**80.3**	**92.2**	**69.2**	**42.7**
Serious rate	3.7	9.4	8.3	4.5	3.0
Dose 1 rate	76.7	106.5	106.6	106.2	63.9
Dose 2 rate	21.8	23.1	9.3	30.0	18.8

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 4,148 AEFI reports received up to October 30, 2021 contained a total of 5,252 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Oct. 30, 2021 **(N=5,252)**



Event Descriptions

Four hundred four reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 223 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Sixty-three reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Two hundred ninety-six reports (7.1%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 279 individuals were admitted to hospital, including 4.6% of cases reported as anaphylaxis.

One hundred and twenty-seven reports contained a diagnosed neurological event. Sixty-five individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Four

individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional two individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging and the other's workup was inconsistent with transverse myelitis. Thirty-nine individuals were reported with seizures (21.6% of which were hospitalized), including 13 with a history of a seizure disorder. Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom had a subsequent encephalopathy. One individual was hospitalized for aseptic meningitis and another for encephalitis presumed to be viral in nature. One individual developed encephalopathy attributed to a workplace toxin exposure and was hospitalized; this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt. There were seven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 36 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were thirteen reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases lead to 23 hospitalizations (63.9% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Fourteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.[†]

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.

- In four individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, while the other had cardiac risk factors and was hospitalized for a myocardial infarction.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.

[†] In previous reports, two records were erroneously included in the death count above. These records do not meet the reporting criteria and have been removed.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 126 were for various thrombotic/ thromboembolic conditions. These included 28 strokes (96.4% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 17 myocardial infarctions (all hospitalized), 33 pulmonary emboli (63.6% hospitalized), 40 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been four non-fatal confirmed cases of TTS reported in BC to date, three of whom were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative.

There have been 125 reports of pericarditis/myocarditis. Thirty-four individuals were diagnosed with myocarditis, 59 with pericarditis, and 39 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.3 years, and 82 were male. Forty-seven had received Moderna Spikevax vaccine, 78 received Pfizer Comirnaty vaccine, and seven received AstraZeneca Verity/Verity COVISHIELD. Sixty-two of these events occurred after a second dose (27 Moderna Spikevax and 34 Pfizer Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Thirty (out of 304) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-seven (out of 59) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-three (out of 39) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Oct. 30, 2021 **(N=125)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**11 (8.8%)**	**11 (8.8%)**	**10 (8%)**	**15 (12%)**	**47 (37.6%)**
Dose 1	N (% Total)	0 (0%)	3 (2.4%)	6 (4.8%)	5 (4%)	6 (4.8%)	20 (16%)
Dose 2	N (% Total)	0 (0%)	8 (6.4%)	5 (4%)	5 (4%)	9 (7.2%)	27 (21.6%)
Pfizer Comirnaty	**N (% Total)**	**15 (12%)**	**15 (12%)**	**4 (3.2%)**	**15 (12%)**	**29 (23.2%)**	**78 (62.4%)**
Dose 1	N (% Total)	6 (4.8%)	4 (3.2%)	1 (0.8%)	13 (10.4%)	20 (16%)	44 (35.2%)
Dose 2	N (% Total)	9 (7.2%)	11 (8.8%)	3 (2.4%)	2 (1.6%)	9 (7.2%)	34 (27.2%)
mRNA Vaccines	**N (% Total)**	**15 (12%)**	**26 (20.8%)**	**15 (12%)**	**25 (20%)**	**44 (35.2%)**	**125 (100%)**

Total = 125 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (6 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Data taken from Panorama up until 30th October, 2021

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Oct. 30, 2021. Stratified by sex, age groups, vaccine trade name, and dose **(N=125)**

Vaccine / Age Group	Reporting Rate* (95% CI)					
	Males			Females		
Moderna Spikevax	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	36.5 (11.3-101.8)	141.8 (69.9-264.5)	86.4 (46.1-151.4)	20.6 (5-76)	21.3 (5.2-78.7)	21 (6.5-58.4)
25-29	**82.2 (33.4-180.2)**	**111.3 (49-228.1)**	**96.2 (51.3-168.5)**	47.9 (14.8-133.5)	0 (0-0)	24.1 (7.5-67.1)
30-39	39.9 (16.2-87.4)	33.3 (12.1-80.1)	36.7 (18.1-68.5)	11.2 (2.7-41.4)	23.7 (7.3-66.1)	17.3 (6.3-41.7)
40+	12.6 (5.1-27.5)	12.9 (5.2-28.3)	12.7 (6.6-23)	6.3 (2-17.6)	15.5 (6.8-31.7)	10.9 (5.4-20.4)
All Ages	26.7 (16-42.4)	**38.4 (24.7-57.4)**	**32.4 (23.1-44.3)**	12.1 (5.7-23.5)	16.1 (8.3-29)	14.1 (8.4-22.4)
Pfizer Comirnaty	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	38.2 (16.8-78.2)	58.1 (28.7-108.4)	47.7 (27.5-78.3)	7.9 (1.9-29)	17 (5.3-47.3)	12.3 (4.5-29.5)
18-24	21.4 (7.8-51.4)	56.4 (27.8-105.2)	37.8 (20.8-64.6)	6.9 (1.7-25.5)	30.6 (12.4-67)	18.2 (8-37.2)
25-29	**8.7 (2.1-32)**	**9.7 (2.4-35.9)**	**9.2 (2.8-25.5)**	0 (0-0)	18.3 (5.7-50.9)	8.7 (2.7-24.3)
30-39	44.7 (24.5-76.3)	5 (1.2-18.5)	26 (14.7-43.5)	12.5 (4.6-30.2)	4.6 (1.1-17)	8.8 (3.6-19.2)
40+	8.6 (4.2-16)	5.7 (2.3-12.4)	7.2 (4.1-12.1)	13.8 (8.1-22.2)	6 (2.6-12.3)	10.1 (6.4-15.3)
All Ages	18.2 (12.4-25.8)	**15.9 (10.4-23.6)**	**17.1 (12.9-22.4)**	11.4 (7.2-17.2)	9.9 (5.9-15.7)	10.7 (7.6-14.7)

mRNA Vaccines	Dose 1	Dose 2	All Doses	Dose 1	Dose 2	All Doses
12-17	37.6 (16.6-77)	57.5 (28.4-107.3)	47.1 (27.2-77.3)	7.7 (1.9-28.6)	16.8 (5.2-46.8)	12.1 (4.4-29.1)
18-24	25.6 (11.3-52.5)	80.7 (48.4-128.1)	51.5 (33.1-77.2)	10.4 (3.2-28.9)	28.1 (12.4-57.6)	18.9 (9.3-35.2)
25-29	30.5 (13.4-62.5)	40.6 (19.1-79)	35.3 (19.9-59)	12.3 (3.8-34.4)	13.3 (4.1-37)	12.8 (5.2-28)
30-39	43.2 (25.9-68.6)	13.8 (5.6-30.3)	29.4 (18.7-44.4)	12.2 (4.9-26.7)	10 (3.6-24)	11.1 (5.5-20.7)
40+	9.7 (5.5-16.2)	7.9 (4-14.2)	8.8 (5.7-13.2)	11.9 (7.3-18.6)	8.6 (4.7-14.7)	10.3 (7-14.8)
All Ages	20.5 (15.1-27.3)	22.3 (16.3-29.8)	21.3 (17.1-26.3)	11.6 (7.8-16.6)	11.5 (7.6-16.8)	11.5 (8.7-15.1)

† Rates calculated per 1 million doses administered. Data taken from Panorama up until 30th October, 2021. These rates were calculated from reports of myocarditis/pericarditis without accounting for Brighton Collaboration levels.

Table 3 shows the rates for Myo/Pericarditis following either dose (or both doses combined) of Moderna Spikevax in BC are higher than those following the respective dose(s) of the Pfizer Comirnaty vaccine for males between 25 and 29 years old. The rates following a second dose (and both doses combined) of Moderna Spikevax are also higher for males of all ages combined. No significant difference in rates was observed by product for females.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on November 3, 2021. Only AEFIs reported and doses administered up to October 30, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Fortnightly COVID-19 AEFI Report
Date: Thursday, November 18, 2021 1:42:50 PM
Attachments: COVID19_AEFI_Fortnightly_Report_2021-11-18.docx
COVID19_AEFI_Fortnightly_Report_2021-11-18.pdf

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to November 13, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including November 13, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

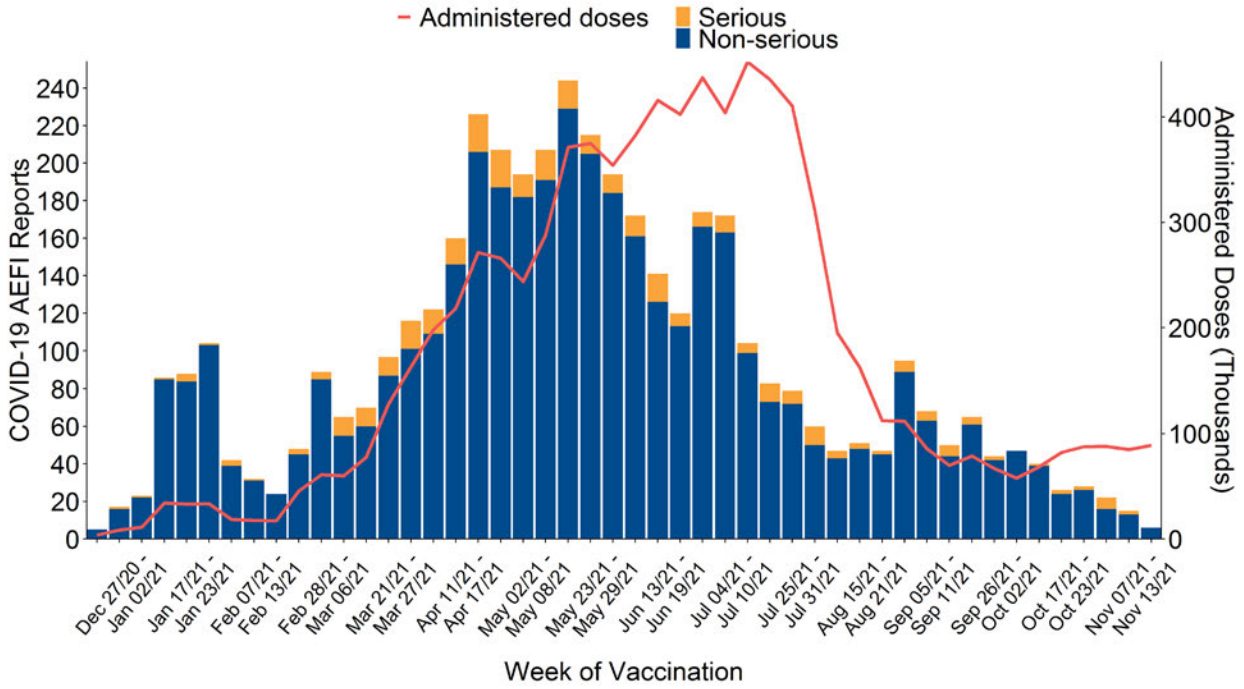
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of November 13, 2021, there have been 8,390,431 COVID-19 vaccine doses administered in BC and 4,431 COVID-19 AEFI reports (52.8 reports per 100,000 doses administered)
- 321 reports (7.2%) met the serious definition, for a rate of 3.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Nov. 13, 2021 **(N=4,431)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including November 13, 2021, a total of 8,390,431 doses have been administered. During this period, there have been 4,431 AEFI reports following a COVID-19 vaccine, for a reporting rate of 52.8 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Nov. 13, 2021 **(N=4,431)**

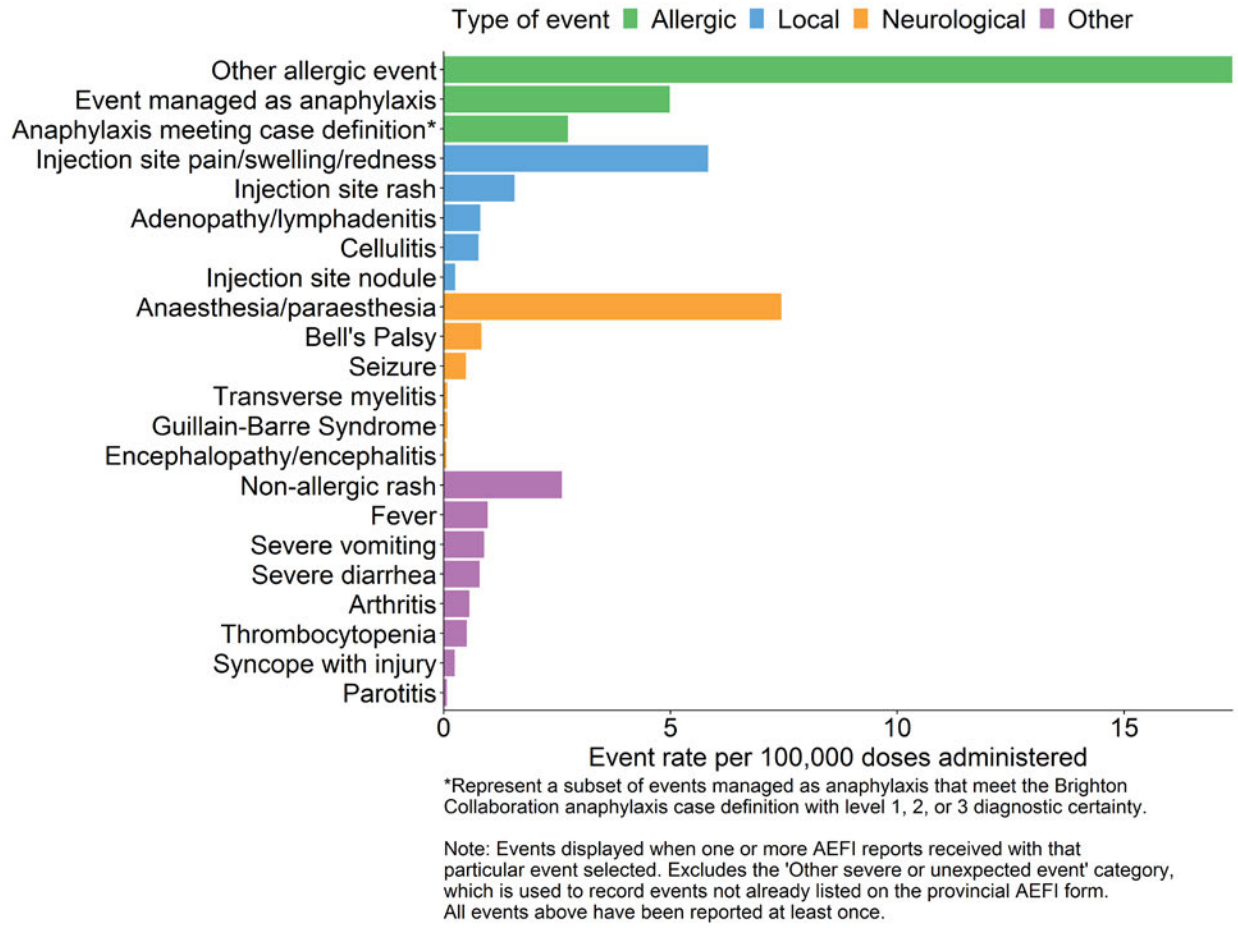
	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**
Total reports	**4431**	**269**	**69**	**1512**	**2581**
Non-serious reports	4110	238	63	1410	2399
Serious reports	321	31	6	102	182
Proportion serious	7.2%	11.5%	8.7%	6.7%	7.1%
Dose 1 reports	3511	244	68	1168	2031
Dose 2 reports	889	25	1	320	543
Total doses administered	**8,390,431**	**331,239**	**73,789**	**2,179,560**	**5,805,842**
Dose 1 administered	4,168,500	226,362	62,405	902,552	2,977,181
Dose 2 administered	3,993,915	104,797	11,362	1,131,687	2,746,068
Total reporting rate	**52.8**	**81.2**	**93.5**	**69.4**	**44.5**
Serious rate	3.8	9.4	8.1	4.7	3.1
Dose 1 rate	84.2	107.8	109.0	129.4	68.2
Dose 2 rate	22.3	23.9	8.8	28.3	19.8

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 4,431 AEFI reports received up to November 13, 2021 contained a total of 5,639 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Nov. 13, 2021 **(N=5,639)**



Event Descriptions

Four hundred eighteen reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 230 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Sixty-five reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred twenty-one reports (7.2%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 304 individuals were admitted to hospital, including 3.1% of cases reported as anaphylaxis.

One hundred and thirty-eight reports contained a diagnosed neurological event. Seventy individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Four

individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Forty-one individuals were reported with seizures (19.5% of which were hospitalized), including 13 with a history of a seizure disorder. Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were seven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 37 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were fourteen reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases lead to 24 hospitalizations (64.9% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine[†].

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

[†] In previous reports, two records were erroneously included in the death count above. These records do not meet the reporting criteria and have been removed.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 138 were for various thrombotic/ thromboembolic conditions. These included 30 strokes (96.7% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 23 myocardial infarctions (95.6% hospitalized), 35 pulmonary emboli (62.9% hospitalized), 42 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been five non-fatal confirmed cases of TTS reported in BC to date, three of whom were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test**.**

There have been 146 reports of pericarditis/myocarditis. Thirty-eight individuals were diagnosed with myocarditis, 66 with pericarditis, and 42 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.3 years, and 91 were male. Fifty-four had received Moderna Spikevax vaccine, 85 received Pfizer-BioNTech Comirnaty vaccine, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Sixty-seven of these events occurred after a second dose (30 Moderna Spikevax and 36 Pfizer-BioNTech Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Thirty-four (out of 38) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-nine (out of 66) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 42) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Nov. 13, 2021 **(N=140)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	N (% Total)	**0 (0%)**	**14 (10%)**	**13 (9.3%)**	**11 (7.9%)**	**16 (11.4%)**	**54 (38.6%)**
Dose 1	N % Total)	0 (0%)	4 (2.9%)	7 (5%)	6 (4.3%)	7 (5%)	24 (17.1%)
Dose 2	N (% Total)	0 (0%)	10 (7.1%)	6 (4.3%)	5 (3.6%)	9 (6.4%)	30 (21.4%)
Pfizer-BioNTech Comirnaty	N (% Total)	**16 (11.4%)**	**16 (11.4%)**	**4 (2.9%)**	**17 (12.1%)**	**33 (23.6%)**	**86 (61.4%)**
Dose 1	N (% Total)	7 (5%)	4 (2.9%)	1 (0.7%)	15 (10.7%)	22 (15.7%)	49 (35%)
Dose 2	N (% Total)	9 (6.4%)	12 (8.6%)	3 (2.1%)	2 (1.4%)	11 (7.9%)	37 (26.4%)
mRNA Vaccines	N (% Total)	**16 (11.4%)**	**30 (21.5%)**	**17 (12.1%)**	**28 (20%)**	**49 (35%)**	**140 (100%)**

Total = 140 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (6 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Data taken from Panorama up until 13th November, 2021.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Nov. 13, 2021. Stratified by sex, age groups, vaccine trade name, and dose **(N=140)**

Vaccine / Age Group	Reporting Rate* (95% CI)					
	Males			Females		
Moderna Spikevax	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	55.5 (20.2-133.6)	174.4 (92.9-305.4)	112.9 (65.1-185.1)	20.9 (5.1-77.1)	20.6 (5-76)	20.5 (6.3-57.1)
25-29	**103.9 (45.8-212.9)**	**126.3 (59.2-245.6)**	**114.2 (64.4-190.9)**	48.6 (15-135.4)	0 (0-0)	23.3 (7.2-65)
30-39	43.1 (17.5-94.6)	29.6 (10.7-71.2)	35.6 (17.6-66.4)	24.1 (7.5-67.2)	21.5 (6.6-59.8)	22.2 (9-48.6)
40+	15.2 (6.2-33.2)	10.8 (4.4-23.7)	11.6 (5.9-20.8)	11.2 (4.1-27)	13.3 (5.9-27.3)	11 (5.7-19.9)
All Ages	34.7 (21.5-53.7)	**38.5 (25.5-56.2)**	**34.7 (25.3-46.6)**	18.1 (9.3-32.6)	14.3 (7.3-25.7)	14.6 (9.1-22.6)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	45.5 (21.3-88.4)	56.9 (28.1-106.1)	50.9 (30-82.1)	7.8 (1.9-28.8)	16.6 (5.1-46.4)	12.1 (4.4-29.1)
18-24	21.3 (7.7-51.3)	62.3 (32-112.3)	40.8 (23-68.1)	6.9 (1.7-25.5)	29.8 (12.1-65.3)	17.9 (7.9-36.6)
25-29	8.6 (2.1-31.9)	9.4 (2.3-34.7)	9 (2.8-25.1)	0 (0-0)	17.9 (5.5-49.8)	8.6 (2.6-23.8)
30-39	53.8 (31.1-88.3)	4.9 (1.2-17.9)	30.2 (17.8-48.7)	12.6 (4.6-30.3)	4.5 (1.1-16.6)	8.6 (3.5-18.9)
40+	10 (5.1-18)	5.5 (2.2-12)	7.7 (4.4-12.6)	15 (9-23.9)	8.2 (4-15.2)	11.4 (7.5-16.8)
All Ages	21.2 (14.9-29.5)	**16.2 (10.6-23.8)**	**18.5 (14.1-24)**	12.1 (7.8-18.2)	11 (6.8-17.1)	11.4 (8.2-15.5)

mRNA Vaccines	Dose 1	Dose 2	All Doses	Dose 1	Dose 2	All Doses
12-17	44.8 (21-87)	56.2 (27.7-104.9)	50.2 (29.6-81)	7.7 (1.9-28.3)	16.4 (5.1-45.8)	11.9 (4.3-28.7)
18-24	30.8 (14.4-59.9)	94.4 (59.3-144.3)	61.1 (40.9-88.5)	10.4 (3.2-29)	27.4 (12-56)	18.6 (9.2-34.6)
25-29	36.6 (17.2-71.3)	45.6 (22.5-85)	40.8 (24-65.8)	12.4 (3.8-34.5)	12.9 (4-36)	12.5 (5.1-27.5)
30-39	50.7 (31.4-78.4)	13 (5.3-28.5)	31.9 (20.7-47.3)	15.6 (6.8-31.9)	9.5 (3.5-22.9)	12.4 (6.4-22.4)
40+	11.3 (6.5-18.5)	7.3 (3.7-13.1)	8.9 (5.8-13.1)	14.2 (8.9-21.7)	9.7 (5.6-16)	11.3 (7.9-15.8)
All Ages	24.5 (18.4-32.1)	23 (17.1-30.4)	23.2 (18.8-28.2)	13.5 (9.3-19)	11.9 (8-17.2)	12.3 (9.3-15.9)

* Rates calculated per 1 million doses administered. Data taken from Panorama up until 13th November, 2021. These rates were calculated from reports of myocarditis/pericarditis without accounting for Brighton Collaboration levels.

Table 3 shows the rates for Myo/Pericarditis following either dose (or both doses combined) of Moderna Spikevax in BC are higher than those following the respective dose(s) of the Pfizer-BioNTech Comirnaty vaccine for males between 25 and 29 years old. The rates following a second dose (and both doses combined) of Moderna Spikevax are also higher for males of all ages combined. No significant difference in rates was observed by product for females

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on November 17, 2021. Only AEFIs reported and doses administered up to November 13, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to November 13, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including November 13, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

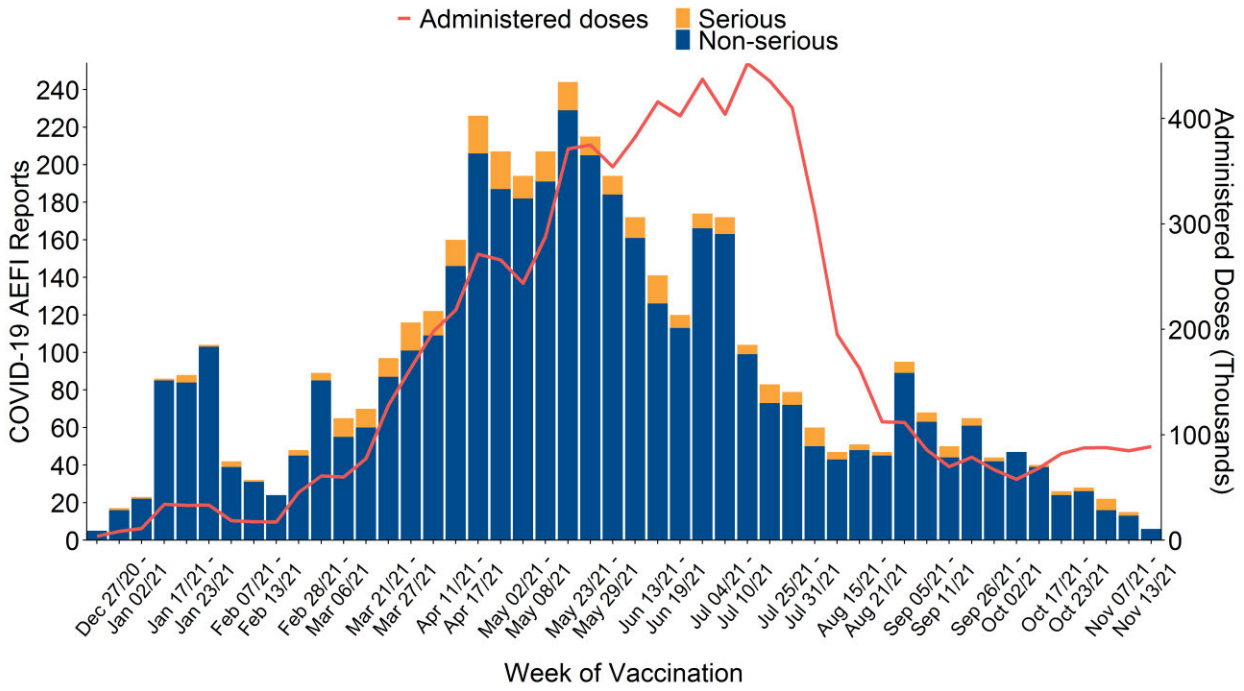
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of November 13, 2021, there have been 8,390,431 COVID-19 vaccine doses administered in BC and 4,431 COVID-19 AEFI reports (52.8 reports per 100,000 doses administered)
- 321 reports (7.2%) met the serious definition, for a rate of 3.8 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Nov. 13, 2021 **(N=4,431)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including November 13, 2021, a total of 8,390,431 doses have been administered. During this period, there have been 4,431 AEFI reports following a COVID-19 vaccine, for a reporting rate of 52.8 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Nov. 13, 2021 **(N=4,431)**

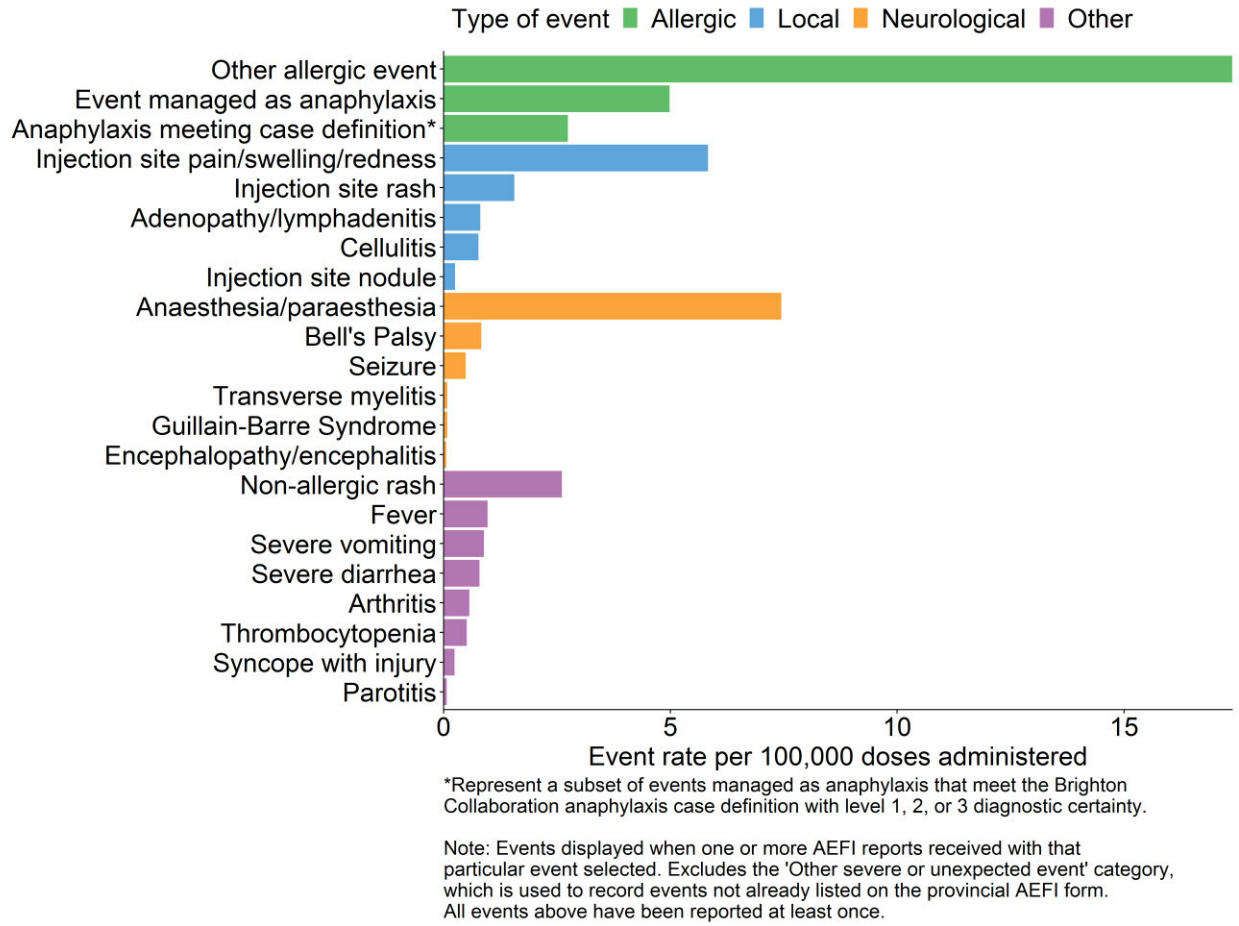
	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**
Total reports	**4431**	**269**	**69**	**1512**	**2581**
Non-serious reports	4110	238	63	1410	2399
Serious reports	321	31	6	102	182
Proportion serious	7.2%	11.5%	8.7%	6.7%	7.1%
Dose 1 reports	3511	244	68	1168	2031
Dose 2 reports	889	25	1	320	543
Total doses administered	**8,390,431**	**331,239**	**73,789**	**2,179,560**	**5,805,842**
Dose 1 administered	4,168,500	226,362	62,405	902,552	2,977,181
Dose 2 administered	3,993,915	104,797	11,362	1,131,687	2,746,068
Total reporting rate	**52.8**	**81.2**	**93.5**	**69.4**	**44.5**
Serious rate	3.8	9.4	8.1	4.7	3.1
Dose 1 rate	84.2	107.8	109.0	129.4	68.2
Dose 2 rate	22.3	23.9	8.8	28.3	19.8

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 4,431 AEFI reports received up to November 13, 2021 contained a total of 5,639 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Nov. 13, 2021 **(N=5,639)**



Event Descriptions

Four hundred eighteen reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 230 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Sixty-five reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred twenty-one reports (7.2%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 304 individuals were admitted to hospital, including 3.1% of cases reported as anaphylaxis.

One hundred and thirty-eight reports contained a diagnosed neurological event. Seventy individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Four

individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Forty-one individuals were reported with seizures (19.5% of which were hospitalized), including 13 with a history of a seizure disorder. Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were seven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Three of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 37 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were fourteen reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases lead to 24 hospitalizations (64.9% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine[†].

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

[†] In previous reports, two records were erroneously included in the death count above. These records do not meet the reporting criteria and have been removed.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 138 were for various thrombotic/ thromboembolic conditions. These included 30 strokes (96.7% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 23 myocardial infarctions (95.6% hospitalized), 35 pulmonary emboli (62.9% hospitalized), 42 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been five non-fatal confirmed cases of TTS reported in BC to date, three of whom were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test**.**

There have been 146 reports of pericarditis/myocarditis. Thirty-eight individuals were diagnosed with myocarditis, 66 with pericarditis, and 42 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.3 years, and 91 were male. Fifty-four had received Moderna Spikevax vaccine, 85 received Pfizer-BioNTech Comirnaty vaccine, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Sixty-seven of these events occurred after a second dose (30 Moderna Spikevax and 36 Pfizer-BioNTech Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Thirty-four (out of 38) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-nine (out of 66) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 42) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Nov. 13, 2021 **(N=140)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	N (% Total)	**0 (0%)**	**14 (10%)**	**13 (9.3%)**	**11 (7.9%)**	**16 (11.4%)**	**54 (38.6%)**
Dose 1	N % Total)	0 (0%)	4 (2.9%)	7 (5%)	6 (4.3%)	7 (5%)	24 (17.1%)
Dose 2	N (% Total)	0 (0%)	10 (7.1%)	6 (4.3%)	5 (3.6%)	9 (6.4%)	30 (21.4%)
Pfizer-BioNTech Comirnaty	N (% Total)	**16 (11.4%)**	**16 (11.4%)**	**4 (2.9%)**	**17 (12.1%)**	**33 (23.6%)**	**86 (61.4%)**
Dose 1	N (% Total)	7 (5%)	4 (2.9%)	1 (0.7%)	15 (10.7%)	22 (15.7%)	49 (35%)
Dose 2	N (% Total)	9 (6.4%)	12 (8.6%)	3 (2.1%)	2 (1.4%)	11 (7.9%)	37 (26.4%)
mRNA Vaccines	N (% Total)	**16 (11.4%)**	**30 (21.5%)**	**17 (12.1%)**	**28 (20%)**	**49 (35%)**	**140 (100%)**

Total = 140 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (6 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Data taken from Panorama up until 13th November, 2021.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Nov. 13, 2021. Stratified by sex, age groups, vaccine trade name, and dose **(N=140)**

Vaccine / Age Group	Reporting Rate* (95% CI)					
	Males			Females		
Moderna Spikevax	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	55.5 (20.2-133.6)	174.4 (92.9-305.4)	112.9 (65.1-185.1)	20.9 (5.1-77.1)	20.6 (5-76)	20.5 (6.3-57.1)
25-29	**103.9 (45.8-212.9)**	**126.3 (59.2-245.6)**	**114.2 (64.4-190.9)**	48.6 (15-135.4)	0 (0-0)	23.3 (7.2-65)
30-39	43.1 (17.5-94.6)	29.6 (10.7-71.2)	35.6 (17.6-66.4)	24.1 (7.5-67.2)	21.5 (6.6-59.8)	22.2 (9-48.6)
40+	15.2 (6.2-33.2)	10.8 (4.4-23.7)	11.6 (5.9-20.8)	11.2 (4.1-27)	13.3 (5.9-27.3)	11 (5.7-19.9)
All Ages	34.7 (21.5-53.7)	**38.5 (25.5-56.2)**	**34.7 (25.3-46.6)**	18.1 (9.3-32.6)	14.3 (7.3-25.7)	14.6 (9.1-22.6)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**All Doses**	**Dose 1**	**Dose 2**	**All Doses**
12-17	45.5 (21.3-88.4)	56.9 (28.1-106.1)	50.9 (30-82.1)	7.8 (1.9-28.8)	16.6 (5.1-46.4)	12.1 (4.4-29.1)
18-24	21.3 (7.7-51.3)	62.3 (32-112.3)	40.8 (23-68.1)	6.9 (1.7-25.5)	29.8 (12.1-65.3)	17.9 (7.9-36.6)
25-29	8.6 (2.1-31.9)	9.4 (2.3-34.7)	9 (2.8-25.1)	0 (0-0)	17.9 (5.5-49.8)	8.6 (2.6-23.8)
30-39	53.8 (31.1-88.3)	4.9 (1.2-17.9)	30.2 (17.8-48.7)	12.6 (4.6-30.3)	4.5 (1.1-16.6)	8.6 (3.5-18.9)
40+	10 (5.1-18)	5.5 (2.2-12)	7.7 (4.4-12.6)	15 (9-23.9)	8.2 (4-15.2)	11.4 (7.5-16.8)
All Ages	21.2 (14.9-29.5)	**16.2 (10.6-23.8)**	**18.5 (14.1-24)**	12.1 (7.8-18.2)	11 (6.8-17.1)	11.4 (8.2-15.5)

mRNA Vaccines	Dose 1	Dose 2	All Doses	Dose 1	Dose 2	All Doses
12-17	44.8 (21-87)	56.2 (27.7-104.9)	50.2 (29.6-81)	7.7 (1.9-28.3)	16.4 (5.1-45.8)	11.9 (4.3-28.7)
18-24	30.8 (14.4-59.9)	94.4 (59.3-144.3)	61.1 (40.9-88.5)	10.4 (3.2-29)	27.4 (12-56)	18.6 (9.2-34.6)
25-29	36.6 (17.2-71.3)	45.6 (22.5-85)	40.8 (24-65.8)	12.4 (3.8-34.5)	12.9 (4-36)	12.5 (5.1-27.5)
30-39	50.7 (31.4-78.4)	13 (5.3-28.5)	31.9 (20.7-47.3)	15.6 (6.8-31.9)	9.5 (3.5-22.9)	12.4 (6.4-22.4)
40+	11.3 (6.5-18.5)	7.3 (3.7-13.1)	8.9 (5.8-13.1)	14.2 (8.9-21.7)	9.7 (5.6-16)	11.3 (7.9-15.8)
All Ages	24.5 (18.4-32.1)	23 (17.1-30.4)	23.2 (18.8-28.2)	13.5 (9.3-19)	11.9 (8-17.2)	12.3 (9.3-15.9)

* Rates calculated per 1 million doses administered. Data taken from Panorama up until 13th November, 2021. These rates were calculated from reports of myocarditis/pericarditis without accounting for Brighton Collaboration levels.

Table 3 shows the rates for Myo/Pericarditis following either dose (or both doses combined) of Moderna Spikevax in BC are higher than those following the respective dose(s) of the Pfizer-BioNTech Comirnaty vaccine for males between 25 and 29 years old. The rates following a second dose (and both doses combined) of Moderna Spikevax are also higher for males of all ages combined. No significant difference in rates was observed by product for females

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on November 17, 2021. Only AEFIs reported and doses administered up to November 13, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Fortnightly COVID-19 AEFI Report
Date: Thursday, December 02, 2021 4:32:39 PM
Attachments: COVID19_AEFI_Fortnightly_Report_2021-12-02.docx
COVID19_AEFI_Fortnightly_Report_2021-12-02.pdf

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to November 27, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including November 27, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

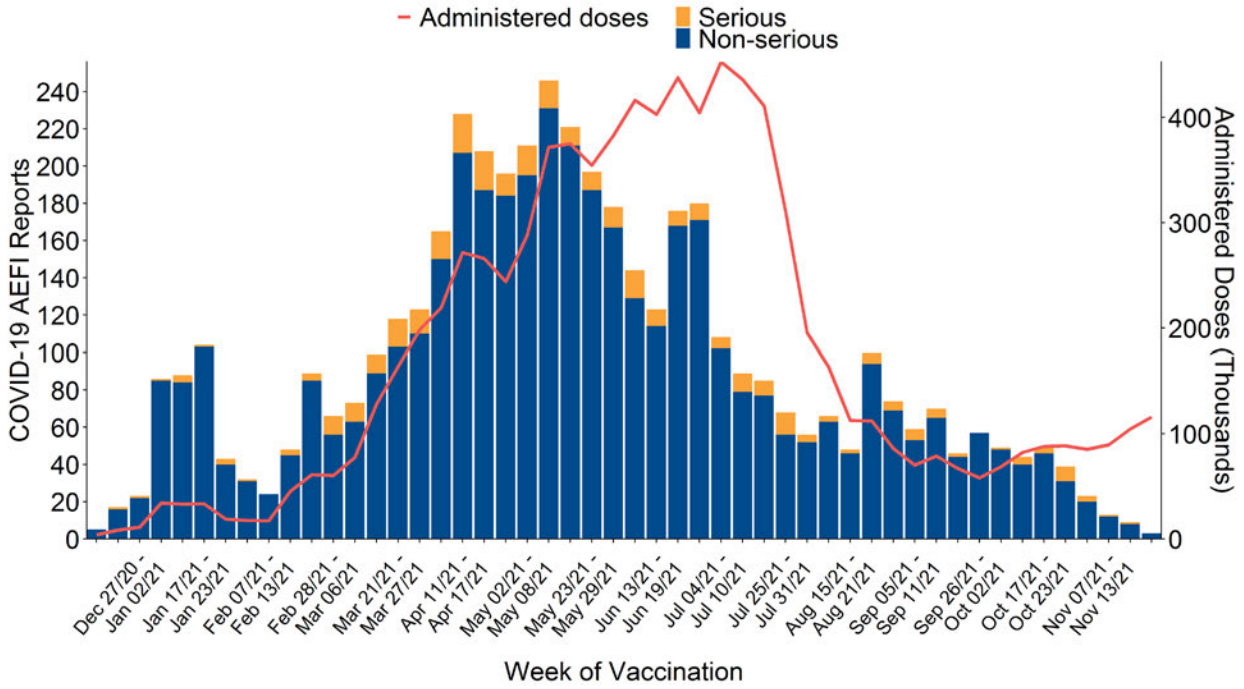
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of November 27, 2021, there have been 8,625,058 COVID-19 vaccine doses administered in BC and 4,666 COVID-19 AEFI reports (54.1 reports per 100,000 doses administered)
- 339 reports (7.3%) met the serious definition, for a rate of 3.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Nov. 27, 2021 **(N=4,666)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including November 27, 2021, a total of 8,625,058 doses have been administered. During this period, there have been 4,666 AEFI reports following a COVID-19 vaccine, for a reporting rate of 54.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Nov. 27, 2021 **(N=4,666)**

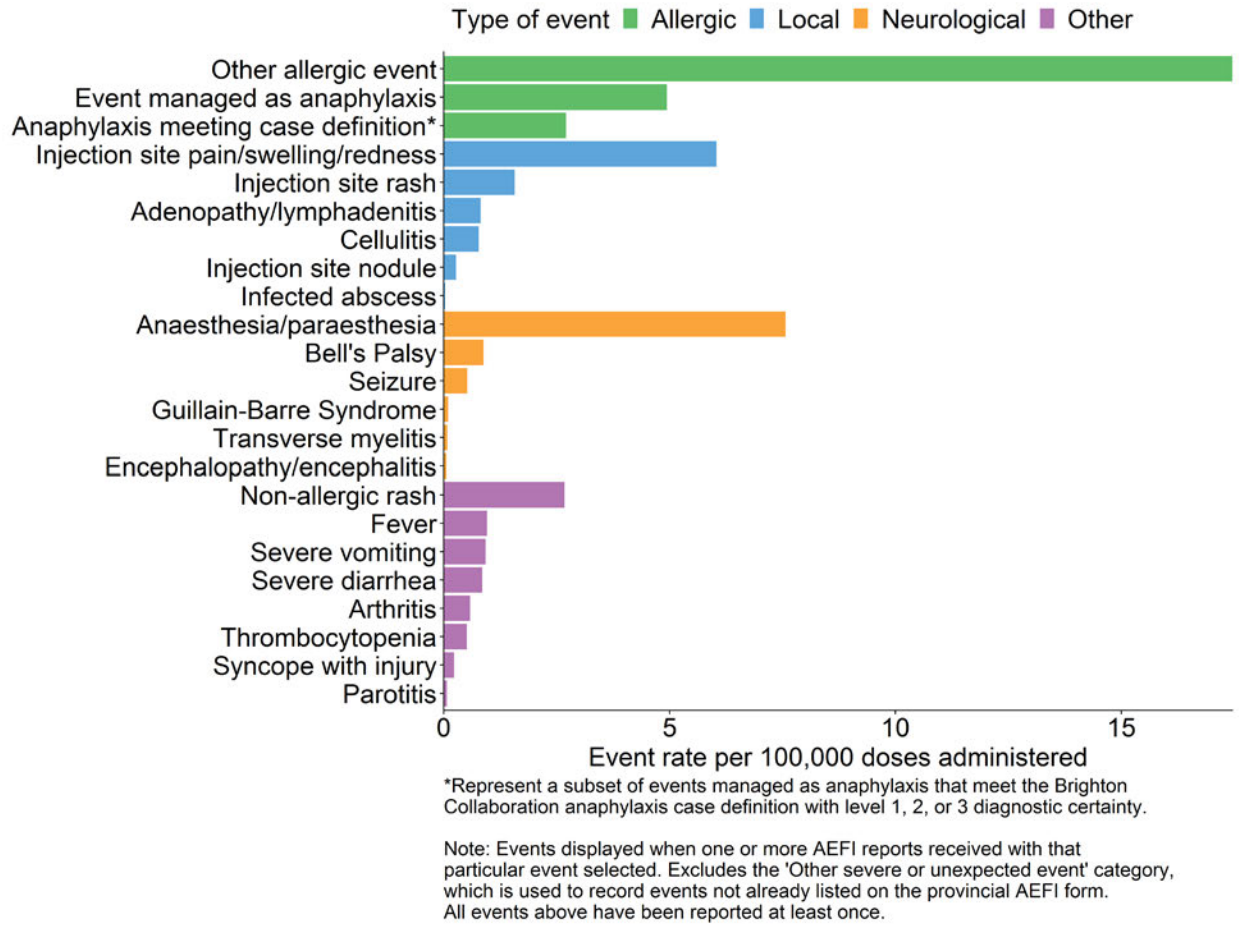
		COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**
Total reports	**4666**	**273**	**70**	**0**	**1595**	**2728**
Non-serious reports	4327	241	64	0	1487	2535
Serious reports	339	32	6	0	108	193
Proportion serious	7.3%	11.7%	8.6%	0.0%	6.8%	7.1%
Dose 1 reports	3668	247	68	0	1219	2134
Dose 2 reports	954	26	2	0	344	582
Total doses administered	**8,625,058**	**332,031**	**74,756**	**4,809**	**2,294,094**	**5,919,358**
Dose 1 administered	4,190,583	226,800	62,892	4,679	907,288	2,988,918
Dose 2 administered	4,033,881	105,150	11,842	125	1,144,276	2,772,484
Total reporting rate	**54.1**	**82.2**	**93.6**	**0.0**	**69.5**	**46.1**
Serious rate	3.9	9.6	8.0	0.0	4.7	3.3
Dose 1 rate	87.5	108.9	108.1	0.0	134.4	71.4
Dose 2 rate	23.6	24.7	16.9	0.0	30.1	21.0

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 4,666 AEFI reports received up to November 27, 2021 contained a total of 5,938 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Nov. 27, 2021 **(N=5,938)**



Event Descriptions

Four hundred twenty-six reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 234 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Sixty-seven reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred thirty-nine reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 321 individuals were admitted to hospital, including 4% of cases reported as anaphylaxis.

One hundred and thirty-eight reports contained a diagnosed neurological event. Seventy-six individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Four individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Forty-four individuals were reported with seizures (20.4% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were nine reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 39 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were fourteen reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases lead to 24 hospitalizations (61.5% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.[†]

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

[†] In previous reports, two records were erroneously included in the death count above. These records do not meet the reporting criteria and have been removed.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 145 were for various thrombotic/ thromboembolic conditions. These included 31 strokes (96.8% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 23 myocardial infarctions (95.6% hospitalized), 39 pulmonary emboli (64.1% hospitalized), 44 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been five non-fatal confirmed cases of TTS reported in BC to date, three of whom were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test.

There have been 158 reports of myocarditis/pericarditis. Forty-two individuals were diagnosed with myocarditis, 72 with pericarditis, and 44 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.9 years, and 98 were male. Sixty had received Moderna Spikevax, 91 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Seventy-six of these events occurred after a second dose (34 Moderna Spikevax and 41 Pfizer-BioNTech Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Thirty-seven (out of 42) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirty-three (out of 72) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-six (out of 44) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Nov. 27, 2021 **(N=151)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**15 (9.9%)**	**14 (9.3%)**	**12 (7.9%)**	**19 (12.6%)**	**60 (39.7%)**
Dose 1	N % Total)	0 (0%)	4 (2.6%)	7 (4.6%)	6 (4%)	7 (4.6%)	24 (15.9%)
Dose 2	N (% Total)	0 (0%)	11 (7.3%)	7 (4.6%)	6 (4%)	10 (6.6%)	34 (22.5%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (1.3%)	2 (1.3%)
Pfizer-BioNTech Comirnaty	**N (% Total)**	**17 (11.3%)**	**16 (10.6%)**	**4 (2.6%)**	**18 (11.9%)**	**36 (23.8%)**	**91 (60.3%)**
Dose 1	N (% Total)	7 (4.6%)	4 (2.6%)	1 (0.7%)	16 (10.6%)	22 (14.6%)	50 (33.1%)
Dose 2	N (% Total)	10 (6.6%)	12 (7.9%)	3 (2%)	2 (1.3%)	14 (9.3%)	41 (27.2%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
mRNA Vaccines	**N (% Total)**	**17 (11.2%)**	**31 (20.4%)**	**18 (11.9%)**	**30 (19.9%)**	**55 (36.4%)**	**151 (100%)**

Total = 151 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Data taken from Panorama up until 27 November, 2021.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Nov. 27, 2021. Stratified by sex, age groups, vaccine trade name, and dose **(N=151)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	55.4 (20.1-133.4)	190.6 (104.6-325.6)	0 (0-0)	120.9 (71.2-194.9)	20.9 (5.1-77.0)	20.4 (4.9-75.1)	0 (0-0)	20.3 (6.3-56.5)
25-29	**103.1 (45.4-211.2)**	**144.4 (71.3-269.4)**	0 (0-0)	**122.5 (70.6-200.8)**	48.3 (14.9-134.6)	0 (0-0)	0 (0-0)	22.9 (7.1-63.8)
30-39	42.8 (17.4-93.9)	29.1 (10.6-70.0)	0 (0-0)	35 (17.3-65.3)	24.0 (7.4-66.8)	31.8 (11.5-76.5)	0 (0-0)	27.2 (12.0-55.7)
40+	15.1 (6.1-33.1)	10.7 (4.4-23.5)	0 (0-0)	10.9 (5.6-19.6)	11.2 (4.1-26.9)	15.9 (7.5-30.9)	15.3 (4.7-42.7)	14.2 (8.0-23.7)
All Ages	34.5 (21.4-53.4)	**41.5 (28-59.7)**	0 (0-0)	**34.9 (25.7-46.5)**	18 (9.3-32.5)	17.7 (9.7-30.2)	14.2 (4.4-39.7)	17.4 (11.3-25.8)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	45.2 (21.2-87.9)	56.1 (27.7-104.6)	0 (0-0)	50.4 (29.7-81.3)	7.8 (1.9-28.7)	24.7 (9.0-59.4)	0 (0-0)	16.0 (6.5-35.0)
18-24	21.2 (7.7-51.0)	61.2 (31.5-110.3)	0 (0-0)	40.2 (22.7-67.3)	6.9 (1.7-25.4)	29.4 (11.9-64.5)	0 (0-0)	17.7 (7.8-36.2)
25-29	**8.6 (2.1-31.7)**	**9.3 (2.2-34.2)**	0 (0-0)	**8.9 (2.7-24.7)**	0 (0-0)	17.7 (5.5-49.2)	0 (0-0)	8.5 (2.6-23.6)
30-39	58.0 (34.1-93.5)	4.8 (1.2-17.7)	0 (0-0)	32.1 (19.3-51)	12.5 (4.5-30.1)	4.4 (1.1-16.4)	0 (0-0)	8.5 (3.5-18.7)
40+	10.0 (5.1-18.0)	9.5 (4.7-17.7)	0 (0-0)	9.3 (5.7-14.6)	15.0 (9.0-23.8)	8.1 (4.0-15.1)	0 (0-0)	11.2 (7.3-16.4)
All Ages	21.8 (15.4-30.2)	**18.3 (12.3-26.3)**	0 (0-0)	**19.6 (15.1-25.2)**	12.1 (7.8-18.1)	11.6 (7.3-17.8)	0 (0-0)	11.5 (8.3-15.6)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All Doses	Dose 1	Dose 2	Dose 3	All Doses
12-17	44.5 (20.9-86.6)	55.4 (27.3-103.3)	0 (0-0)	49.7 (29.3-80.2)	7.6 (1.9-28.2)	24.3 (8.8-58.6)	0 (0-0)	15.7 (6.4-34.5)
18-24	30.7 (14.4-59.6)	98.3 (62.4-148.6)	0 (0-0)	63.0 (42.5-90.6)	10.4 (3.2-28.9)	27.0 (11.9-55.4)	0 (0-0)	18.4 (9.1-34.3)
25-29	36.4 (17.1-70.7)	51.1 (26.3-92.2)	0 (0-0)	43.3 (26.0-68.8)	12.3 (3.8-34.3)	12.7 (3.9-35.5)	0 (0-0)	12.4 (5.0-27.1)
30-39	53.5 (33.6-81.8)	12.8 (5.2-28.1)	0 (0-0)	33.0 (21.7-48.6)	15.5 (6.8-31.7)	12.5 (5.1-27.4)	0 (0-0)	13.8 (7.3-24.1)
40+	11.2 (6.5-18.4)	9.9 (5.6-16.6)	0 (0-0)	9.8 (6.6-14.2)	14.1 (8.9-21.6)	10.5 (6.2-16.9)	9.4 (2.9-26.1)	12.0 (8.6-16.6)
All Ages	25.0 (18.8-32.6)	25.4 (19.2-33.1)	0 (0-0)	24.1 (19.7-29.1)	13.4 (9.2-18.9)	13.3 (9.2-18.8)	8.6 (2.7-24.1)	13.1 (10.1-16.8)

* Rates calculated per 1 million doses administered. Data taken from Panorama up until 27th November, 2021. These rates were calculated from reports of myocarditis/pericarditis without accounting for Brighton Collaboration levels.

Table 3 shows the rates for Myo/Pericarditis following dose 1 and dose 2 (as well as all doses combined) of Moderna Spikevax in BC are higher than those following the respective doses of the Pfizer-BioNTech Comirnaty vaccine for males between 25 and 29 years old. The rates following a second dose (and all doses combined) of Moderna Spikevax are also higher for males of all ages combined. No significant difference in rates was observed by product for females.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on December 1, 2021. Only AEFIs reported and doses administered up to November 27, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to November 27, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including November 27, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

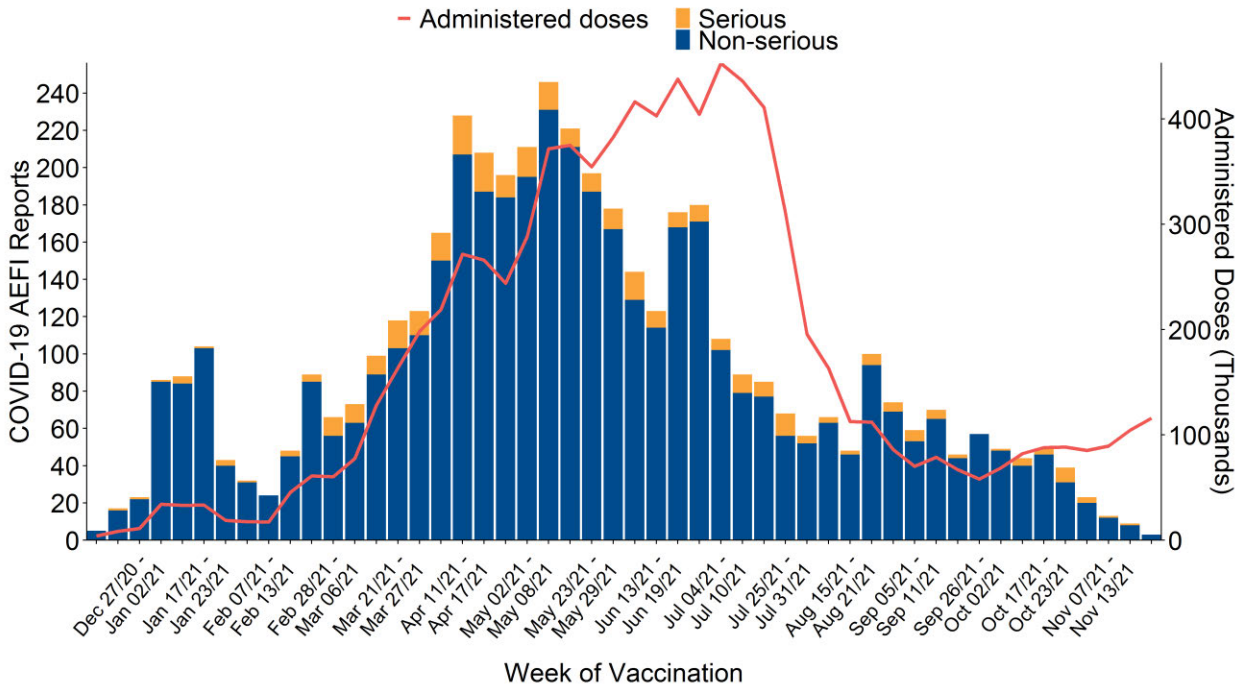
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of November 27, 2021, there have been 8,625,058 COVID-19 vaccine doses administered in BC and 4,666 COVID-19 AEFI reports (54.1 reports per 100,000 doses administered)
- 339 reports (7.3%) met the serious definition, for a rate of 3.9 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Nov. 27, 2021 **(N=4,666)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including November 27, 2021, a total of 8,625,058 doses have been administered. During this period, there have been 4,666 AEFI reports following a COVID-19 vaccine, for a reporting rate of 54.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Nov. 27, 2021 **(N=4,666)**

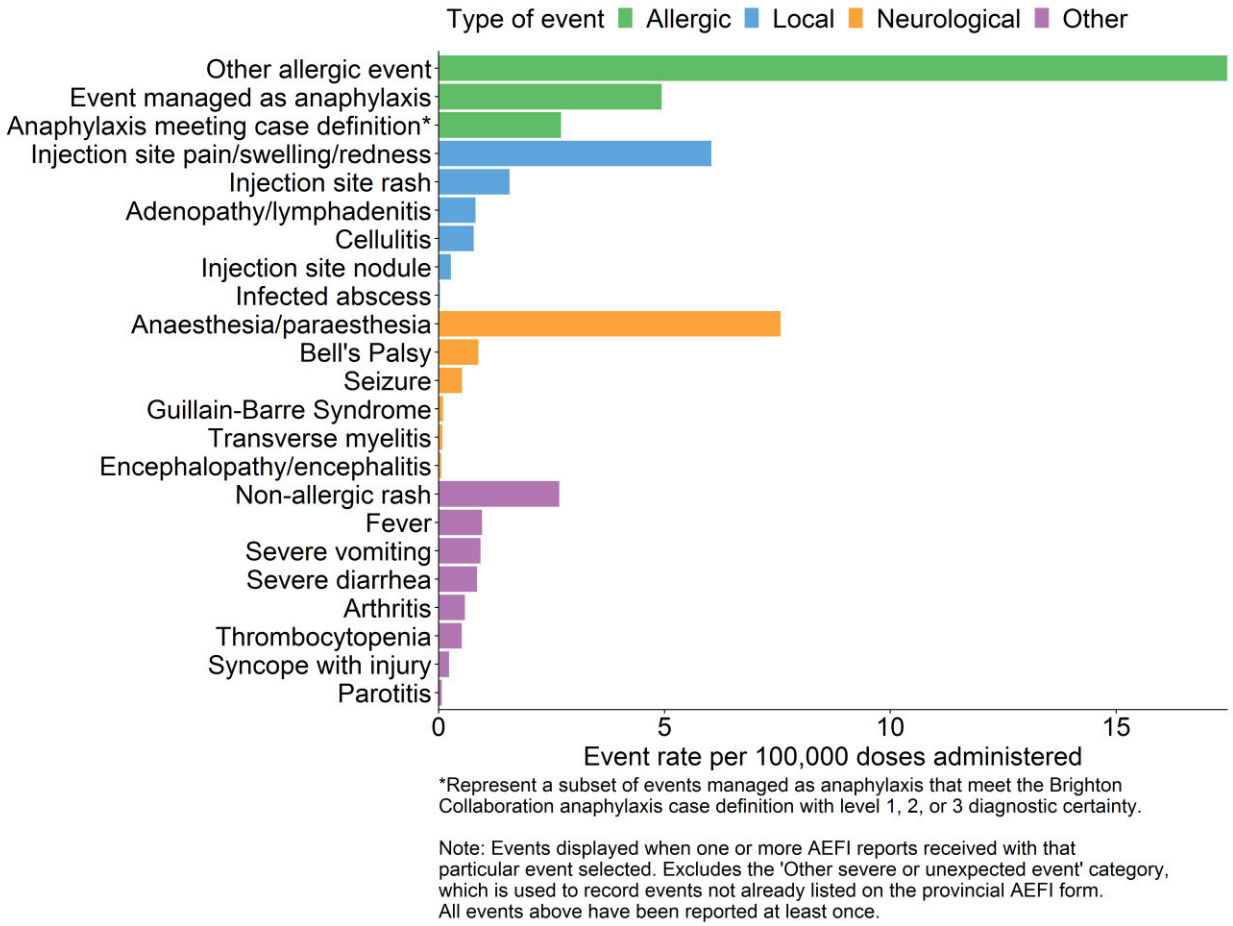
		COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**
Total reports	**4666**	**273**	**70**	**0**	**1595**	**2728**
Non-serious reports	4327	241	64	0	1487	2535
Serious reports	339	32	6	0	108	193
Proportion serious	7.3%	11.7%	8.6%	0.0%	6.8%	7.1%
Dose 1 reports	3668	247	68	0	1219	2134
Dose 2 reports	954	26	2	0	344	582
Total doses administered	**8,625,058**	**332,031**	**74,756**	**4,809**	**2,294,094**	**5,919,358**
Dose 1 administered	4,190,583	226,800	62,892	4,679	907,288	2,988,918
Dose 2 administered	4,033,881	105,150	11,842	125	1,144,276	2,772,484
Total reporting rate	**54.1**	**82.2**	**93.6**	**0.0**	**69.5**	**46.1**
Serious rate	3.9	9.6	8.0	0.0	4.7	3.3
Dose 1 rate	87.5	108.9	108.1	0.0	134.4	71.4
Dose 2 rate	23.6	24.7	16.9	0.0	30.1	21.0

Note: Rates calculated per 100,000 doses administered

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 4,666 AEFI reports received up to November 27, 2021 contained a total of 5,938 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Nov. 27, 2021 **(N=5,938)**



Event Descriptions

Four hundred twenty-six reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 234 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Sixty-seven reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred thirty-nine reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 321 individuals were admitted to hospital, including 4% of cases reported as anaphylaxis.

One hundred and thirty-eight reports contained a diagnosed neurological event. Seventy-six individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Four individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Forty-four individuals were reported with seizures (20.4% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were nine reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 39 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were fourteen reports of idiopathic thrombocytopenia (i.e., thrombocytopenia without a known cause). Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases lead to 24 hospitalizations (61.5% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.[†]

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

[†] In previous reports, two records were erroneously included in the death count above. These records do not meet the reporting criteria and have been removed.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 145 were for various thrombotic/ thromboembolic conditions. These included 31 strokes (96.8% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 23 myocardial infarctions (95.6% hospitalized), 39 pulmonary emboli (64.1% hospitalized), 44 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been five non-fatal confirmed cases of TTS reported in BC to date, three of whom were adults in their 30s or 40s and the fourth was in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test.

There have been 158 reports of myocarditis/pericarditis. Forty-two individuals were diagnosed with myocarditis, 72 with pericarditis, and 44 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.9 years, and 98 were male. Sixty had received Moderna Spikevax, 91 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Seventy-six of these events occurred after a second dose (34 Moderna Spikevax and 41 Pfizer-BioNTech Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Thirty-seven (out of 42) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirty-three (out of 72) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-six (out of 44) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Nov. 27, 2021 **(N=151)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**15 (9.9%)**	**14 (9.3%)**	**12 (7.9%)**	**19 (12.6%)**	**60 (39.7%)**
Dose 1	N % Total)	0 (0%)	4 (2.6%)	7 (4.6%)	6 (4%)	7 (4.6%)	24 (15.9%)
Dose 2	N (% Total)	0 (0%)	11 (7.3%)	7 (4.6%)	6 (4%)	10 (6.6%)	34 (22.5%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (1.3%)	2 (1.3%)
Pfizer-BioNTech Comirnaty	**N (% Total)**	**17 (11.3%)**	**16 (10.6%)**	**4 (2.6%)**	**18 (11.9%)**	**36 (23.8%)**	**91 (60.3%)**
Dose 1	N (% Total)	7 (4.6%)	4 (2.6%)	1 (0.7%)	16 (10.6%)	22 (14.6%)	50 (33.1%)
Dose 2	N (% Total)	10 (6.6%)	12 (7.9%)	3 (2%)	2 (1.3%)	14 (9.3%)	41 (27.2%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
mRNA Vaccines	**N (% Total)**	**17 (11.2%)**	**31 (20.4%)**	**18 (11.9%)**	**30 (19.9%)**	**55 (36.4%)**	**151 (100%)**

Total = 151 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Data taken from Panorama up until 27 November, 2021.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Nov. 27, 2021. Stratified by sex, age groups, vaccine trade name, and dose **(N=151)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	55.4 (20.1-133.4)	190.6 (104.6-325.6)	0 (0-0)	120.9 (71.2-194.9)	20.9 (5.1-77.0)	20.4 (4.9-75.1)	0 (0-0)	20.3 (6.3-56.5)
25-29	**103.1 (45.4-211.2)**	**144.4 (71.3-269.4)**	0 (0-0)	**122.5 (70.6-200.8)**	48.3 (14.9-134.6)	0 (0-0)	0 (0-0)	22.9 (7.1-63.8)
30-39	42.8 (17.4-93.9)	29.1 (10.6-70.0)	0 (0-0)	35 (17.3-65.3)	24.0 (7.4-66.8)	31.8 (11.5-76.5)	0 (0-0)	27.2 (12.0-55.7)
40+	15.1 (6.1-33.1)	10.7 (4.4-23.5)	0 (0-0)	10.9 (5.6-19.6)	11.2 (4.1-26.9)	15.9 (7.5-30.9)	15.3 (4.7-42.7)	14.2 (8.0-23.7)
All Ages	34.5 (21.4-53.4)	**41.5 (28-59.7)**	0 (0-0)	**34.9 (25.7-46.5)**	18 (9.3-32.5)	17.7 (9.7-30.2)	14.2 (4.4-39.7)	17.4 (11.3-25.8)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	45.2 (21.2-87.9)	56.1 (27.7-104.6)	0 (0-0)	50.4 (29.7-81.3)	7.8 (1.9-28.7)	24.7 (9.0-59.4)	0 (0-0)	16.0 (6.5-35.0)
18-24	21.2 (7.7-51.0)	61.2 (31.5-110.3)	0 (0-0)	40.2 (22.7-67.3)	6.9 (1.7-25.4)	29.4 (11.9-64.5)	0 (0-0)	17.7 (7.8-36.2)
25-29	**8.6 (2.1-31.7)**	**9.3 (2.2-34.2)**	0 (0-0)	**8.9 (2.7-24.7)**	0 (0-0)	17.7 (5.5-49.2)	0 (0-0)	8.5 (2.6-23.6)
30-39	58.0 (34.1-93.5)	4.8 (1.2-17.7)	0 (0-0)	32.1 (19.3-51)	12.5 (4.5-30.1)	4.4 (1.1-16.4)	0 (0-0)	8.5 (3.5-18.7)
40+	10.0 (5.1-18.0)	9.5 (4.7-17.7)	0 (0-0)	9.3 (5.7-14.6)	15.0 (9.0-23.8)	8.1 (4.0-15.1)	0 (0-0)	11.2 (7.3-16.4)
All Ages	21.8 (15.4-30.2)	**18.3 (12.3-26.3)**	0 (0-0)	**19.6 (15.1-25.2)**	12.1 (7.8-18.1)	11.6 (7.3-17.8)	0 (0-0)	11.5 (8.3-15.6)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All Doses	Dose 1	Dose 2	Dose 3	All Doses
12-17	44.5 (20.9-86.6)	55.4 (27.3-103.3)	0 (0-0)	49.7 (29.3-80.2)	7.6 (1.9-28.2)	24.3 (8.8-58.6)	0 (0-0)	15.7 (6.4-34.5)
18-24	30.7 (14.4-59.6)	98.3 (62.4-148.6)	0 (0-0)	63.0 (42.5-90.6)	10.4 (3.2-28.9)	27.0 (11.9-55.4)	0 (0-0)	18.4 (9.1-34.3)
25-29	36.4 (17.1-70.7)	51.1 (26.3-92.2)	0 (0-0)	43.3 (26.0-68.8)	12.3 (3.8-34.3)	12.7 (3.9-35.5)	0 (0-0)	12.4 (5.0-27.1)
30-39	53.5 (33.6-81.8)	12.8 (5.2-28.1)	0 (0-0)	33.0 (21.7-48.6)	15.5 (6.8-31.7)	12.5 (5.1-27.4)	0 (0-0)	13.8 (7.3-24.1)
40+	11.2 (6.5-18.4)	9.9 (5.6-16.6)	0 (0-0)	9.8 (6.6-14.2)	14.1 (8.9-21.6)	10.5 (6.2-16.9)	9.4 (2.9-26.1)	12.0 (8.6-16.6)
All Ages	25.0 (18.8-32.6)	25.4 (19.2-33.1)	0 (0-0)	24.1 (19.7-29.1)	13.4 (9.2-18.9)	13.3 (9.2-18.8)	8.6 (2.7-24.1)	13.1 (10.1-16.8)

* Rates calculated per 1 million doses administered. Data taken from Panorama up until 27th November, 2021. These rates were calculated from reports of myocarditis/pericarditis without accounting for Brighton Collaboration levels.

Table 3 shows the rates for Myo/Pericarditis following dose 1 and dose 2 (as well as all doses combined) of Moderna Spikevax in BC are higher than those following the respective doses of the Pfizer-BioNTech Comirnaty vaccine for males between 25 and 29 years old. The rates following a second dose (and all doses combined) of Moderna Spikevax are also higher for males of all ages combined. No significant difference in rates was observed by product for females.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on December 1, 2021. Only AEFIs reported and doses administered up to November 27, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: RE: Fortnightly COVID-19 AEFI Report
Date: Monday, December 13, 2021 4:02:20 PM

Hi Heather,
Apologies for the delay, Monika and I just discussed it with the Vaccine Safety Working Group and we will be producing reports on Dec 16 and Jan 13 but will skip the Dec 30 report.
Thank you.
Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ílwətaʔ/Selilwitulh (TsleilWaututh) Nations.

From: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Sent: Friday, December 10, 2021 10:56 AM
To: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: RE: Fortnightly COVID-19 AEFI Report

Hi Hadi,
I thought I'd touch base quickly to confirm the schedule for the AEFI report over the next few weeks in case there were any plans to change the timing because of holidays. Are these the dates we're expecting to post?

- Dec 16
- Dec 30
- Jan 13

Thanks,
Heather

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, December 02, 2021 4:33 PM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Fortnightly COVID-19 AEFI Report

Hello all,
Please find attached the latest fortnightly COVID-19 AEFI report for posting.
As always, thank you for all your hard work.
Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl ̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Fortnightly COVID-19 AEFI Report
Date: Thursday, December 16, 2021 2:37:17 PM
Attachments: COVID19_AEFI_Fortnightly_Report_2021-12-16.docx
COVID19_AEFI_Fortnightly_Report_2021-12-16.pdf

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to December 11, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including December 11, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

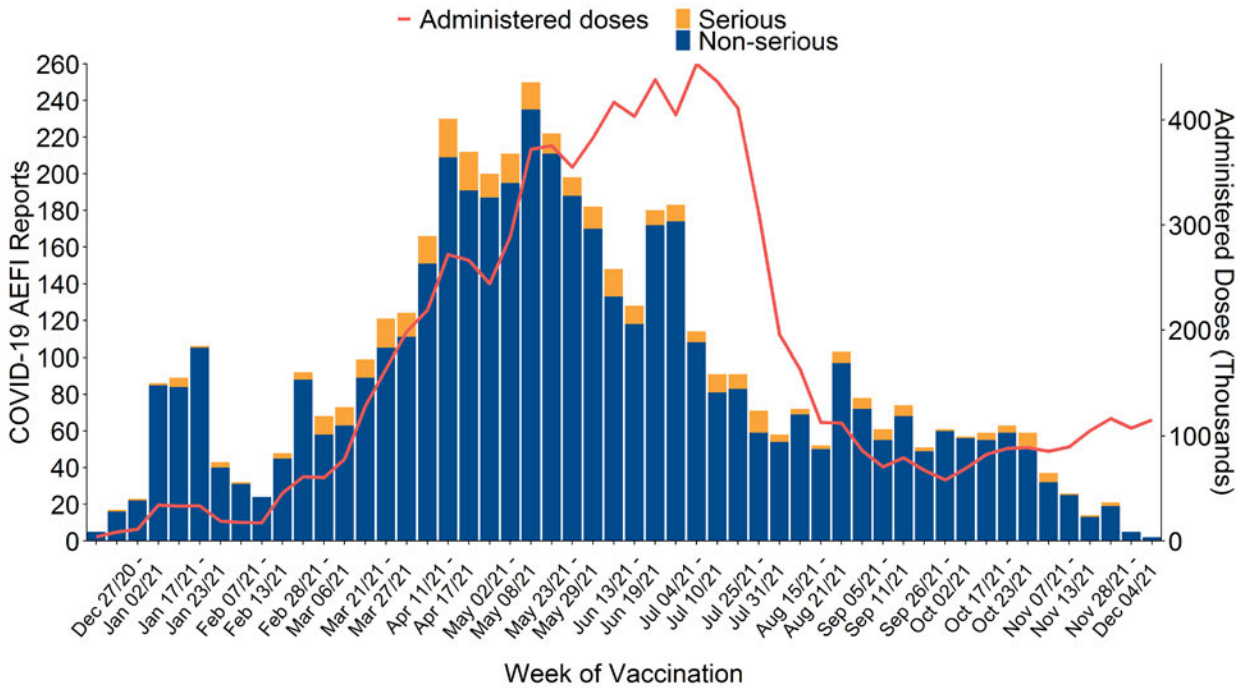
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of December 11, 2021, there have been 8,858,036 COVID-19 vaccine doses administered in BC and 4,880 COVID-19 AEFI reports (55.1 reports per 100,000 doses administered)
- 354 reports (7.3%) met the serious definition, for a rate of 4.0 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Dec. 11, 2021 **(N=4,880)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including December 11, 2021, a total of 8,858,036 doses have been administered. During this period, there have been 4,880 AEFI reports following a COVID-19 vaccine, for a reporting rate of 55.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Dec. 11, 2021 **(N=4,880)**

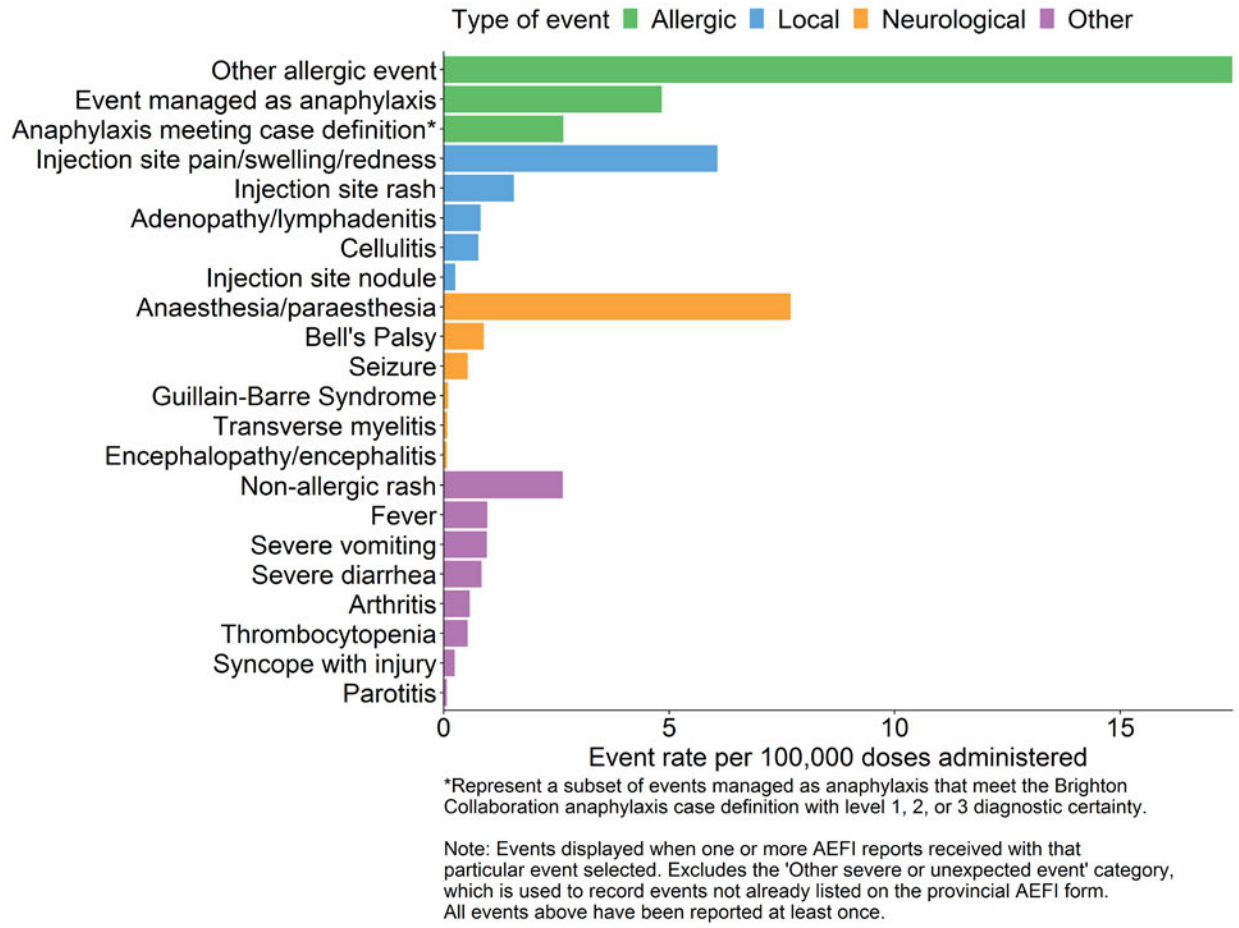
		COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**
Total reports	**4880**	**276**	**73**	**3**	**1674**	**2854**
Non-serious reports	4526	244	66	2	1560	2654
Serious reports	354	32	7	1	114	200
Proportion serious	7.3%	11.6%	9.6%	33.3%	6.8%	7%
Dose 1 reports	3779	250	71	3	1254	2201
Dose 2 reports	1040	26	2	0	374	638
Total doses administered	**8,858,036**	**333,057**	**75,916**	**6,233**	**2,411,584**	**6,031,246**
Dose 1 administered	4,207,191	227,390	63,510	5,984	911,349	2,998,958
Dose 2 administered	4,066,687	105,580	12,384	226	1,154,295	2,794,202
Total reporting rate	**55.1**	**82.9**	**96.2**	**48.1**	**69.4**	**47.3**
Serious rate	4.0	9.6	9.2	16.0	4.7	3.3
Dose 1 rate	89.8	109.9	111.8	50.1	137.6	73.4
Dose 2 rate	25.6	24.6	16.1	0.0	32.4	22.8

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 4,880 AEFI reports received up to December 11, 2021 contained a total of 6,204 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Dec. 11, 2021 **(N=6,204)**



Event Descriptions

Four hundred twenty-nine reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 235 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Sixty-eight reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred fifty-four reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 335 individuals were admitted to hospital, including 3% of cases reported as anaphylaxis.

One hundred and fifty-four reports contained a diagnosed neurological event. Seventy-nine individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Four individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Forty-seven individuals were reported with seizures (21.3% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were nine reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 42 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were fourteen reports of thrombocytopenia. Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases lead to 22 hospitalizations (52.4% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 149 were for various thrombotic/ thromboembolic conditions. These included 31 strokes (96.8% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 23 myocardial infarctions (95.6% hospitalized), 41 pulmonary emboli (63.4% hospitalized), 46 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

There have been 163 reports of myocarditis/pericarditis. Forty-five individuals were diagnosed with myocarditis, 73 with pericarditis, and 45 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.6 years, and 100 were male. Sixty-one had received Moderna Spikevax, 95 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Seventy-nine of these events occurred after a second dose (35 Moderna Spikevax and 43 Pfizer-BioNTech Comirnaty) and two occurred after a third dose (both Moderna Spikevax). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Forty (out of 45) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirty-three (out of 73) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Eighteen (out of 45) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Dec. 11, 2021 **(N=156)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**16 (10.3%)**	**14 (9%)**	**12 (7.7%)**	**19 (12.2%)**	**61 (39.1%)**
Dose 1	N (% Total)	0 (0%)	4 (2.6%)	7 (4.5%)	6 (3.8%)	7 (4.5%)	24 (15.4%)
Dose 2	N (% Total)	0 (0%)	12 (7.7%)	7 (4.5%)	6 (3.8%)	10 (6.4%)	35 (22.4%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (1.3%)	2 (1.3%)
Pfizer-BioNTech Comirnaty	**N (% Total)**	**17 (10.9%)**	**18 (11.5%)**	**5 (3.2%)**	**18 (11.5%)**	**37 (23.7%)**	**95 (60.9%)**
Dose 1	N (% Total)	7 (4.5%)	5 (3.2%)	2 (1.3%)	16 (10.3%)	22 (14.1%)	52 (33.3%)
Dose 2	N (% Total)	10 (6.4%)	13 (8.3%)	3 (1.9%)	2 (1.3%)	15 (9.6%)	43 (27.6%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
mRNA Vaccines	**N (% Total)**	**17 (10.9%)**	**34 (21.8%)**	**19 (12.2%)**	**30 (19.2%)**	**56 (35.9%)**	**156 (100%)**

Total = 156 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including December 11, 2021.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Dec. 11, 2021. Stratified by sex, age groups, vaccine trade name, and dose **(N=156)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	55.3 (20.1-133.2)	**207.0 (116.7-346.1)**	0 (0-0)	**128.7 (77.2-204.4)**	20.8 (5.0-76.8)	20.2 (4.9-74.5)	0 (0-0)	20.0 (6.2-55.8)
25-29	**102.6 (45.2-210.1)**	**142.2 (70.2-265.4)**	0 (0-0)	**120.6 (69.6-197.9)**	48.1 (14.9-133.9)	0 (0-0)	0 (0-0)	22.5 (7.0-62.6)
30-39	42.6 (17.3-93.3)	28.7 (10.4-69.0)	0 (0-0)	34.4 (17.0-64.1)	23.8 (7.4-66.4)	31.4 (11.4-75.7)	0 (0-0)	26.7 (11.7-54.6)
40+	15.0 (6.1-32.9)	10.7 (4.3-23.4)	0 (0-0)	10.2 (5.2-18.3)	11.1 (4.0-26.8)	15.8 (7.4-30.7)	11.0 (3.4-30.7)	13.2 (7.5-22.1)
All Ages	34.4 (21.3-53.2)	**42.8 (29.1-61.2)**	0 (0-0)	**34.1 (25.2-45.3)**	18.0 (9.2-32.4)	17.5 (9.6-30.0)	10.2 (3.2-28.5)	16.5 (10.7-24.5)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	45.0 (21.1-87.5)	55.4 (27.3-103.3)	0 (0-0)	50.0 (29.4-80.6)	7.7 (1.9-28.6)	24.4 (8.9-58.7)	0 (0-0)	15.8 (6.4-34.7)
18-24	21.1 (7.7-50.8)	**60.3 (31.0-108.7)**	0 (0-0)	**39.8 (22.4-66.5)**	13.7 (4.2-38.3)	36.4 (16.0-74.7)	0 (0-0)	24.5 (12.1-45.8)
25-29	**8.5 (2.1-31.5)**	**9.1 (2.2-33.7)**	0 (0-0)	**8.8 (2.7-24.4)**	8.2 (2.0-30.4)	17.5 (5.4-48.7)	0 (0-0)	12.6 (4.6-30.2)
30-39	57.7 (33.9-93)	4.7 (1.1-17.4)	0 (0-0)	31.8 (19.1-50.5)	12.5 (4.5-30.0)	4.4 (1.1-16.2)	0 (0-0)	8.4 (3.4-18.5)
40+	9.9 (5.1-17.9)	10.8 (5.5-19.4)	0 (0-0)	9.7 (6.0-15.0)	15.0 (9.0-23.7)	8.1 (4.0-15.1)	0 (0-0)	10.9 (7.2-16.0)
All Ages	21.8 (15.4-30.1)	**18.9 (12.8-27.0)**	0 (0-0)	**19.6 (15.1-25.1)**	13.3 (8.8-19.6)	12.2 (7.8-18.5)	0 (0-0)	12.3 (9.0-16.4)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	44.3 (20.8-86.1)	54.6 (27.0-101.9)	0 (0-0)	49.2 (29.0-79.4)	7.6 (1.8-28.1)	24.0 (8.7-57.9)	0 (0-0)	15.6 (6.3-34.2)
18-24	30.5 (14.3-59.4)	102.3 (65.7-153.1)	0 (0-0)	64.9 (44.1-92.7)	15.5 (5.6-37.3)	32.1 (15.1-62.5)	0 (0-0)	23.4 (12.5-41.0)
25-29	36.2 (17.0-70.3)	50.4 (25.9-90.8)	0 (0-0)	42.7 (25.6-67.9)	18.4 (6.7-44.3)	12.6 (3.9-35.1)	0 (0-0)	15.3 (6.7-31.2)
30-39	53.2 (33.4-81.3)	12.7 (5.1-27.7)	0 (0-0)	32.6 (21.4-47.9)	15.4 (6.8-31.5)	12.4 (5.0-27.1)	0 (0-0)	13.6 (7.2-23.8)
40+	11.2 (6.5-18.4)	10.7 (6.2-17.6)	0 (0-0)	9.9 (6.6-14.2)	14.1 (8.8-21.5)	10.4 (6.1-16.8)	6.6 (2.0-18.3)	11.6 (8.2-16.0)
All Ages	24.4 (18.4-31.9)	26.2 (19.9-34.0)	0 (0-0)	23.7 (19.4-28.7)	14.1 (9.9-19.7)	13.7 (9.5-19.2)	6.1 (1.9-16.9)	13.3 (10.3-16.9)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including December 11, 2021. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.

Table 3 interpretation: the rates for myopericarditis following dose 2 and calculate as a rate for all doses combined of Moderna Spikevax in BC are higher than rates following the respective doses of the Pfizer-BioNTech Comirnaty vaccine for males aged 18 to 24 years old and for all ages combined. Rates following dose 1 and dose 2 (as well as all doses combined) of Moderna Spikevax are also higher for males aged 25 to 29 years old. No significant difference in rates was observed by product for females.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on December 15, 2021. Only AEFIs reported and doses administered up to December 11, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to December 11, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including December 11, 2021. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

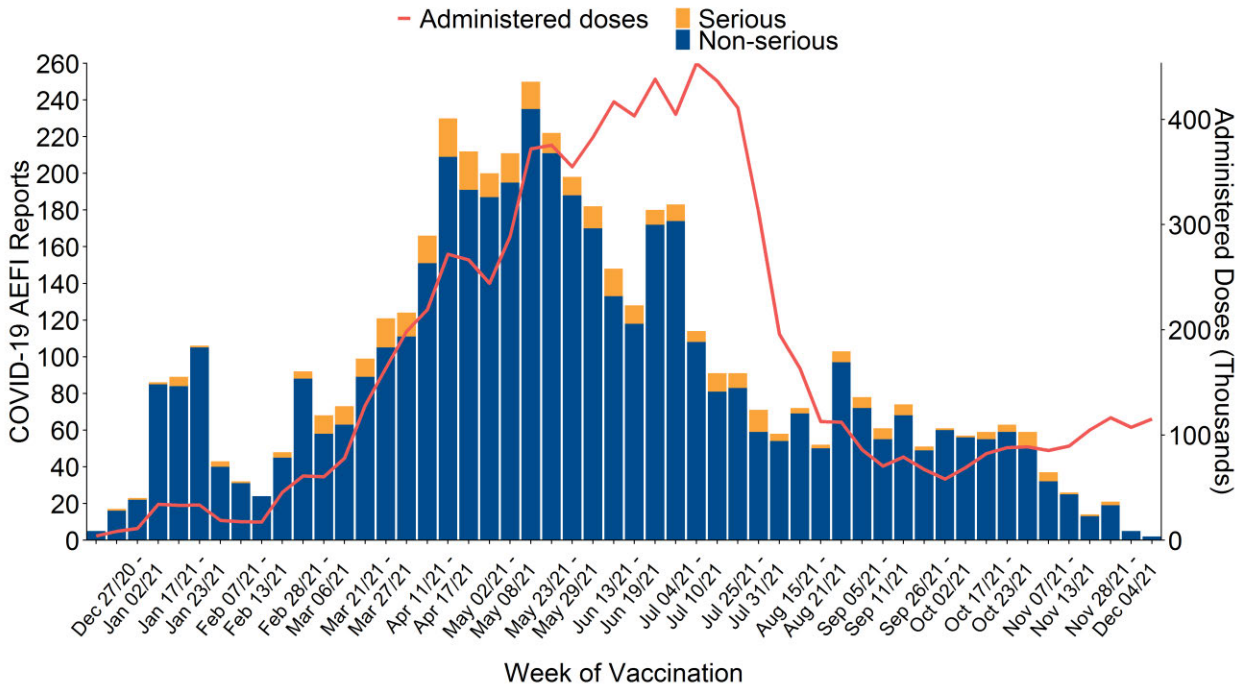
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of December 11, 2021, there have been 8,858,036 COVID-19 vaccine doses administered in BC and 4,880 COVID-19 AEFI reports (55.1 reports per 100,000 doses administered)
- 354 reports (7.3%) met the serious definition, for a rate of 4.0 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Dec. 11, 2021 **(N=4,880)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including December 11, 2021, a total of 8,858,036 doses have been administered. During this period, there have been 4,880 AEFI reports following a COVID-19 vaccine, for a reporting rate of 55.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Dec. 11, 2021 **(N=4,880)**

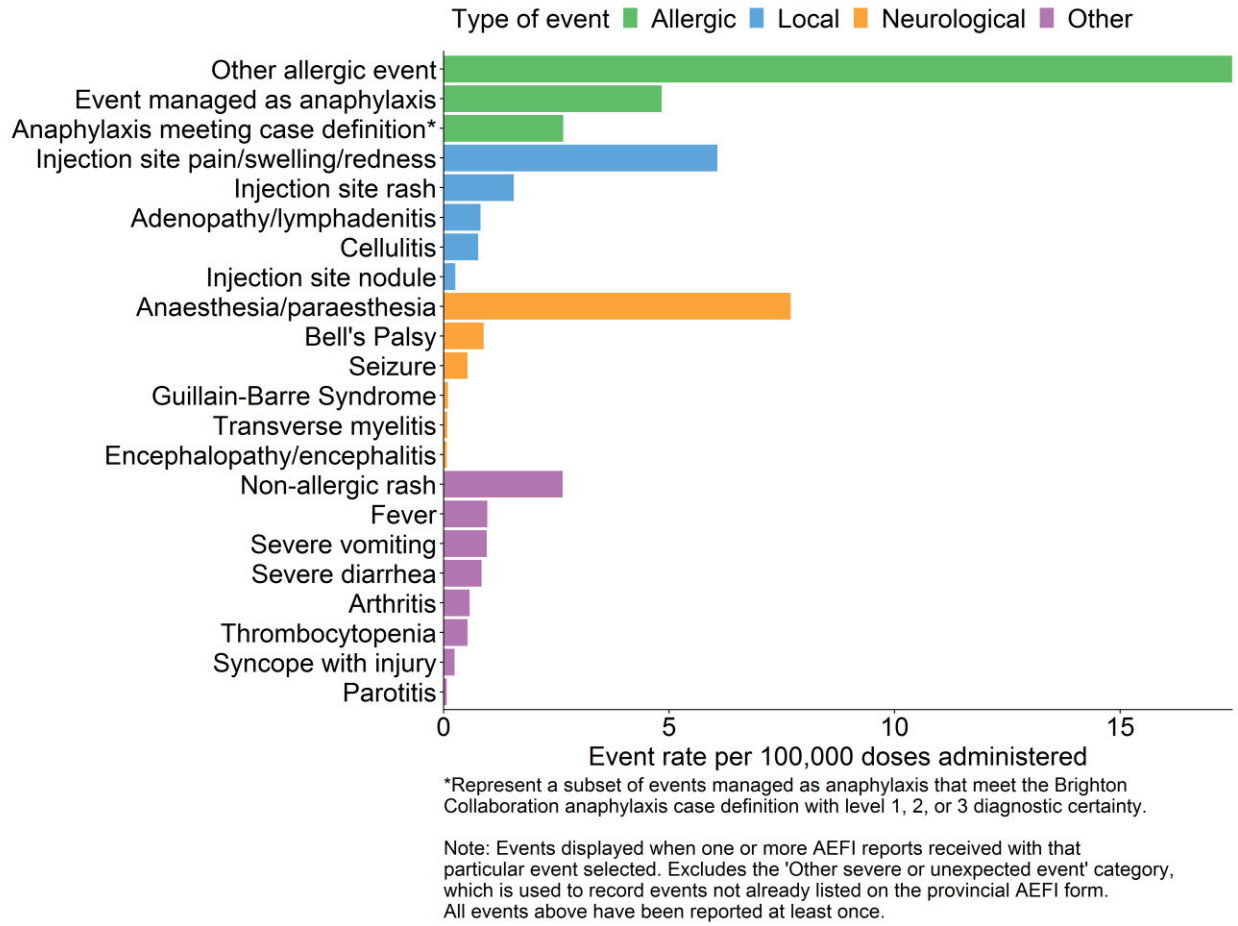
		COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**
Total reports	**4880**	**276**	**73**	**3**	**1674**	**2854**
Non-serious reports	4526	244	66	2	1560	2654
Serious reports	354	32	7	1	114	200
Proportion serious	7.3%	11.6%	9.6%	33.3%	6.8%	7%
Dose 1 reports	3779	250	71	3	1254	2201
Dose 2 reports	1040	26	2	0	374	638
Total doses administered	**8,858,036**	**333,057**	**75,916**	**6,233**	**2,411,584**	**6,031,246**
Dose 1 administered	4,207,191	227,390	63,510	5,984	911,349	2,998,958
Dose 2 administered	4,066,687	105,580	12,384	226	1,154,295	2,794,202
Total reporting rate	**55.1**	**82.9**	**96.2**	**48.1**	**69.4**	**47.3**
Serious rate	4.0	9.6	9.2	16.0	4.7	3.3
Dose 1 rate	89.8	109.9	111.8	50.1	137.6	73.4
Dose 2 rate	25.6	24.6	16.1	0.0	32.4	22.8

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 4,880 AEFI reports received up to December 11, 2021 contained a total of 6,204 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Dec. 11, 2021 **(N=6,204)**



Event Descriptions

Four hundred twenty-nine reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 235 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Sixty-eight reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred fifty-four reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 335 individuals were admitted to hospital, including 3% of cases reported as anaphylaxis.

One hundred and fifty-four reports contained a diagnosed neurological event. Seventy-nine individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Four individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Forty-seven individuals were reported with seizures (21.3% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were nine reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 42 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were fourteen reports of thrombocytopenia. Seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases lead to 22 hospitalizations (52.4% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 149 were for various thrombotic/ thromboembolic conditions. These included 31 strokes (96.8% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 23 myocardial infarctions (95.6% hospitalized), 41 pulmonary emboli (63.4% hospitalized), 46 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

There have been 163 reports of myocarditis/pericarditis. Forty-five individuals were diagnosed with myocarditis, 73 with pericarditis, and 45 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.6 years, and 100 were male. Sixty-one had received Moderna Spikevax, 95 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Seventy-nine of these events occurred after a second dose (35 Moderna Spikevax and 43 Pfizer-BioNTech Comirnaty) and two occurred after a third dose (both Moderna Spikevax). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Forty (out of 45) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirty-three (out of 73) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Eighteen (out of 45) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Dec. 11, 2021 **(N=156)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	N (% Total)	**0 (0%)**	**16 (10.3%)**	**14 (9%)**	**12 (7.7%)**	**19 (12.2%)**	**61 (39.1%)**
Dose 1	N (% Total)	0 (0%)	4 (2.6%)	7 (4.5%)	6 (3.8%)	7 (4.5%)	24 (15.4%)
Dose 2	N (% Total)	0 (0%)	12 (7.7%)	7 (4.5%)	6 (3.8%)	10 (6.4%)	35 (22.4%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (1.3%)	2 (1.3%)
Pfizer-BioNTech Comirnaty	N (% Total)	**17 (10.9%)**	**18 (11.5%)**	**5 (3.2%)**	**18 (11.5%)**	**37 (23.7%)**	**95 (60.9%)**
Dose 1	N (% Total)	7 (4.5%)	5 (3.2%)	2 (1.3%)	16 (10.3%)	22 (14.1%)	52 (33.3%)
Dose 2	N (% Total)	10 (6.4%)	13 (8.3%)	3 (1.9%)	2 (1.3%)	15 (9.6%)	43 (27.6%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
mRNA Vaccines	N (% Total)	**17 (10.9%)**	**34 (21.8%)**	**19 (12.2%)**	**30 (19.2%)**	**56 (35.9%)**	**156 (100%)**

Total = 156 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including December 11, 2021.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Dec. 11, 2021. Stratified by sex, age groups, vaccine trade name, and dose **(N=156)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	55.3 (20.1-133.2)	**207.0 (116.7-346.1)**	0 (0-0)	**128.7 (77.2-204.4)**	20.8 (5.0-76.8)	20.2 (4.9-74.5)	0 (0-0)	20.0 (6.2-55.8)
25-29	**102.6 (45.2-210.1)**	**142.2 (70.2-265.4)**	0 (0-0)	**120.6 (69.6-197.9)**	48.1 (14.9-133.9)	0 (0-0)	0 (0-0)	22.5 (7.0-62.6)
30-39	42.6 (17.3-93.3)	28.7 (10.4-69.0)	0 (0-0)	34.4 (17.0-64.1)	23.8 (7.4-66.4)	31.4 (11.4-75.7)	0 (0-0)	26.7 (11.7-54.6)
40+	15.0 (6.1-32.9)	10.7 (4.3-23.4)	0 (0-0)	10.2 (5.2-18.3)	11.1 (4.0-26.8)	15.8 (7.4-30.7)	11.0 (3.4-30.7)	13.2 (7.5-22.1)
All Ages	34.4 (21.3-53.2)	**42.8 (29.1-61.2)**	0 (0-0)	**34.1 (25.2-45.3)**	18.0 (9.2-32.4)	17.5 (9.6-30.0)	10.2 (3.2-28.5)	16.5 (10.7-24.5)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	45.0 (21.1-87.5)	55.4 (27.3-103.3)	0 (0-0)	50.0 (29.4-80.6)	7.7 (1.9-28.6)	24.4 (8.9-58.7)	0 (0-0)	15.8 (6.4-34.7)
18-24	21.1 (7.7-50.8)	**60.3 (31.0-108.7)**	0 (0-0)	**39.8 (22.4-66.5)**	13.7 (4.2-38.3)	36.4 (16.0-74.7)	0 (0-0)	24.5 (12.1-45.8)
25-29	**8.5 (2.1-31.5)**	**9.1 (2.2-33.7)**	0 (0-0)	**8.8 (2.7-24.4)**	8.2 (2.0-30.4)	17.5 (5.4-48.7)	0 (0-0)	12.6 (4.6-30.2)
30-39	57.7 (33.9-93)	4.7 (1.1-17.4)	0 (0-0)	31.8 (19.1-50.5)	12.5 (4.5-30.0)	4.4 (1.1-16.2)	0 (0-0)	8.4 (3.4-18.5)
40+	9.9 (5.1-17.9)	10.8 (5.5-19.4)	0 (0-0)	9.7 (6.0-15.0)	15.0 (9.0-23.7)	8.1 (4.0-15.1)	0 (0-0)	10.9 (7.2-16.0)
All Ages	21.8 (15.4-30.1)	**18.9 (12.8-27.0)**	0 (0-0)	**19.6 (15.1-25.1)**	13.3 (8.8-19.6)	12.2 (7.8-18.5)	0 (0-0)	12.3 (9.0-16.4)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	44.3 (20.8-86.1)	54.6 (27.0-101.9)	0 (0-0)	49.2 (29.0-79.4)	7.6 (1.8-28.1)	24.0 (8.7-57.9)	0 (0-0)	15.6 (6.3-34.2)
18-24	30.5 (14.3-59.4)	102.3 (65.7-153.1)	0 (0-0)	64.9 (44.1-92.7)	15.5 (5.6-37.3)	32.1 (15.1-62.5)	0 (0-0)	23.4 (12.5-41.0)
25-29	36.2 (17.0-70.3)	50.4 (25.9-90.8)	0 (0-0)	42.7 (25.6-67.9)	18.4 (6.7-44.3)	12.6 (3.9-35.1)	0 (0-0)	15.3 (6.7-31.2)
30-39	53.2 (33.4-81.3)	12.7 (5.1-27.7)	0 (0-0)	32.6 (21.4-47.9)	15.4 (6.8-31.5)	12.4 (5.0-27.1)	0 (0-0)	13.6 (7.2-23.8)
40+	11.2 (6.5-18.4)	10.7 (6.2-17.6)	0 (0-0)	9.9 (6.6-14.2)	14.1 (8.8-21.5)	10.4 (6.1-16.8)	6.6 (2.0-18.3)	11.6 (8.2-16.0)
All Ages	24.4 (18.4-31.9)	26.2 (19.9-34.0)	0 (0-0)	23.7 (19.4-28.7)	14.1 (9.9-19.7)	13.7 (9.5-19.2)	6.1 (1.9-16.9)	13.3 (10.3-16.9)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including December 11, 2021. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.

Table 3 interpretation: the rates for myopericarditis following dose 2 and calculate as a rate for all doses combined of Moderna Spikevax in BC are higher than rates following the respective doses of the Pfizer-BioNTech Comirnaty vaccine for males aged 18 to 24 years old and for all ages combined. Rates following dose 1 and dose 2 (as well as all doses combined) of Moderna Spikevax are also higher for males aged 25 to 29 years old. No significant difference in rates was observed by product for females.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on December 15, 2021. Only AEFIs reported and doses administered up to December 11, 2021 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Fortnightly COVID-19 AEFI Report
Date: Thursday, January 13, 2022 4:28:33 PM
Attachments: COVID19_AEFI_Fortnightly_Report_2022-01-13.docx
COVID19_AEFI_Fortnightly_Report_2022-01-13.pdf

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

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BC Centre for Disease Control

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to January 8, 2022

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including January 8, 2022. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

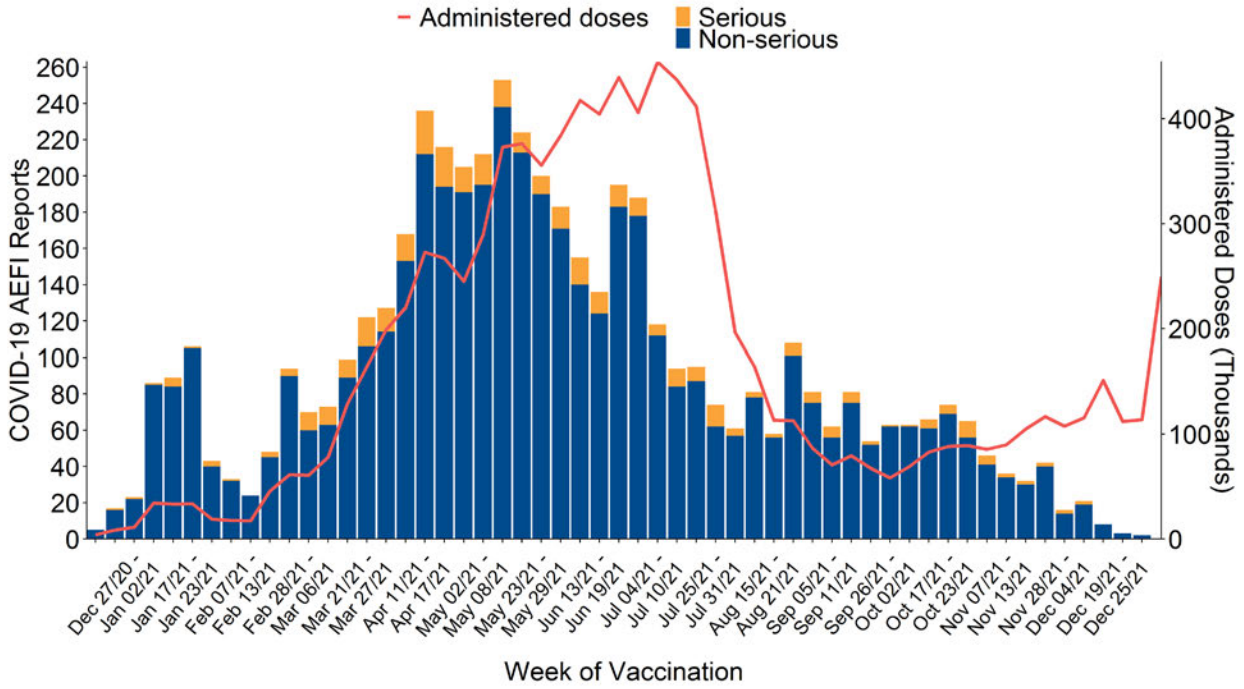
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of January 8, 2022, there have been 9,508,249 COVID-19 vaccine doses administered in BC and 5,134 COVID-19 AEFI reports (54.0 reports per 100,000 doses administered)
- 376 reports (7.3%) met the serious definition, for a rate of 4.0 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jan. 8, 2022 **(N=5,134)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including January 8, 2022, a total of 9,508,249 doses have been administered. During this period, there have been 5,134 AEFI reports following a COVID-19 vaccine, for a reporting rate of 54.0 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jan. 8, 2022 **(N=5,134)**

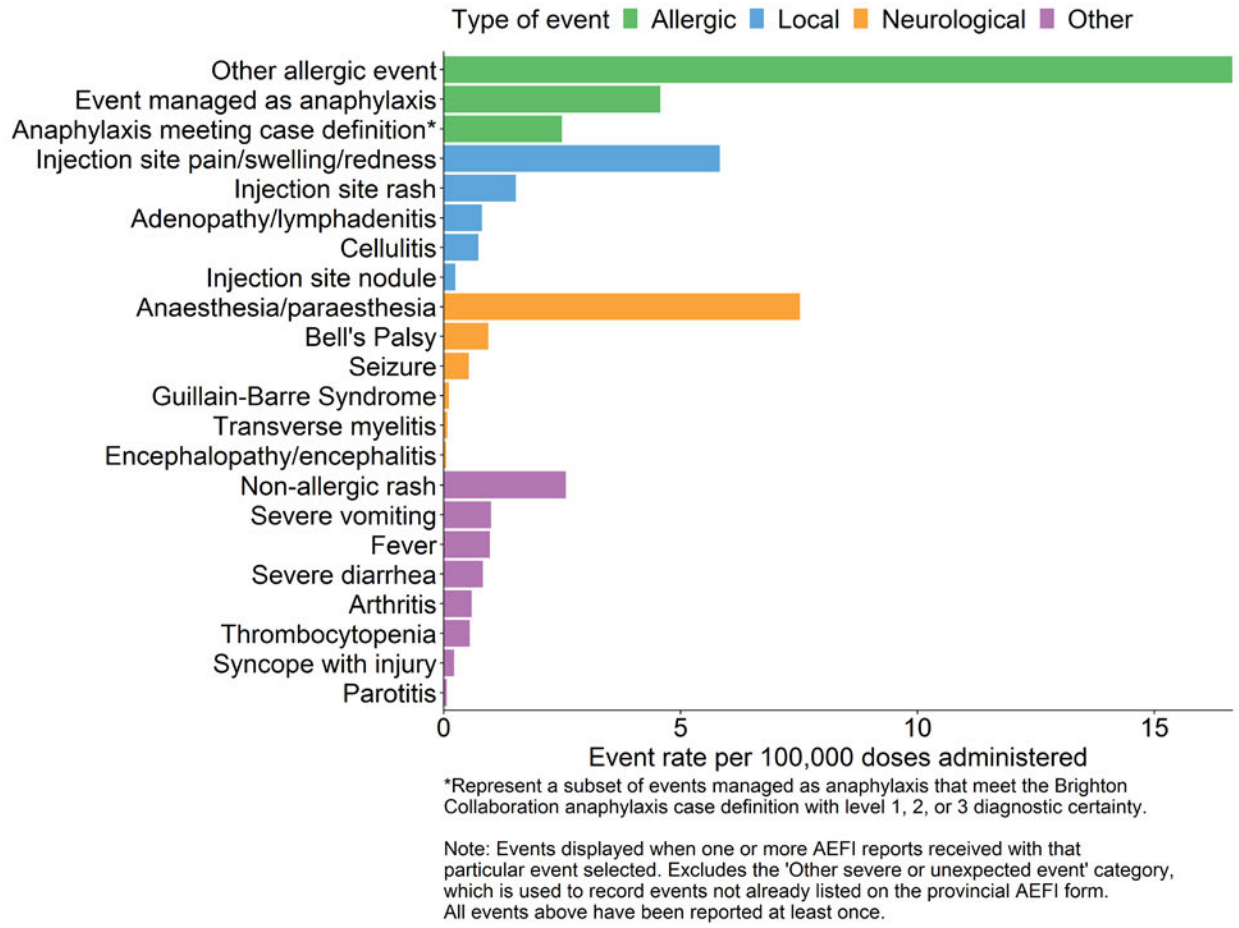
		COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**
Total reports	**5134**	**283**	**74**	**5**	**1765**	**3003**
Non-serious reports	4758	248	67	4	1644	2791
Serious reports	376	35	7	1	121	212
Proportion serious	7.3%	12.4%	9.5%	20%	6.9%	7.1%
Dose 1 reports	3890	254	72	5	1282	2273
Dose 2 reports	1146	29	2	0	410	705
Total doses administered	**9,508,249**	**335,816**	**79,335**	**8,230**	**2,781,166**	**6,303,702**
Dose 1 administered	4,235,028	228,925	65,408	7,866	917,561	3,015,268
Dose 2 administered	4,104,941	106,772	13,902	294	1,165,651	2,818,322
Total reporting rate	**54.0**	**84.3**	**93.3**	**60.8**	**63.5**	**47.6**
Serious rate	4.0	10.4	8.8	12.2	4.4	3.4
Dose 1 rate	91.9	111.0	110.1	63.6	139.7	75.4
Dose 2 rate	27.9	27.2	14.4	0.0	35.2	25.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,134 AEFI reports received up to January 8, 2022 contained a total of 6,519 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jan. 8, 2022 **(N=6,519)**



Event Descriptions

Four hundred thirty-five reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 238 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Sixty-nine reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred seventy-six reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 357 individuals were admitted to hospital, including 3.6% of cases reported as anaphylaxis. No serious AEFIs were reported in the 5-11 years old age group currently receiving the pediatric Pfizer vaccine.

One hundred and sixty-nine reports contained a diagnosed neurological event. Eighty-nine individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Five individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Fifty individuals were reported with seizures (20% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were ten reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine, 5 followed Pfizer-BioNTech Comirnaty, and 1 followed Moderna Spikevax. A possible infectious cause of GBS was not identified in eight of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 47 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were fifteen reports of idiopathic thrombocytopenic purpura: seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases lead to 22 hospitalizations (52.4% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 156 were for various thrombotic/ thromboembolic conditions. These included 33 strokes (93.9% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 24 myocardial infarctions (95.8% hospitalized), 44 pulmonary emboli (59.1% hospitalized), 47 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

There have been 179 reports of myocarditis/pericarditis. Forty-nine individuals were diagnosed with myocarditis, 82 with pericarditis, and 48 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.6 years, and 114 were male. There were no reports of myocarditis/pericarditis in the 5-11 year old age group. Sixty-seven had received Moderna Spikevax, 105 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Eighty-four of these events occurred after a second dose (37 Moderna Spikevax and 46 Pfizer-BioNTech Comirnaty) and four occurred after a third dose (all following Moderna Spikevax). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Forty-four (out of 49) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirty-seven (out of 82) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty (out of 48) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jan. 8, 2022 **(N=172)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**17 (9.9%)**	**16 (9.3%)**	**12 (7%)**	**22 (12.8%)**	**67 (39%)**
Dose 1	N (% Total)	0 (0%)	4 (2.3%)	8 (4.7%)	6 (3.5%)	8 (4.7%)	26 (15.1%)
Dose 2	N (% Total)	0 (0%)	12 (7%)	7 (4.1%)	6 (3.5%)	12 (7%)	37 (21.5%)
Dose 3	N (% Total)	0 (0%)	1 (0.6%)	1 (0.6%)	0 (0%)	2 (1.2%)	4 (2.3%)
Pfizer-BioNTech Comirnaty	**N (% Total)**	**17 (9.9%)**	**20 (11.6%)**	**6 (3.5%)**	**21 (12.2%)**	**41 (23.8%)**	**105 (61%)**
Dose 1	N (% Total)	7 (4.1%)	6 (3.5%)	2 (1.2%)	18 (10.5%)	26 (15.1%)	59 (34.3%)
Dose 2	N (% Total)	10 (5.8%)	14 (8.1%)	4 (2.3%)	3 (1.7%)	15 (8.7%)	46 (26.7%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
mRNA Vaccines	**N (% Total)**	**17 (9.9%)**	**37 (21.5%)**	**22 (12.9%)**	**33 (19.2%)**	**63 (36.7%)**	**172 (99.9%)**

Total = 172 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including January 8, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jan. 8, 2022. Stratified by sex, age groups, vaccine trade name, and dose **(N=172)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	55.6 (20.2-133.9)	205.7 (116-343.9)	287.4 (69.6-1060)	**135.2 (82.4-211.8)**	20.9 (5.1-77)	20.1 (4.9-74.2)	0 (0-0)	19.2 (5.9-53.6)
25-29	**122.2 (57.3-237.6)**	**139.9 (69-261)**	234.9 (56.9-866.5)	**135.4 (81.2-215)**	47.8 (14.8-133.2)	0 (0-0)	0 (0-0)	21 (6.5-58.6)
30-39	42.1 (17.1-92.3)	28.2 (10.2-67.9)	0 (0-0)	31.7 (15.7-59.2)	23.6 (7.3-65.7)	31 (11.3-74.7)	0 (0-0)	23.7 (10.5-48.6)
40+	18.6 (8.2-38.1)	13.2 (5.8-27)	0 (0-0)	10.5 (5.8-17.9)	11 (4-26.6)	18.3 (9-34.2)	5.5 (1.7-15.4)	11.8 (6.8-19.4)
All Ages	38.4 (24.4-58)	**44 (30.1-62.5)**	6 (1.9-16.7)	33 (24.8-43.2)	17.8 (9.2-32.2)	19.1 (10.8-32)	4.9 (1.5-13.7)	14.7 (9.6-21.6)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	44.8 (21-87.2)	54.9 (27.1-102.5)	0 (0-0)	49.7 (29.3-80.1)	7.7 (1.9-28.5)	24.2 (8.8-58.4)	0 (0-0)	15.8 (6.4-34.6)
18-24	27.9 (11.3-61.1)	66.7 (35.5-116.8)	0 (0-0)	**45.7 (26.9-73.7)**	13.7 (4.2-38)	36 (15.9-73.8)	0 (0-0)	23.7 (11.7-44.3)
25-29	**8.5 (2-31.2)**	**18 (5.6-50)**	0 (0-0)	**12.7 (4.6-30.6)**	8.2 (2-30.1)	17.3 (5.3-48.1)	0 (0-0)	12 (4.4-28.9)
30-39	66 (40.2-103.3)	9.3 (2.9-26)	0 (0-0)	37.4 (23.5-57.1)	12.4 (4.5-29.8)	4.3 (1.1-16)	0 (0-0)	8.1 (3.3-17.8)
40+	13.6 (7.7-22.7)	10.7 (5.5-19.3)	0 (0-0)	10.8 (7-16.2)	15.9 (9.7-25)	8 (4-15)	0 (0-0)	10.7 (7.1-15.7)
All Ages	25.8 (18.8-34.8)	**21 (14.5-29.4)**	0 (0-0)	21.7 (17.1-27.3)	13.9 (9.2-20.3)	12.1 (7.7-18.4)	0 (0-0)	12 (8.8-16)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	44 (20.6-85.6)	54.1 (26.7-101)	0 (0-0)	48.8 (28.8-78.8)	7.6 (1.8-28)	23.9 (8.7-57.5)	0 (0-0)	15.5 (6.3-34)
18-24	35.4 (17.5-66.1)	106.1 (69-157.5)	107.3 (26-395.8)	70.8 (49.1-99.4)	15.4 (5.6-37.2)	31.8 (14.9-61.9)	0 (0-0)	22.6 (12-39.5)
25-29	41.8 (20.6-78)	55.8 (29.7-97.7)	94.4 (22.9-348.3)	50.1 (31.4-76.6)	18.3 (6.6-44)	12.5 (3.9-34.7)	0 (0-0)	14.5 (6.4-29.7)
30-39	59 (37.9-88.3)	15.6 (6.9-32)	0 (0-0)	35.5 (24-51.1)	15.3 (6.7-31.3)	12.2 (5-26.8)	0 (0-0)	12.8 (6.8-22.4)
40+	14.8 (9.2-22.9)	11.5 (6.8-18.6)	0 (0-0)	10.7 (7.5-14.9)	14.8 (9.4-22.4)	11.1 (6.7-17.7)	3.4 (1-9.3)	11.1 (8-15.1)
All Ages	27.8 (21.4-35.6)	28 (21.5-36)	3.6 (1.1-10)	24.9 (20.7-29.7)	14.3 (10-19.8)	14.1 (9.8-19.7)	2.9 (0.9-8.2)	12.6 (9.8-15.9)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including January 8, 2021. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age groups.

Table 3 interpretation: the rates for myopericarditis calculated as a rate for all doses combined of Moderna Spikevax in BC are higher than rates following the respective doses of the Pfizer-BioNTech Comirnaty vaccine for males aged 18 to 24 years old. Rates following dose 1 and dose 2 (as well as all doses combined) of Moderna Spikevax are higher for males aged 25 to 29 years old. Rates following dose 2 of Moderna Spikevax are also higher for all ages combined. No significant difference in rates was observed by product for females.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on January 12, 2022. Only AEFIs reported and doses administered up to January 8, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to January 8, 2022

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including January 8, 2022. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been four reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 350,000 doses of the ChAdOx1 (chimpanzee adenovirus vector vaccines AstraZeneca/COVISHIELD) administered. This syndrome was identified in March in Europe in association with the AstraZeneca vaccine, with a small number of cases accumulating in Canada associated with use of these vaccines; the rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

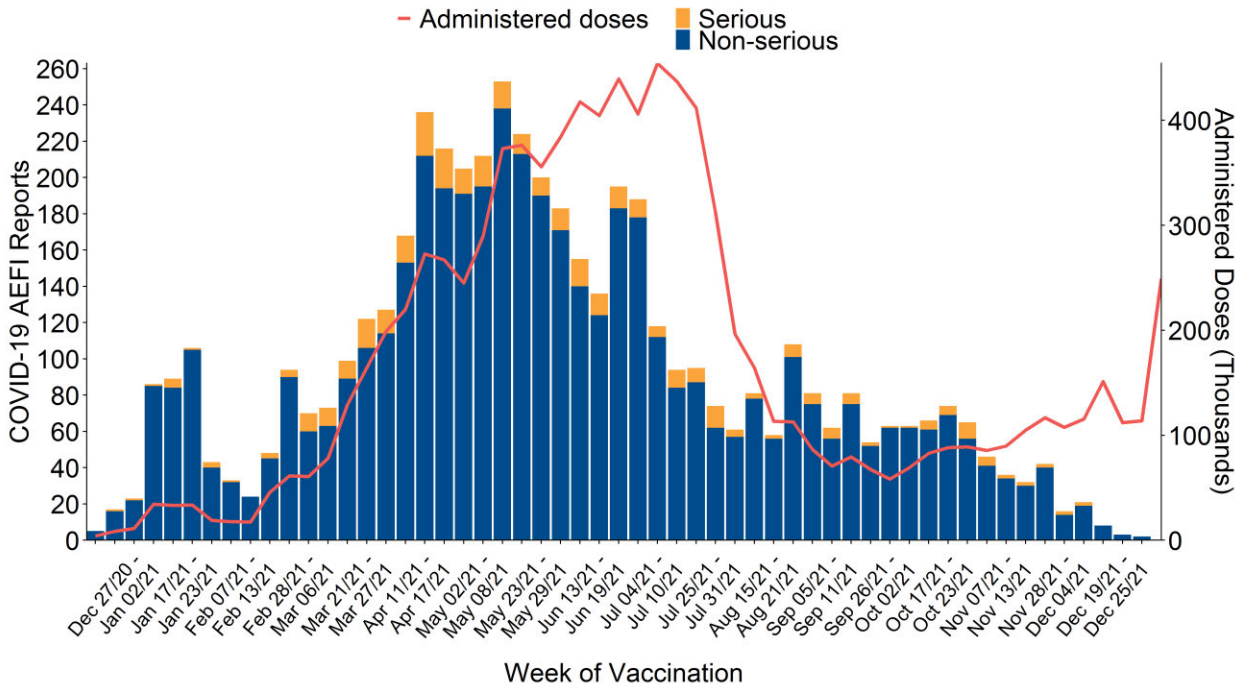
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of January 8, 2022, there have been 9,508,249 COVID-19 vaccine doses administered in BC and 5,134 COVID-19 AEFI reports (54.0 reports per 100,000 doses administered)
- 376 reports (7.3%) met the serious definition, for a rate of 4.0 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jan. 8, 2022 **(N=5,134)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including January 8, 2022, a total of 9,508,249 doses have been administered. During this period, there have been 5,134 AEFI reports following a COVID-19 vaccine, for a reporting rate of 54.0 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rate associated with second doses of all COVID-19 vaccines administered has been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jan. 8, 2022 **(N=5,134)**

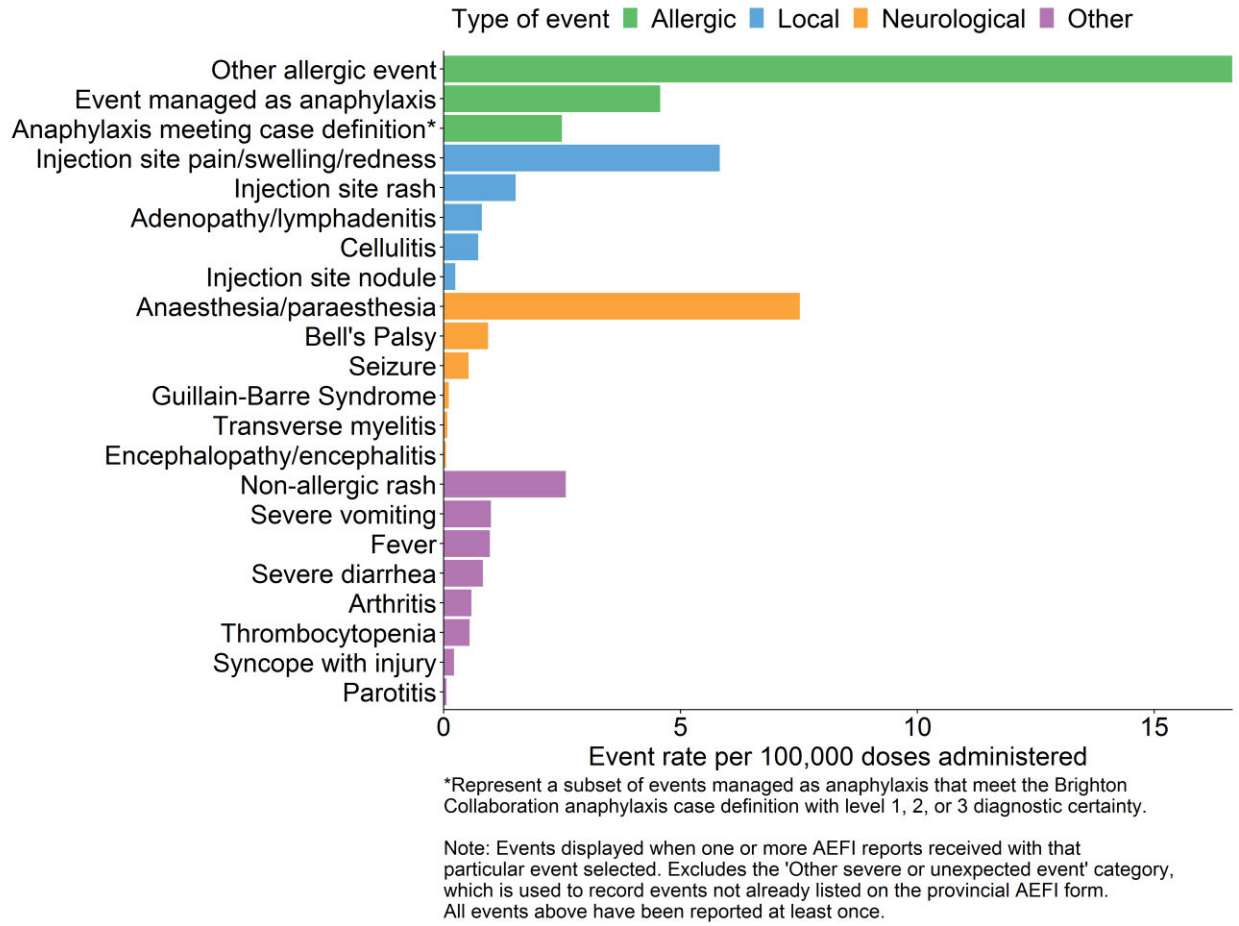
		COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**
Total reports	**5134**	**283**	**74**	**5**	**1765**	**3003**
Non-serious reports	4758	248	67	4	1644	2791
Serious reports	376	35	7	1	121	212
Proportion serious	7.3%	12.4%	9.5%	20%	6.9%	7.1%
Dose 1 reports	3890	254	72	5	1282	2273
Dose 2 reports	1146	29	2	0	410	705
Total doses administered	**9,508,249**	**335,816**	**79,335**	**8,230**	**2,781,166**	**6,303,702**
Dose 1 administered	4,235,028	228,925	65,408	7,866	917,561	3,015,268
Dose 2 administered	4,104,941	106,772	13,902	294	1,165,651	2,818,322
Total reporting rate	**54.0**	**84.3**	**93.3**	**60.8**	**63.5**	**47.6**
Serious rate	4.0	10.4	8.8	12.2	4.4	3.4
Dose 1 rate	91.9	111.0	110.1	63.6	139.7	75.4
Dose 2 rate	27.9	27.2	14.4	0.0	35.2	25.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,134 AEFI reports received up to January 8, 2022 contained a total of 6,519 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jan. 8, 2022 **(N=6,519)**



Event Descriptions

Four hundred thirty-five reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 238 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Sixty-nine reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred seventy-six reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 357 individuals were admitted to hospital, including 3.6% of cases reported as anaphylaxis. No serious AEFIs were reported in the 5-11 years old age group currently receiving the pediatric Pfizer vaccine.

One hundred and sixty-nine reports contained a diagnosed neurological event. Eighty-nine individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Five individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Fifty individuals were reported with seizures (20% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were ten reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine, 5 followed Pfizer-BioNTech Comirnaty, and 1 followed Moderna Spikevax. A possible infectious cause of GBS was not identified in eight of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 47 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were fifteen reports of idiopathic thrombocytopenic purpura: seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases lead to 22 hospitalizations (52.4% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 156 were for various thrombotic/ thromboembolic conditions. These included 33 strokes (93.9% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 24 myocardial infarctions (95.8% hospitalized), 44 pulmonary emboli (59.1% hospitalized), 47 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

There have been 179 reports of myocarditis/pericarditis. Forty-nine individuals were diagnosed with myocarditis, 82 with pericarditis, and 48 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.6 years, and 114 were male. There were no reports of myocarditis/pericarditis in the 5-11 year old age group. Sixty-seven had received Moderna Spikevax, 105 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Eighty-four of these events occurred after a second dose (37 Moderna Spikevax and 46 Pfizer-BioNTech Comirnaty) and four occurred after a third dose (all following Moderna Spikevax). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Forty-four (out of 49) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirty-seven (out of 82) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty (out of 48) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jan. 8, 2022 **(N=172)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	N (% Total)	**0 (0%)**	**17 (9.9%)**	**16 (9.3%)**	**12 (7%)**	**22 (12.8%)**	**67 (39%)**
Dose 1	N (% Total)	0 (0%)	4 (2.3%)	8 (4.7%)	6 (3.5%)	8 (4.7%)	26 (15.1%)
Dose 2	N (% Total)	0 (0%)	12 (7%)	7 (4.1%)	6 (3.5%)	12 (7%)	37 (21.5%)
Dose 3	N (% Total)	0 (0%)	1 (0.6%)	1 (0.6%)	0 (0%)	2 (1.2%)	4 (2.3%)
Pfizer-BioNTech Comirnaty	N (% Total)	**17 (9.9%)**	**20 (11.6%)**	**6 (3.5%)**	**21 (12.2%)**	**41 (23.8%)**	**105 (61%)**
Dose 1	N (% Total)	7 (4.1%)	6 (3.5%)	2 (1.2%)	18 (10.5%)	26 (15.1%)	59 (34.3%)
Dose 2	N (% Total)	10 (5.8%)	14 (8.1%)	4 (2.3%)	3 (1.7%)	15 (8.7%)	46 (26.7%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
mRNA Vaccines	N (% Total)	**17 (9.9%)**	**37 (21.5%)**	**22 (12.9%)**	**33 (19.2%)**	**63 (36.7%)**	**172 (99.9%)**

Total = 172 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including January 8, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jan. 8, 2022. Stratified by sex, age groups, vaccine trade name, and dose **(N=172)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	55.6 (20.2-133.9)	205.7 (116-343.9)	287.4 (69.6-1060)	**135.2 (82.4-211.8)**	20.9 (5.1-77)	20.1 (4.9-74.2)	0 (0-0)	19.2 (5.9-53.6)
25-29	**122.2 (57.3-237.6)**	**139.9 (69-261)**	234.9 (56.9-866.5)	**135.4 (81.2-215)**	47.8 (14.8-133.2)	0 (0-0)	0 (0-0)	21 (6.5-58.6)
30-39	42.1 (17.1-92.3)	28.2 (10.2-67.9)	0 (0-0)	31.7 (15.7-59.2)	23.6 (7.3-65.7)	31 (11.3-74.7)	0 (0-0)	23.7 (10.5-48.6)
40+	18.6 (8.2-38.1)	13.2 (5.8-27)	0 (0-0)	10.5 (5.8-17.9)	11 (4-26.6)	18.3 (9-34.2)	5.5 (1.7-15.4)	11.8 (6.8-19.4)
All Ages	38.4 (24.4-58)	**44 (30.1-62.5)**	6 (1.9-16.7)	33 (24.8-43.2)	17.8 (9.2-32.2)	19.1 (10.8-32)	4.9 (1.5-13.7)	14.7 (9.6-21.6)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	44.8 (21-87.2)	54.9 (27.1-102.5)	0 (0-0)	49.7 (29.3-80.1)	7.7 (1.9-28.5)	24.2 (8.8-58.4)	0 (0-0)	15.8 (6.4-34.6)
18-24	27.9 (11.3-61.1)	66.7 (35.5-116.8)	0 (0-0)	**45.7 (26.9-73.7)**	13.7 (4.2-38)	36 (15.9-73.8)	0 (0-0)	23.7 (11.7-44.3)
25-29	**8.5 (2-31.2)**	**18 (5.6-50)**	0 (0-0)	**12.7 (4.6-30.6)**	8.2 (2-30.1)	17.3 (5.3-48.1)	0 (0-0)	12 (4.4-28.9)
30-39	66 (40.2-103.3)	9.3 (2.9-26)	0 (0-0)	37.4 (23.5-57.1)	12.4 (4.5-29.8)	4.3 (1.1-16)	0 (0-0)	8.1 (3.3-17.8)
40+	13.6 (7.7-22.7)	10.7 (5.5-19.3)	0 (0-0)	10.8 (7-16.2)	15.9 (9.7-25)	8 (4-15)	0 (0-0)	10.7 (7.1-15.7)
All Ages	25.8 (18.8-34.8)	**21 (14.5-29.4)**	0 (0-0)	21.7 (17.1-27.3)	13.9 (9.2-20.3)	12.1 (7.7-18.4)	0 (0-0)	12 (8.8-16)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	44 (20.6-85.6)	54.1 (26.7-101)	0 (0-0)	48.8 (28.8-78.8)	7.6 (1.8-28)	23.9 (8.7-57.5)	0 (0-0)	15.5 (6.3-34)
18-24	35.4 (17.5-66.1)	106.1 (69-157.5)	107.3 (26-395.8)	70.8 (49.1-99.4)	15.4 (5.6-37.2)	31.8 (14.9-61.9)	0 (0-0)	22.6 (12-39.5)
25-29	41.8 (20.6-78)	55.8 (29.7-97.7)	94.4 (22.9-348.3)	50.1 (31.4-76.6)	18.3 (6.6-44)	12.5 (3.9-34.7)	0 (0-0)	14.5 (6.4-29.7)
30-39	59 (37.9-88.3)	15.6 (6.9-32)	0 (0-0)	35.5 (24-51.1)	15.3 (6.7-31.3)	12.2 (5-26.8)	0 (0-0)	12.8 (6.8-22.4)
40+	14.8 (9.2-22.9)	11.5 (6.8-18.6)	0 (0-0)	10.7 (7.5-14.9)	14.8 (9.4-22.4)	11.1 (6.7-17.7)	3.4 (1-9.3)	11.1 (8-15.1)
All Ages	27.8 (21.4-35.6)	28 (21.5-36)	3.6 (1.1-10)	24.9 (20.7-29.7)	14.3 (10-19.8)	14.1 (9.8-19.7)	2.9 (0.9-8.2)	12.6 (9.8-15.9)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including January 8, 2021. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age groups.

Table 3 interpretation: the rates for myopericarditis calculated as a rate for all doses combined of Moderna Spikevax in BC are higher than rates following the respective doses of the Pfizer-BioNTech Comirnaty vaccine for males aged 18 to 24 years old. Rates following dose 1 and dose 2 (as well as all doses combined) of Moderna Spikevax are higher for males aged 25 to 29 years old. Rates following dose 2 of Moderna Spikevax are also higher for all ages combined. No significant difference in rates was observed by product for females.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on January 12, 2022. Only AEFIs reported and doses administered up to January 8, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Fortnightly COVID-19 AEFI Report
Date: Thursday, January 27, 2022 3:44:43 PM
Attachments: COVID19_AEFI_Fortnightly_Report_2022-01-27.pdf
COVID19_AEFI_Fortnightly_Report_2022-01-27.docx

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to January 22, 2022

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including January 22, 2022. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

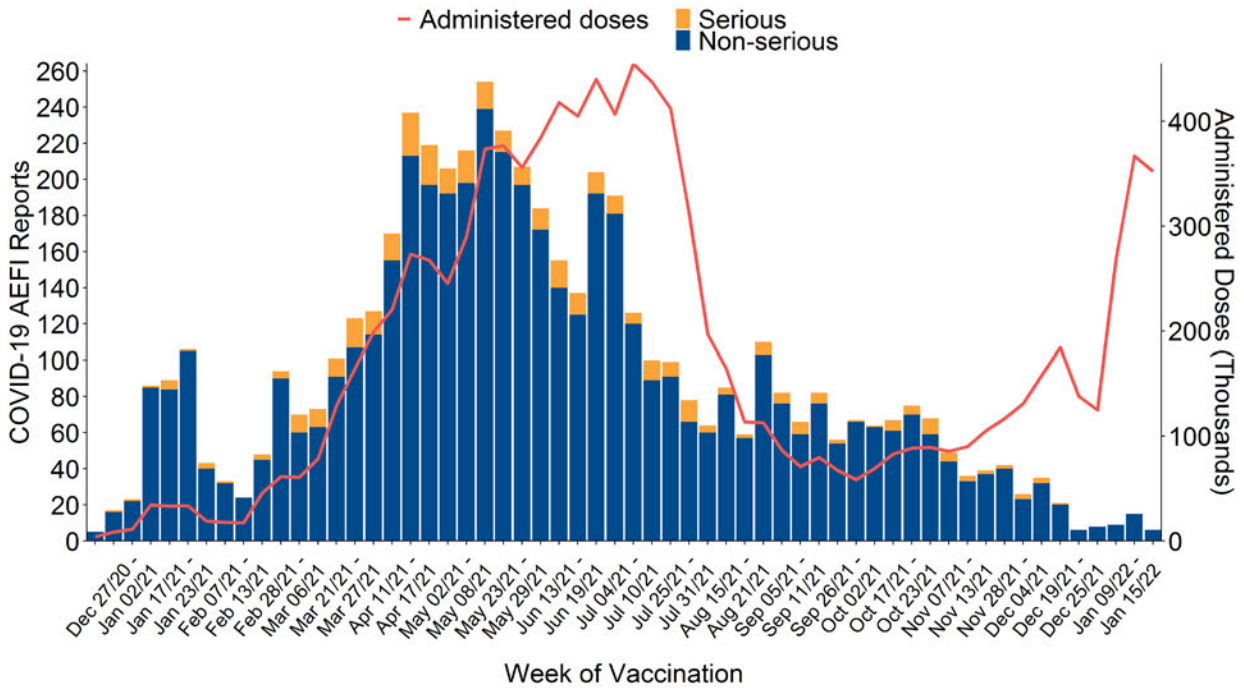
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of January 22, 2022, there have been 10,393,199 COVID-19 vaccine doses administered in BC and 5,309 COVID-19 AEFI reports (51.1 reports per 100,000 doses administered)
- 386 reports (7.3%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jan. 22, 2022 **(N=5,309)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including January 22, 2022, a total of 10,393,199 doses have been administered. During this period, there have been 5,309 AEFI reports following a COVID-19 vaccine, for a reporting rate of 51.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second and third doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jan. 22, 2022 **(N=5,309)**

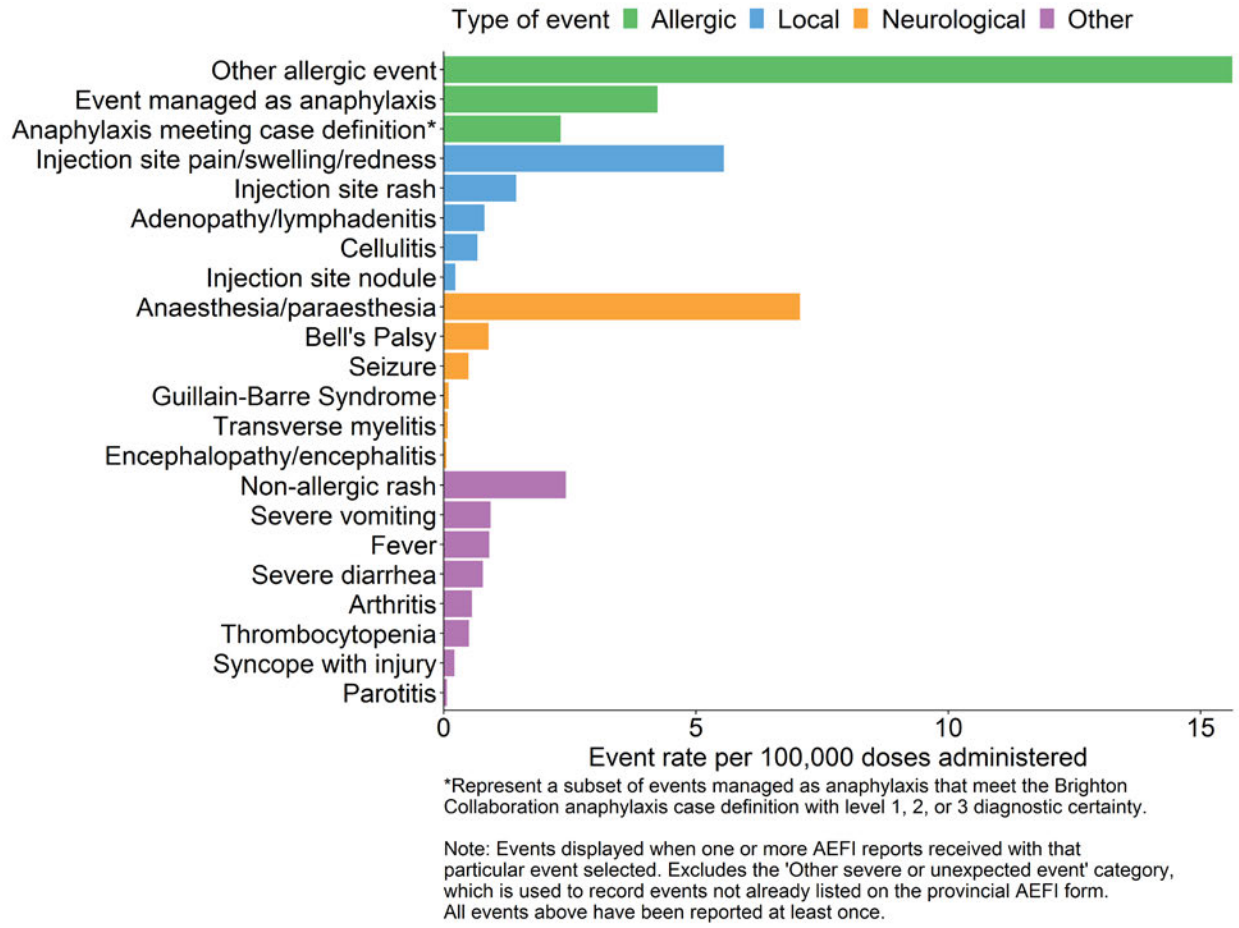
	COVID-19 Vaccine*						
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5309**	**283**	**74**	**8**	**1834**	**3095**	**15**
Non-serious reports	4923	248	67	7	1711	2876	14
Serious reports	386	35	7	1	123	219	1
Proportion serious	7.3%	12.4%	9.5%	12.5%	6.7%	7.1%	6.7%
Dose 1 reports	3966	254	72	7	1299	2319	15
Dose 2 reports	1204	29	2	1	434	738	0
Total doses administered	**10,393,199**	**337,016**	**81,322**	**9,130**	**3,194,678**	**6,596,171**	**174,882**
Dose 1 administered	4,424,981	229,564	66,457	8,693	921,329	3,024,722	174,216
Dose 2 administered	4,123,390	107,287	14,838	336	1,170,911	2,829,352	666
Total reporting rate	**51.1**	**84.0**	**91.0**	**87.6**	**57.4**	**46.9**	**8.6**
Serious rate	3.7	10.4	8.6	11.0	3.9	3.3	0.6
Dose 1 rate	89.6	110.6	108.3	80.5	141.0	76.7	8.6
Dose 2 rate	29.2	27.0	13.5	297.6	37.1	26.1	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,309 AEFI reports received up to January 22, 2022 contained a total of 6,735 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jan. 22, 2022 **(N=6,735)**



Event Descriptions

Four hundred forty-one reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 241 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Seventy reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred eighty-six reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 367 individuals were admitted to hospital, including 2.95% of cases reported as anaphylaxis.

One hundred and seventy-three reports contained a diagnosed neurological event. Ninety-two individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Five individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Fifty-one individuals were reported with seizures (19.6% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were ten reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine, 5 followed Pfizer-BioNTech Comirnaty, and 1 followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 52 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were fifteen reports of idiopathic thrombocytopenic purpura: seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases were associated with 27 hospitalizations (51.6% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 153 were for various thrombotic/ thromboembolic conditions. These included 31 strokes (96.8% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 24 myocardial infarctions (95.8% hospitalized), 44 pulmonary emboli (59.1% hospitalized), 46 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

A single serious AEFI report in the 5-11 year age group has been reported, of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19. [23]

There have been 182 reports of myocarditis/pericarditis. Forty-nine individuals were diagnosed with myocarditis, 85 with pericarditis, and 48 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.9 years, and 114 were male. There were no reports of myocarditis/pericarditis in the 5-11 year old age group. Sixty-nine had received Moderna Spikevax, 106 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Eighty-six of these events occurred after a second dose (39 Moderna Spikevax and 46 Pfizer-BioNTech Comirnaty) and four occurred after a third dose (all following Moderna Spikevax). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Forty-four (out of 49) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirty-eight (out of 85) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty (out of 48) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[24] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jan. 22, 2022 **(N=175)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**17 (9.7%)**	**16 (9.1%)**	**14 (8%)**	**22 (12.6%)**	**69 (39.4%)**
Dose 1	N (% Total)	0 (0%)	4 (2.3%)	8 (4.6%)	6 (3.4%)	8 (4.6%)	26 (14.9%)
Dose 2	N (% Total)	0 (0%)	12 (6.9%)	7 (4%)	8 (4.6%)	12 (6.9%)	39 (22.3%)
Dose 3	N (% Total)	0 (0%)	1 (0.6%)	1 (0.6%)	0 (0%)	2 (1.1%)	4 (2.3%)
Pfizer-BioNTech Comirnaty	**N (% Total)**	**17 (9.7%)**	**20 (11.4%)**	**6 (3.4%)**	**21 (12%)**	**42 (24%)**	**106 (60.6%)**
Dose 1	N (% Total)	7 (4%)	6 (3.4%)	2 (1.1%)	18 (10.3%)	27 (15.4%)	60 (34.3%)
Dose 2	N (% Total)	10 (5.7%)	14 (8%)	4 (2.3%)	3 (1.7%)	15 (8.6%)	46 (26.3%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
mRNA Vaccines	**N (% Total)**	**17 (9.7%)**	**37 (21.2%)**	**22 (12.6%)**	**35 (20%)**	**64 (36.6%)**	**175 (100.1%)**

Total = 175 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including January 22, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jan. 22, 2022. Stratified by sex, age groups, vaccine trade name, and dose **(N=175)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	55.8 (20.3-134.3)	**205.7 (116-344)**	142.3 (34.5-524.8)	**131.2 (80-205.5)**	20.9 (5.1-77.1)	20.1 (4.9-74.1)	0 (0-0)	18.3 (5.6-50.8)
25-29	**121.6 (57.1-236.5)**	**138.8 (68.5-259)**	112.9 (27.4-416.6)	**128.9 (77.3-204.7)**	47.6 (14.7-132.6)	0 (0-0)	0 (0-0)	19.6 (6.1-54.7)
30-39	41.8 (17-91.6)	28 (10.2-67.4)	0 (0-0)	27.3 (13.4-50.8)	23.5 (7.3-65.4)	**51.4 (22.6-105.3)**	0 (0-0)	28.1 (13.9-52.4)
40+	18.5 (8.2-37.9)	13.1 (5.8-26.9)	0 (0-0)	9.1 (5-15.5)	11 (4-26.5)	18.2 (9-34)	3.9 (1.2-10.7)	10.2 (5.9-16.7)
All Ages	38.2 (24.3-57.8)	**43.8 (30-62.2)**	3.8 (1.2-10.6)	29 (21.8-37.9)	17.8 (9.1-32)	22.5 (13.2-36.3)	3.3 (1-9.1)	14 (9.4-20.3)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	44.8 (21-87.2)	54.9 (27.1-102.5)	0 (0-0)	49.7 (29.2-80.1)	7.7 (1.9-28.5)	24.3 (8.8-58.4)	0 (0-0)	15.8 (6.4-34.6)
18-24	27.7 (11.3-60.8)	**66.1 (35.2-115.8)**	0 (0-0)	**43.3 (25.5-69.8)**	13.6 (4.2-37.8)	35.8 (15.8-73.3)	0 (0-0)	22.1 (10.9-41.3)
25-29	**8.4 (2-31)**	**17.8 (5.5-49.6)**	0 (0-0)	**11.9 (4.3-28.7)**	8.1 (2-30)	17.2 (5.3-47.9)	0 (0-0)	11.2 (4.1-26.9)
30-39	65.7 (40.1-102.9)	9.3 (2.9-25.9)	0 (0-0)	35.5 (22.3-54.3)	12.3 (4.5-29.7)	**4.3 (1-16)**	0 (0-0)	7.7 (3.1-16.9)
40+	13.5 (7.6-22.6)	10.7 (5.5-19.2)	0 (0-0)	10.4 (6.7-15.5)	17 (10.5-26.2)	8 (3.9-14.9)	0 (0-0)	10.7 (7.2-15.6)
All Ages	25.7 (18.7-34.7)	**20.9 (14.5-29.3)**	0 (0-0)	20.8 (16.3-26.1)	14.5 (9.7-21)	12.1 (7.7-18.3)	0 (0-0)	11.7 (8.7-15.6)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	43.8 (20.6-85.2)	54.1 (26.7-101)	0 (0-0)	48.7 (28.7-78.5)	7.5 (1.8-27.8)	23.9 (8.7-57.5)	0 (0-0)	15.5 (6.3-33.9)
18-24	35.3 (17.4-65.9)	105.5 (68.6-156.5)	36.9 (8.9-136.2)	67.5 (46.8-94.7)	15.4 (5.6-37)	31.7 (14.8-61.6)	0 (0-0)	21.1 (11.3-37)
25-29	41.6 (20.5-77.5)	55.3 (29.5-96.9)	33.7 (8.2-124.5)	47.1 (29.6-72)	18.2 (6.6-43.8)	12.4 (3.8-34.5)	0 (0-0)	13.5 (5.9-27.7)
30-39	58.6 (37.7-87.8)	15.5 (6.8-31.7)	0 (0-0)	32.6 (22-46.9)	15.2 (6.7-31.2)	18.3 (8.6-35.5)	0 (0-0)	14.3 (8.1-23.9)
40+	14.8 (9.1-22.9)	11.5 (6.8-18.5)	0 (0-0)	9.9 (6.9-13.8)	15.6 (10-23.4)	11.1 (6.7-17.6)	2.4 (0.7-6.6)	10.6 (7.6-14.3)
All Ages	27.5 (21.2-35.2)	27.9 (21.4-35.8)	2.3 (0.7-6.4)	23.1 (19.2-27.6)	14.6 (10.3-20.2)	15 (10.6-20.7)	1.9 (0.6-5.4)	12.2 (9.6-15.4)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including January 22, 2021. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age groups.

Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following dose and age groups:

Males:

- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 only

Females:

- 30-39 years old: Dose 2 only

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on January 25, 2022. Only AEFIs reported and doses administered up to January 22, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to January 22, 2022

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including January 22, 2022. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

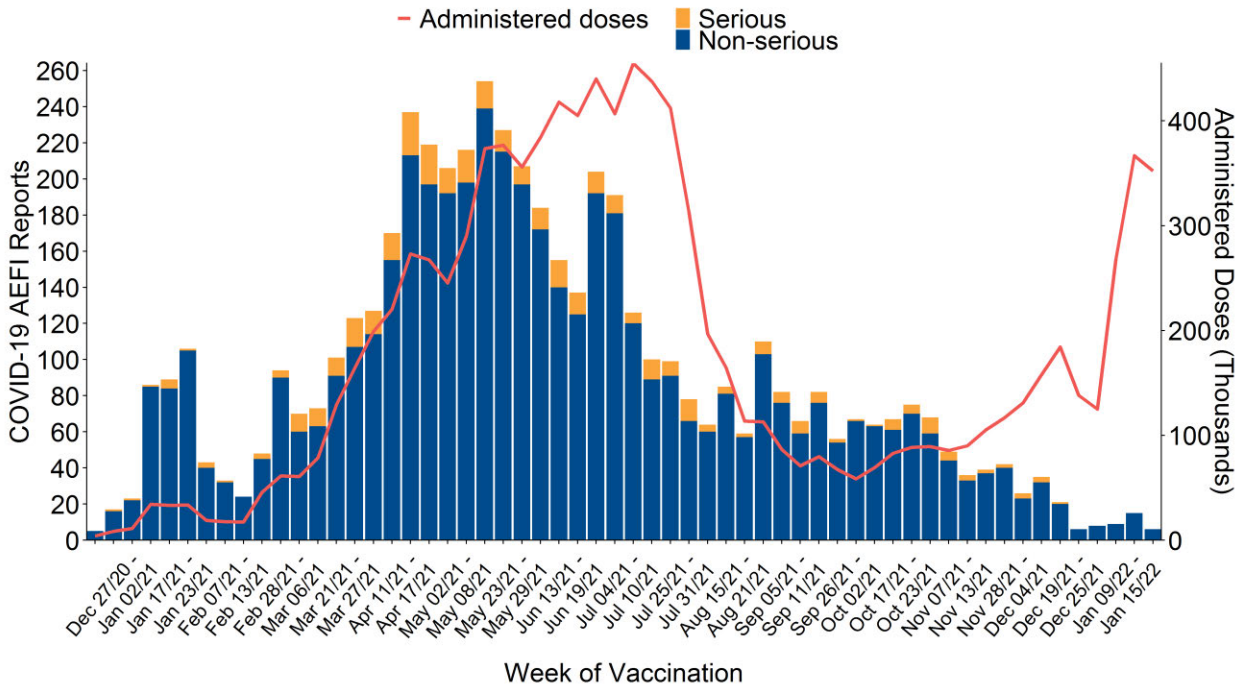
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of January 22, 2022, there have been 10,393,199 COVID-19 vaccine doses administered in BC and 5,309 COVID-19 AEFI reports (51.1 reports per 100,000 doses administered)
- 386 reports (7.3%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jan. 22, 2022 **(N=5,309)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including January 22, 2022, a total of 10,393,199 doses have been administered. During this period, there have been 5,309 AEFI reports following a COVID-19 vaccine, for a reporting rate of 51.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second and third doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jan. 22, 2022 **(N=5,309)**

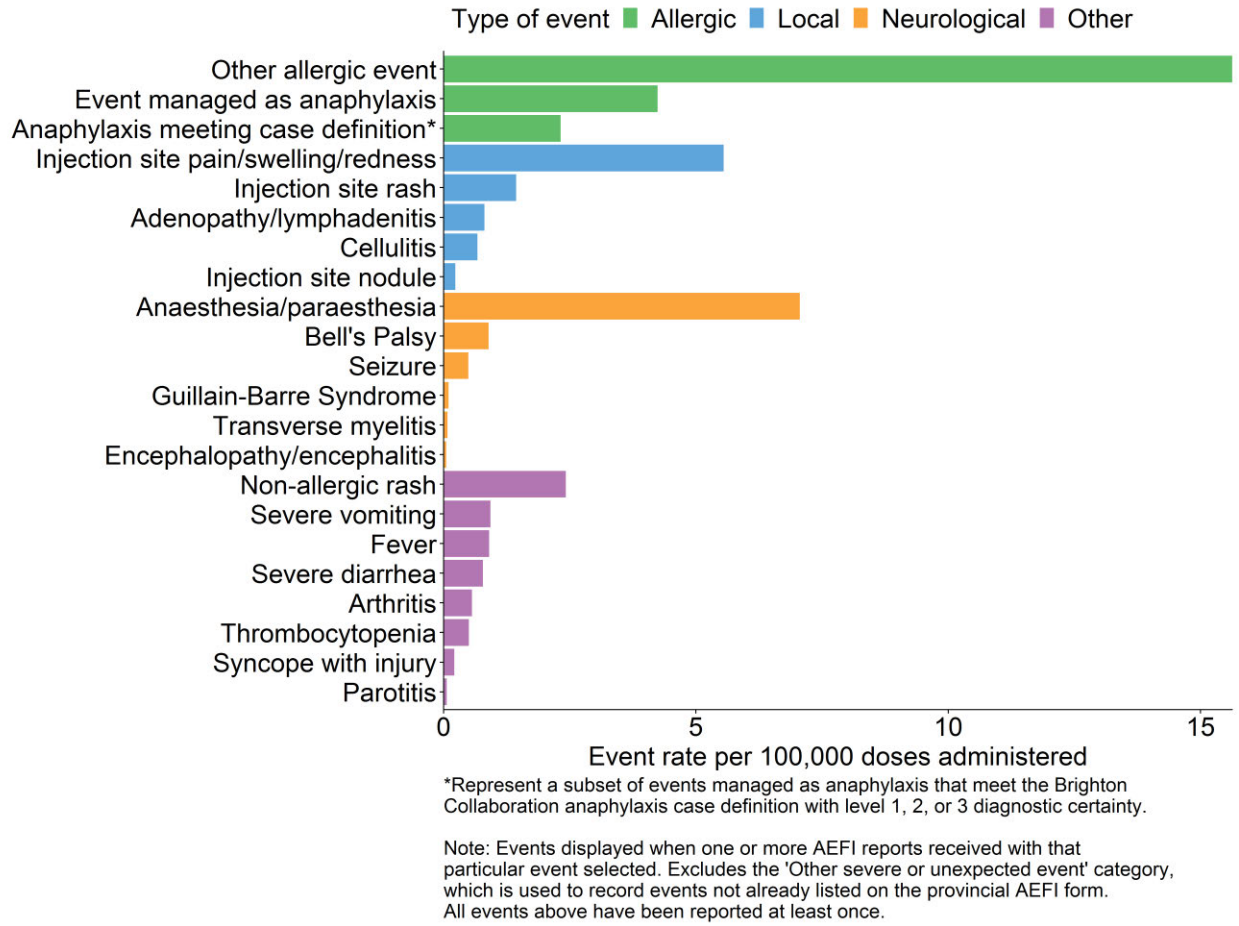
	COVID-19 Vaccine*						
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5309**	**283**	**74**	**8**	**1834**	**3095**	**15**
Non-serious reports	4923	248	67	7	1711	2876	14
Serious reports	386	35	7	1	123	219	1
Proportion serious	7.3%	12.4%	9.5%	12.5%	6.7%	7.1%	6.7%
Dose 1 reports	3966	254	72	7	1299	2319	15
Dose 2 reports	1204	29	2	1	434	738	0
Total doses administered	**10,393,199**	**337,016**	**81,322**	**9,130**	**3,194,678**	**6,596,171**	**174,882**
Dose 1 administered	4,424,981	229,564	66,457	8,693	921,329	3,024,722	174,216
Dose 2 administered	4,123,390	107,287	14,838	336	1,170,911	2,829,352	666
Total reporting rate	**51.1**	**84.0**	**91.0**	**87.6**	**57.4**	**46.9**	**8.6**
Serious rate	3.7	10.4	8.6	11.0	3.9	3.3	0.6
Dose 1 rate	89.6	110.6	108.3	80.5	141.0	76.7	8.6
Dose 2 rate	29.2	27.0	13.5	297.6	37.1	26.1	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,309 AEFI reports received up to January 22, 2022 contained a total of 6,735 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jan. 22, 2022 **(N=6,735)**



Event Descriptions

Four hundred forty-one reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 241 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Seventy reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred eighty-six reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 367 individuals were admitted to hospital, including 2.95% of cases reported as anaphylaxis.

One hundred and seventy-three reports contained a diagnosed neurological event. Ninety-two individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Five individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Fifty-one individuals were reported with seizures (19.6% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were ten reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine, 5 followed Pfizer-BioNTech Comirnaty, and 1 followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 52 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were fifteen reports of idiopathic thrombocytopenic purpura: seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases were associated with 27 hospitalizations (51.6% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:

Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 153 were for various thrombotic/ thromboembolic conditions. These included 31 strokes (96.8% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 24 myocardial infarctions (95.8% hospitalized), 44 pulmonary emboli (59.1% hospitalized), 46 deep vein thromboses, and seven superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

A single serious AEFI report in the 5-11 year age group has been reported, of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19. [23]

There have been 182 reports of myocarditis/pericarditis. Forty-nine individuals were diagnosed with myocarditis, 85 with pericarditis, and 48 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.9 years, and 114 were male. There were no reports of myocarditis/pericarditis in the 5-11 year old age group. Sixty-nine had received Moderna Spikevax, 106 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Eighty-six of these events occurred after a second dose (39 Moderna Spikevax and 46 Pfizer-BioNTech Comirnaty) and four occurred after a third dose (all following Moderna Spikevax). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Forty-four (out of 49) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Thirty-eight (out of 85) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty (out of 48) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[24] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jan. 22, 2022 **(N=175)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	N (% Total)	**0 (0%)**	**17 (9.7%)**	**16 (9.1%)**	**14 (8%)**	**22 (12.6%)**	**69 (39.4%)**
Dose 1	N (% Total)	0 (0%)	4 (2.3%)	8 (4.6%)	6 (3.4%)	8 (4.6%)	26 (14.9%)
Dose 2	N (% Total)	0 (0%)	12 (6.9%)	7 (4%)	8 (4.6%)	12 (6.9%)	39 (22.3%)
Dose 3	N (% Total)	0 (0%)	1 (0.6%)	1 (0.6%)	0 (0%)	2 (1.1%)	4 (2.3%)
Pfizer-BioNTech Comirnaty	N (% Total)	**17 (9.7%)**	**20 (11.4%)**	**6 (3.4%)**	**21 (12%)**	**42 (24%)**	**106 (60.6%)**
Dose 1	N (% Total)	7 (4%)	6 (3.4%)	2 (1.1%)	18 (10.3%)	27 (15.4%)	60 (34.3%)
Dose 2	N (% Total)	10 (5.7%)	14 (8%)	4 (2.3%)	3 (1.7%)	15 (8.6%)	46 (26.3%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
mRNA Vaccines	N (% Total)	**17 (9.7%)**	**37 (21.2%)**	**22 (12.6%)**	**35 (20%)**	**64 (36.6%)**	**175 (100.1%)**

Total = 175 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including January 22, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jan. 22, 2022. Stratified by sex, age groups, vaccine trade name, and dose **(N=175)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	55.8 (20.3-134.3)	**205.7 (116-344)**	142.3 (34.5-524.8)	**131.2 (80-205.5)**	20.9 (5.1-77.1)	20.1 (4.9-74.1)	0 (0-0)	18.3 (5.6-50.8)
25-29	**121.6 (57.1-236.5)**	**138.8 (68.5-259)**	112.9 (27.4-416.6)	**128.9 (77.3-204.7)**	47.6 (14.7-132.6)	0 (0-0)	0 (0-0)	19.6 (6.1-54.7)
30-39	41.8 (17-91.6)	28 (10.2-67.4)	0 (0-0)	27.3 (13.4-50.8)	23.5 (7.3-65.4)	**51.4 (22.6-105.3)**	0 (0-0)	28.1 (13.9-52.4)
40+	18.5 (8.2-37.9)	13.1 (5.8-26.9)	0 (0-0)	9.1 (5-15.5)	11 (4-26.5)	18.2 (9-34)	3.9 (1.2-10.7)	10.2 (5.9-16.7)
All Ages	38.2 (24.3-57.8)	**43.8 (30-62.2)**	3.8 (1.2-10.6)	29 (21.8-37.9)	17.8 (9.1-32)	22.5 (13.2-36.3)	3.3 (1-9.1)	14 (9.4-20.3)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	44.8 (21-87.2)	54.9 (27.1-102.5)	0 (0-0)	49.7 (29.2-80.1)	7.7 (1.9-28.5)	24.3 (8.8-58.4)	0 (0-0)	15.8 (6.4-34.6)
18-24	27.7 (11.3-60.8)	**66.1 (35.2-115.8)**	0 (0-0)	**43.3 (25.5-69.8)**	13.6 (4.2-37.8)	35.8 (15.8-73.3)	0 (0-0)	22.1 (10.9-41.3)
25-29	**8.4 (2-31)**	**17.8 (5.5-49.6)**	0 (0-0)	**11.9 (4.3-28.7)**	8.1 (2-30)	17.2 (5.3-47.9)	0 (0-0)	11.2 (4.1-26.9)
30-39	65.7 (40.1-102.9)	9.3 (2.9-25.9)	0 (0-0)	35.5 (22.3-54.3)	12.3 (4.5-29.7)	**4.3 (1-16)**	0 (0-0)	7.7 (3.1-16.9)
40+	13.5 (7.6-22.6)	10.7 (5.5-19.2)	0 (0-0)	10.4 (6.7-15.5)	17 (10.5-26.2)	8 (3.9-14.9)	0 (0-0)	10.7 (7.2-15.6)
All Ages	25.7 (18.7-34.7)	**20.9 (14.5-29.3)**	0 (0-0)	20.8 (16.3-26.1)	14.5 (9.7-21)	12.1 (7.7-18.3)	0 (0-0)	11.7 (8.7-15.6)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	43.8 (20.6-85.2)	54.1 (26.7-101)	0 (0-0)	48.7 (28.7-78.5)	7.5 (1.8-27.8)	23.9 (8.7-57.5)	0 (0-0)	15.5 (6.3-33.9)
18-24	35.3 (17.4-65.9)	105.5 (68.6-156.5)	36.9 (8.9-136.2)	67.5 (46.8-94.7)	15.4 (5.6-37)	31.7 (14.8-61.6)	0 (0-0)	21.1 (11.3-37)
25-29	41.6 (20.5-77.5)	55.3 (29.5-96.9)	33.7 (8.2-124.5)	47.1 (29.6-72)	18.2 (6.6-43.8)	12.4 (3.8-34.5)	0 (0-0)	13.5 (5.9-27.7)
30-39	58.6 (37.7-87.8)	15.5 (6.8-31.7)	0 (0-0)	32.6 (22-46.9)	15.2 (6.7-31.2)	18.3 (8.6-35.5)	0 (0-0)	14.3 (8.1-23.9)
40+	14.8 (9.1-22.9)	11.5 (6.8-18.5)	0 (0-0)	9.9 (6.9-13.8)	15.6 (10-23.4)	11.1 (6.7-17.6)	2.4 (0.7-6.6)	10.6 (7.6-14.3)
All Ages	27.5 (21.2-35.2)	27.9 (21.4-35.8)	2.3 (0.7-6.4)	23.1 (19.2-27.6)	14.6 (10.3-20.2)	15 (10.6-20.7)	1.9 (0.6-5.4)	12.2 (9.6-15.4)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including January 22, 2021. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age groups.

Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following dose and age groups:

Males:

- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 only

Females:

- 30-39 years old: Dose 2 only

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on January 25, 2022. Only AEFIs reported and doses administered up to January 22, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Fortnightly COVID-19 AEFI Report
Date: Thursday, February 10, 2022 3:26:11 PM
Attachments: COVID19_AEFI_Fortnightly_Report_2022-02-10.docx
COVID19_AEFI_Fortnightly_Report_2022-02-10.pdf

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to February 5, 2022

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including February 5, 2022. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

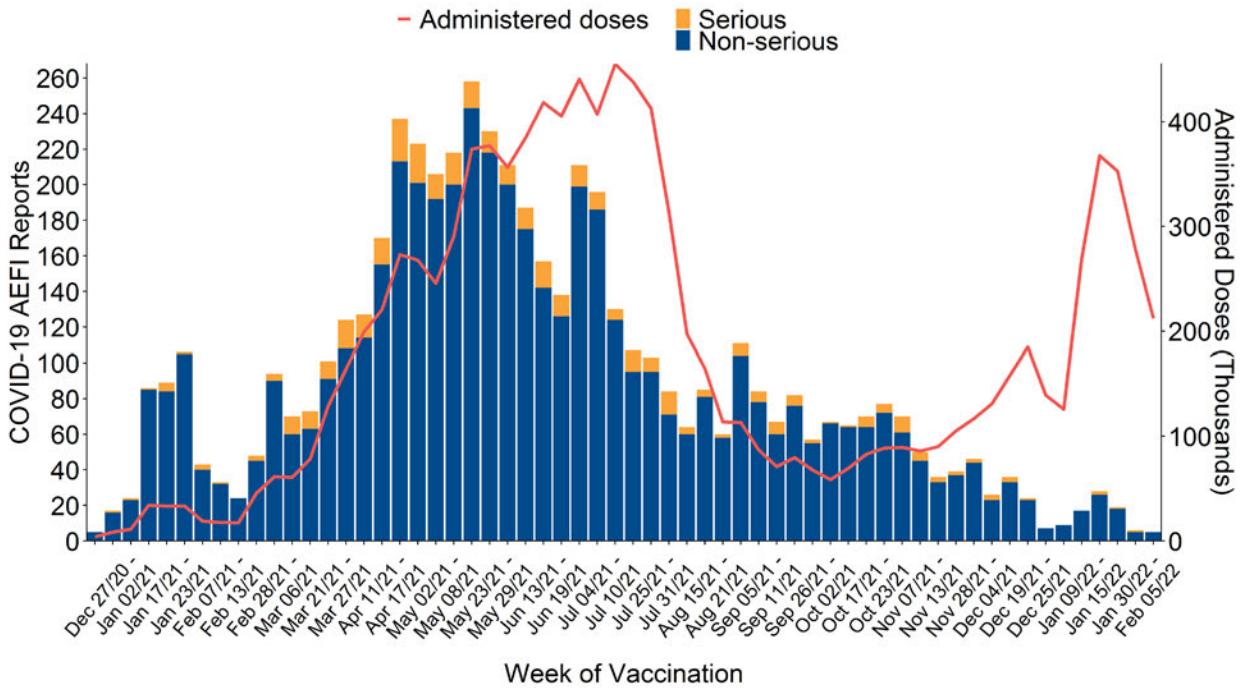
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of February 5, 2022, there have been 10,899,702 COVID-19 vaccine doses administered in BC and 5,437 COVID-19 AEFI reports (49.9 reports per 100,000 doses administered)
- 393 reports (7.2%) met the serious definition, for a rate of 3.6 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Feb. 5, 2022 **(N=5,437)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including February 5, 2022, a total of 10,899,702 doses have been administered. During this period, there have been 5,437 AEFI reports following a COVID-19 vaccine, for a reporting rate of 49.9 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second and third doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Feb. 5, 2022 **(N=5,437)**

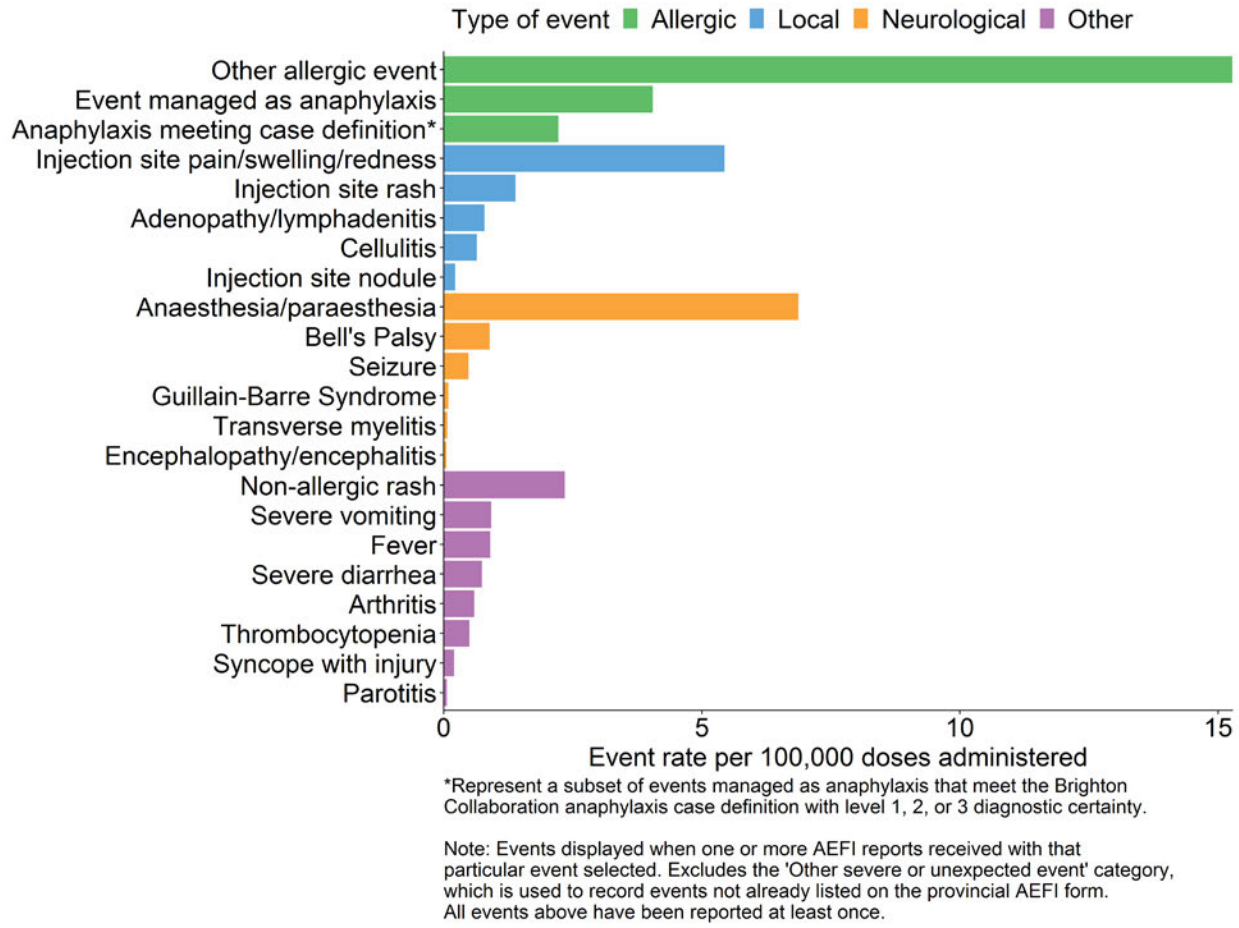
	COVID-19 Vaccine*						
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5437**	**282**	**75**	**8**	**1898**	**3154**	**20**
Non-serious reports	5044	247	68	7	1773	2931	18
Serious reports	393	35	7	1	125	223	2
Proportion serious	7.2%	12.4%	9.3%	12.5%	6.6%	7.1%	10%
Dose 1 reports	3943	252	73	6	1266	2326	20
Dose 2 reports	1307	29	2	2	503	771	0
Total doses administered	**10,899,702**	**338,325**	**83,216**	**9,999**	**3,417,922**	**6,835,594**	**214,646**
Dose 1 administered	4,450,396	230,248	67,459	9,498	923,991	3,032,076	187,124
Dose 2 administered	4,165,878	107,839	15,724	378	1,175,034	2,839,381	27,522
Total reporting rate	**49.9**	**83.4**	**90.1**	**80.0**	**55.5**	**46.1**	**9.3**
Serious rate	3.6	10.3	8.4	10.0	3.7	3.3	0.9
Dose 1 rate	88.6	109.4	108.2	63.2	137.0	76.7	10.7
Dose 2 rate	31.4	26.9	12.7	529.1	42.8	27.2	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,437 AEFI reports received up to February 5, 2022 contained a total of 6,907 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Feb. 5, 2022 **(N=6,907)**



Event Descriptions

Four hundred forty-one reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 242 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Seventy reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred ninety-three reports (7.2%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 374 individuals were admitted to hospital, including 2.95% of cases reported as anaphylaxis.

One hundred and seventy-eight reports contained a diagnosed neurological event. Ninety-seven individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Five individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Fifty-one individuals were reported with seizures (19.6% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were ten reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine, 5 followed Pfizer-BioNTech Comirnaty, and 1 followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 54 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were sixteen reports of immune thrombocytopenia purpura: seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases were associated with 27 hospitalizations (51.8% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals (median age: 76.5 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 164 were for various thrombotic/ thromboembolic conditions. These included 35 strokes (94.3% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 24 myocardial infarctions (95.8% hospitalized), 47 pulmonary emboli (55.3% hospitalized), 50 deep vein thromboses, and eight superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Two serious AEFI reports in the 5-11 year age group has been reported. One was of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[23] The second was a report of hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital.

There have been 189 reports of myocarditis/pericarditis. Fifty-one individuals were diagnosed with myocarditis, 87 with pericarditis, and 51 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.7 years, and 119 (63%) were male. Seventy-three had received Moderna Spikevax, 109 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Eighty-nine of these events occurred after a second dose (41 Moderna Spikevax and 48 Pfizer-BioNTech Comirnaty) and seven occurred after a third dose (6 Moderna Spikevax and 1 Pfizer-BioNTech Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Forty-six (out of 51) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-one (out of 87) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-one (out of 51) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[24] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Feb. 5, 2022 **(N=182)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**17 (9.3%)**	**18 (9.9%)**	**15 (8.2%)**	**23 (12.6%)**	**73 (40.1%)**
Dose 1	N (% Total)	0 (0%)	4 (2.2%)	8 (4.4%)	6 (3.3%)	8 (4.4%)	26 (14.3%)
Dose 2	N (% Total)	0 (0%)	12 (6.6%)	8 (4.4%)	9 (4.9%)	12 (6.6%)	41 (22.5%)
Dose 3	N (% Total)	0 (0%)	1 (0.5%)	2 (1.1%)	0 (0%)	3 (1.6%)	6 (3.3%)
Pfizer-BioNTech Comirnaty	**N (% Total)**	**17 (9.3%)**	**21 (11.5%)**	**6 (3.3%)**	**21 (11.5%)**	**44 (24.2%)**	**109 (59.9%)**
Dose 1	N (% Total)	7 (3.8%)	6 (3.3%)	2 (1.1%)	18 (9.9%)	27 (14.8%)	60 (33%)
Dose 2	N (% Total)	10 (5.5%)	15 (8.2%)	4 (2.2%)	3 (1.6%)	16 (8.8%)	48 (26.4%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.5%)	1 (0.5%)
mRNA Vaccines	**N (% Total)**	**17 (9.3%)**	**38 (20.8%)**	**24 (13.2%)**	**36 (19.7%)**	**67 (36.7%)**	**182 (100%)**

Total = 182 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including February 5, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Feb. 5, 2022. Stratified by sex, age groups, vaccine trade name, and dose **(N=182)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	56 (20.3-134.8)	**206.1 (116.2-344.5)**	100.7 (24.4-371.4)	**128.3 (78.2-200.9)**	21 (5.1-77.4)	20.1 (4.9-74.2)	0 (0-0)	17.6 (5.5-49.2)
25-29	**121.3 (56.9-235.9)**	**157.9 (81.2-284.6)**	161.4 (49.9-449.7)	**142.2 (88-219.9)**	47.5 (14.7-132.4)	0 (0-0)	0 (0-0)	18.8 (5.8-52.4)
30-39	41.6 (16.9-91.2)	37.1 (15.1-81.4)	0 (0-0)	28.1 (14.4-50.6)	23.4 (7.2-65.1)	**51.1 (22.5-104.7)**	0 (0-0)	25.3 (12.5-47.2)
40+	18.4 (8.1-37.8)	13.1 (5.8-26.8)	0 (0-0)	8.6 (4.7-14.6)	11 (4-26.4)	18.2 (9-33.9)	5.2 (1.9-12.4)	10.5 (6.2-16.9)
All Ages	38.1 (24.2-57.6)	**47 (32.6-66)**	4.8 (1.8-11.7)	29 (22-37.7)	17.7 (9.1-32)	22.4 (13.2-36.2)	4.2 (1.5-10.2)	13.8 (9.3-19.8)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	44.9 (21.1-87.3)	54.9 (27.1-102.4)	0 (0-0)	47.9 (28.2-77.3)	7.7 (1.9-28.5)	24.2 (8.8-58.3)	0 (0-0)	15.2 (6.2-33.2)
18-24	27.6 (11.2-60.5)	**65.6 (35-114.9)**	0 (0-0)	**40.6 (23.9-65.4)**	13.5 (4.2-37.7)	42.7 (20-83)	0 (0-0)	23.6 (12.1-42.5)
25-29	**8.4 (2-30.8)**	**17.7 (5.5-49.4)**	0 (0-0)	**11.1 (4-26.7)**	8.1 (2-29.9)	17.1 (5.3-47.6)	0 (0-0)	10.5 (3.8-25.2)
30-39	65.5 (39.9-102.5)	9.2 (2.9-25.7)	0 (0-0)	34.1 (21.4-52.1)	12.3 (4.5-29.6)	**4.3 (1-15.9)**	0 (0-0)	7.4 (3-16.3)
40+	13.5 (7.6-22.6)	11.9 (6.4-20.9)	3.2 (0.8-11.8)	11.2 (7.3-16.4)	16.9 (10.5-26.2)	8 (3.9-14.9)	0 (0-0)	10.5 (7-15.2)
All Ages	25.7 (18.7-34.6)	**21.5 (15-30)**	2.2 (0.5-8.2)	20.7 (16.3-25.9)	14.5 (9.7-20.9)	12.7 (8.2-19.1)	0 (0-0)	11.6 (8.6-15.4)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	43.7 (20.5-85)	54 (26.6-100.8)	0 (0-0)	46.9 (27.6-75.6)	7.5 (1.8-27.7)	23.8 (8.7-57.4)	0 (0-0)	14.8 (6-32.5)
18-24	35.3 (17.4-65.8)	105 (68.2-155.7)	20.8 (5-76.6)	64 (44.4-89.8)	15.3 (5.6-37)	36.8 (18.2-68.6)	0 (0-0)	22.1 (12.1-37.7)
25-29	41.4 (20.4-77.2)	61.1 (33.6-104.4)	39.9 (12.3-111.1)	49.6 (31.9-74.3)	18.1 (6.6-43.6)	12.3 (3.8-34.3)	0 (0-0)	12.7 (5.6-26)
30-39	58.4 (37.6-87.5)	18.5 (8.7-36)	0 (0-0)	31.9 (21.7-45.6)	15.2 (6.7-31.1)	18.2 (8.5-35.4)	0 (0-0)	13.5 (7.6-22.5)
40+	14.7 (9.1-22.8)	12.3 (7.4-19.6)	1.2 (0.3-4.4)	10.2 (7.2-14)	15.6 (10-23.3)	11.1 (6.6-17.6)	3.2 (1.1-7.6)	10.5 (7.6-14.2)
All Ages	27.4 (21-35)	29.1 (22.5-37.1)	3.7 (1.5-8.2)	23 (19.2-27.4)	14.5 (10.3-20.1)	15.3 (10.9-21.1)	2.4 (0.9-5.8)	12.1 (9.5-15.1)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including February 5, 2021. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age groups.

Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following dose and age groups:

Males:

- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 only

Females:

- 30-39 years old: Dose 2 only

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on February 9, 2022. Only AEFIs reported and doses administered up to February 5, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to February 5, 2022

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including February 5, 2022. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

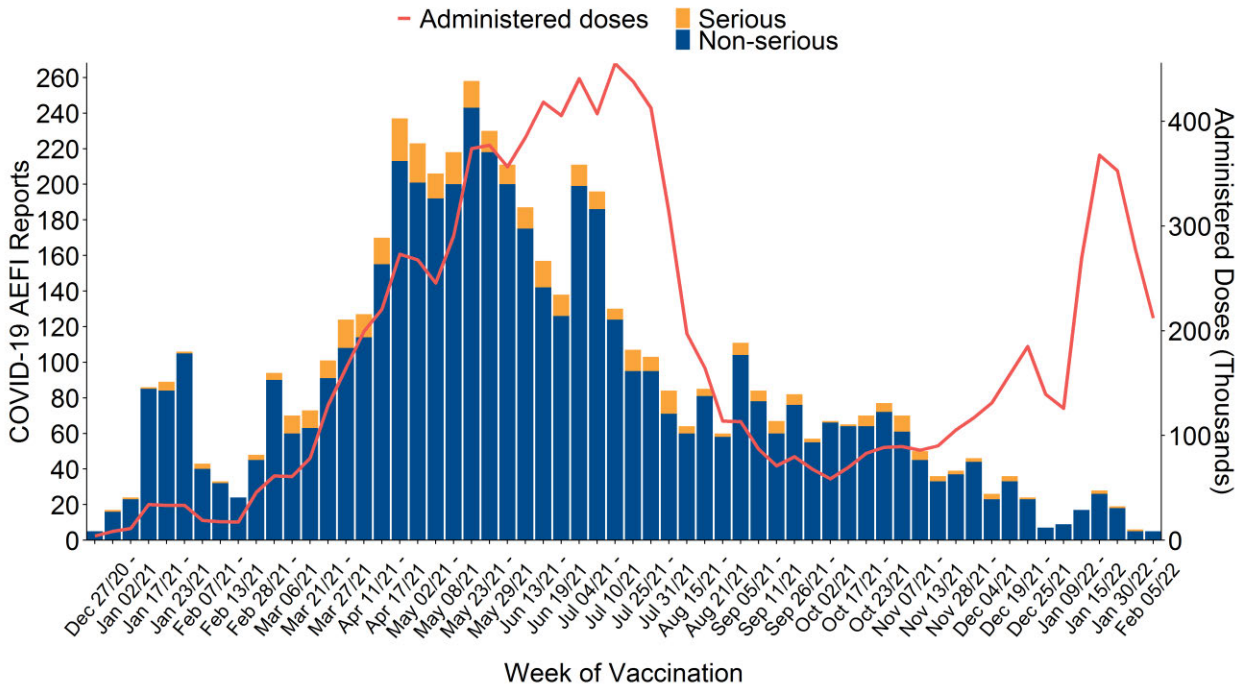
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of February 5, 2022, there have been 10,899,702 COVID-19 vaccine doses administered in BC and 5,437 COVID-19 AEFI reports (49.9 reports per 100,000 doses administered)
- 393 reports (7.2%) met the serious definition, for a rate of 3.6 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Feb. 5, 2022 **(N=5,437)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including February 5, 2022, a total of 10,899,702 doses have been administered. During this period, there have been 5,437 AEFI reports following a COVID-19 vaccine, for a reporting rate of 49.9 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second and third doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Feb. 5, 2022 **(N=5,437)**

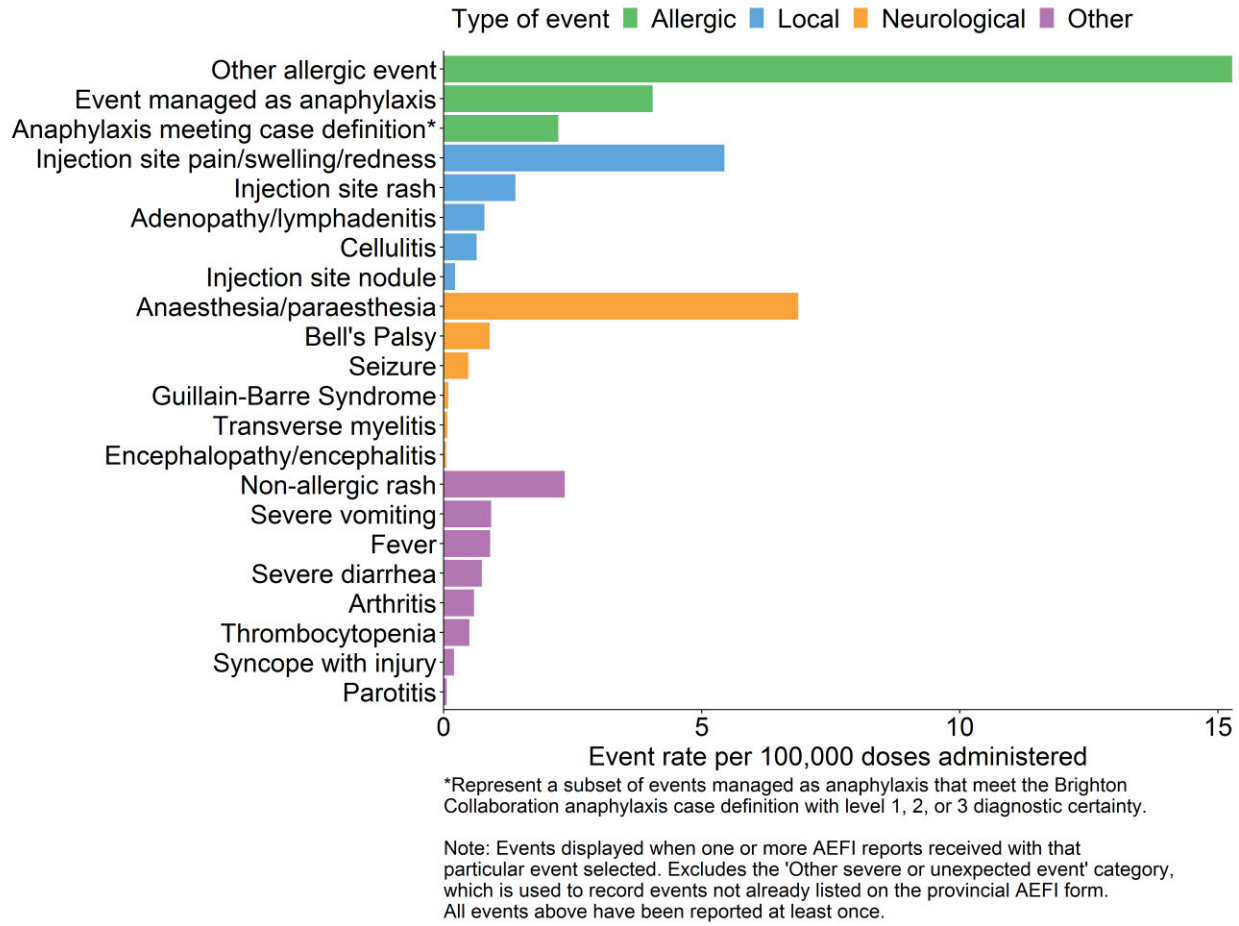
	COVID-19 Vaccine*						
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5437**	**282**	**75**	**8**	**1898**	**3154**	**20**
Non-serious reports	5044	247	68	7	1773	2931	18
Serious reports	393	35	7	1	125	223	2
Proportion serious	7.2%	12.4%	9.3%	12.5%	6.6%	7.1%	10%
Dose 1 reports	3943	252	73	6	1266	2326	20
Dose 2 reports	1307	29	2	2	503	771	0
Total doses administered	**10,899,702**	**338,325**	**83,216**	**9,999**	**3,417,922**	**6,835,594**	**214,646**
Dose 1 administered	4,450,396	230,248	67,459	9,498	923,991	3,032,076	187,124
Dose 2 administered	4,165,878	107,839	15,724	378	1,175,034	2,839,381	27,522
Total reporting rate	**49.9**	**83.4**	**90.1**	**80.0**	**55.5**	**46.1**	**9.3**
Serious rate	3.6	10.3	8.4	10.0	3.7	3.3	0.9
Dose 1 rate	88.6	109.4	108.2	63.2	137.0	76.7	10.7
Dose 2 rate	31.4	26.9	12.7	529.1	42.8	27.2	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,437 AEFI reports received up to February 5, 2022 contained a total of 6,907 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Feb. 5, 2022 **(N=6,907)**



Event Descriptions

Four hundred forty-one reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 242 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Seventy reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Three hundred ninety-three reports (7.2%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 374 individuals were admitted to hospital, including 2.95% of cases reported as anaphylaxis.

One hundred and seventy-eight reports contained a diagnosed neurological event. Ninety-seven individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Five individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Fifty-one individuals were reported with seizures (19.6% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were ten reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine, 5 followed Pfizer-BioNTech Comirnaty, and 1 followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 54 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were sixteen reports of immune thrombocytopenia purpura: seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases were associated with 27 hospitalizations (51.8% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals (median age: 76.5 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 164 were for various thrombotic/ thromboembolic conditions. These included 35 strokes (94.3% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 24 myocardial infarctions (95.8% hospitalized), 47 pulmonary emboli (55.3% hospitalized), 50 deep vein thromboses, and eight superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Two serious AEFI reports in the 5-11 year age group has been reported. One was of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[23] The second was a report of hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital.

There have been 189 reports of myocarditis/pericarditis. Fifty-one individuals were diagnosed with myocarditis, 87 with pericarditis, and 51 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.7 years, and 119 (63%) were male. Seventy-three had received Moderna Spikevax, 109 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Eighty-nine of these events occurred after a second dose (41 Moderna Spikevax and 48 Pfizer-BioNTech Comirnaty) and seven occurred after a third dose (6 Moderna Spikevax and 1 Pfizer-BioNTech Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Forty-six (out of 51) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-one (out of 87) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-one (out of 51) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[24] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Feb. 5, 2022 **(N=182)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**17 (9.3%)**	**18 (9.9%)**	**15 (8.2%)**	**23 (12.6%)**	**73 (40.1%)**
Dose 1	N (% Total)	0 (0%)	4 (2.2%)	8 (4.4%)	6 (3.3%)	8 (4.4%)	26 (14.3%)
Dose 2	N (% Total)	0 (0%)	12 (6.6%)	8 (4.4%)	9 (4.9%)	12 (6.6%)	41 (22.5%)
Dose 3	N (% Total)	0 (0%)	1 (0.5%)	2 (1.1%)	0 (0%)	3 (1.6%)	6 (3.3%)
Pfizer-BioNTech Comirnaty	**N (% Total)**	**17 (9.3%)**	**21 (11.5%)**	**6 (3.3%)**	**21 (11.5%)**	**44 (24.2%)**	**109 (59.9%)**
Dose 1	N (% Total)	7 (3.8%)	6 (3.3%)	2 (1.1%)	18 (9.9%)	27 (14.8%)	60 (33%)
Dose 2	N (% Total)	10 (5.5%)	15 (8.2%)	4 (2.2%)	3 (1.6%)	16 (8.8%)	48 (26.4%)
Dose 3	N (% Total)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0.5%)	1 (0.5%)
mRNA Vaccines	**N (% Total)**	**17 (9.3%)**	**38 (20.8%)**	**24 (13.2%)**	**36 (19.7%)**	**67 (36.7%)**	**182 (100%)**

Total = 182 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including February 5, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Feb. 5, 2022. Stratified by sex, age groups, vaccine trade name, and dose **(N=182)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	56 (20.3-134.8)	**206.1 (116.2-344.5)**	100.7 (24.4-371.4)	**128.3 (78.2-200.9)**	21 (5.1-77.4)	20.1 (4.9-74.2)	0 (0-0)	17.6 (5.5-49.2)
25-29	**121.3 (56.9-235.9)**	**157.9 (81.2-284.6)**	161.4 (49.9-449.7)	**142.2 (88-219.9)**	47.5 (14.7-132.4)	0 (0-0)	0 (0-0)	18.8 (5.8-52.4)
30-39	41.6 (16.9-91.2)	37.1 (15.1-81.4)	0 (0-0)	28.1 (14.4-50.6)	23.4 (7.2-65.1)	**51.1 (22.5-104.7)**	0 (0-0)	25.3 (12.5-47.2)
40+	18.4 (8.1-37.8)	13.1 (5.8-26.8)	0 (0-0)	8.6 (4.7-14.6)	11 (4-26.4)	18.2 (9-33.9)	5.2 (1.9-12.4)	10.5 (6.2-16.9)
All Ages	38.1 (24.2-57.6)	**47 (32.6-66)**	4.8 (1.8-11.7)	29 (22-37.7)	17.7 (9.1-32)	22.4 (13.2-36.2)	4.2 (1.5-10.2)	13.8 (9.3-19.8)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	44.9 (21.1-87.3)	54.9 (27.1-102.4)	0 (0-0)	47.9 (28.2-77.3)	7.7 (1.9-28.5)	24.2 (8.8-58.3)	0 (0-0)	15.2 (6.2-33.2)
18-24	27.6 (11.2-60.5)	**65.6 (35-114.9)**	0 (0-0)	**40.6 (23.9-65.4)**	13.5 (4.2-37.7)	42.7 (20-83)	0 (0-0)	23.6 (12.1-42.5)
25-29	**8.4 (2-30.8)**	**17.7 (5.5-49.4)**	0 (0-0)	**11.1 (4-26.7)**	8.1 (2-29.9)	17.1 (5.3-47.6)	0 (0-0)	10.5 (3.8-25.2)
30-39	65.5 (39.9-102.5)	9.2 (2.9-25.7)	0 (0-0)	34.1 (21.4-52.1)	12.3 (4.5-29.6)	**4.3 (1-15.9)**	0 (0-0)	7.4 (3-16.3)
40+	13.5 (7.6-22.6)	11.9 (6.4-20.9)	3.2 (0.8-11.8)	11.2 (7.3-16.4)	16.9 (10.5-26.2)	8 (3.9-14.9)	0 (0-0)	10.5 (7-15.2)
All Ages	25.7 (18.7-34.6)	**21.5 (15-30)**	2.2 (0.5-8.2)	20.7 (16.3-25.9)	14.5 (9.7-20.9)	12.7 (8.2-19.1)	0 (0-0)	11.6 (8.6-15.4)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	43.7 (20.5-85)	54 (26.6-100.8)	0 (0-0)	46.9 (27.6-75.6)	7.5 (1.8-27.7)	23.8 (8.7-57.4)	0 (0-0)	14.8 (6-32.5)
18-24	35.3 (17.4-65.8)	105 (68.2-155.7)	20.8 (5-76.6)	64 (44.4-89.8)	15.3 (5.6-37)	36.8 (18.2-68.6)	0 (0-0)	22.1 (12.1-37.7)
25-29	41.4 (20.4-77.2)	61.1 (33.6-104.4)	39.9 (12.3-111.1)	49.6 (31.9-74.3)	18.1 (6.6-43.6)	12.3 (3.8-34.3)	0 (0-0)	12.7 (5.6-26)
30-39	58.4 (37.6-87.5)	18.5 (8.7-36)	0 (0-0)	31.9 (21.7-45.6)	15.2 (6.7-31.1)	18.2 (8.5-35.4)	0 (0-0)	13.5 (7.6-22.5)
40+	14.7 (9.1-22.8)	12.3 (7.4-19.6)	1.2 (0.3-4.4)	10.2 (7.2-14)	15.6 (10-23.3)	11.1 (6.6-17.6)	3.2 (1.1-7.6)	10.5 (7.6-14.2)
All Ages	27.4 (21-35)	29.1 (22.5-37.1)	3.7 (1.5-8.2)	23 (19.2-27.4)	14.5 (10.3-20.1)	15.3 (10.9-21.1)	2.4 (0.9-5.8)	12.1 (9.5-15.1)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including February 5, 2021. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age groups.

Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following dose and age groups:

Males:

- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 only

Females:

- 30-39 years old: Dose 2 only

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on February 9, 2022. Only AEFIs reported and doses administered up to February 5, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From: Minhas, Sableen
To: Dalati, Hadi [BCCDC]; Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: Fortnightly COVID-19 AEFI Report
Date: Thursday, February 10, 2022 3:51:47 PM

Thanks Hadi!
Sableen

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, February 10, 2022 3:26 PM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Fortnightly COVID-19 AEFI Report

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaɁ/Selilwitulh (TsleilWaututh) Nations.

From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Fortnightly COVID-19 AEFI Report
Date: Thursday, February 24, 2022 4:22:00 PM
Attachments: COVID19_AEFI_Fortnightly_Report_2022-02-24.docx
COVID19_AEFI_Fortnightly_Report_2022-02-24.pdf

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to February 19, 2022

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including February 19, 2022. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

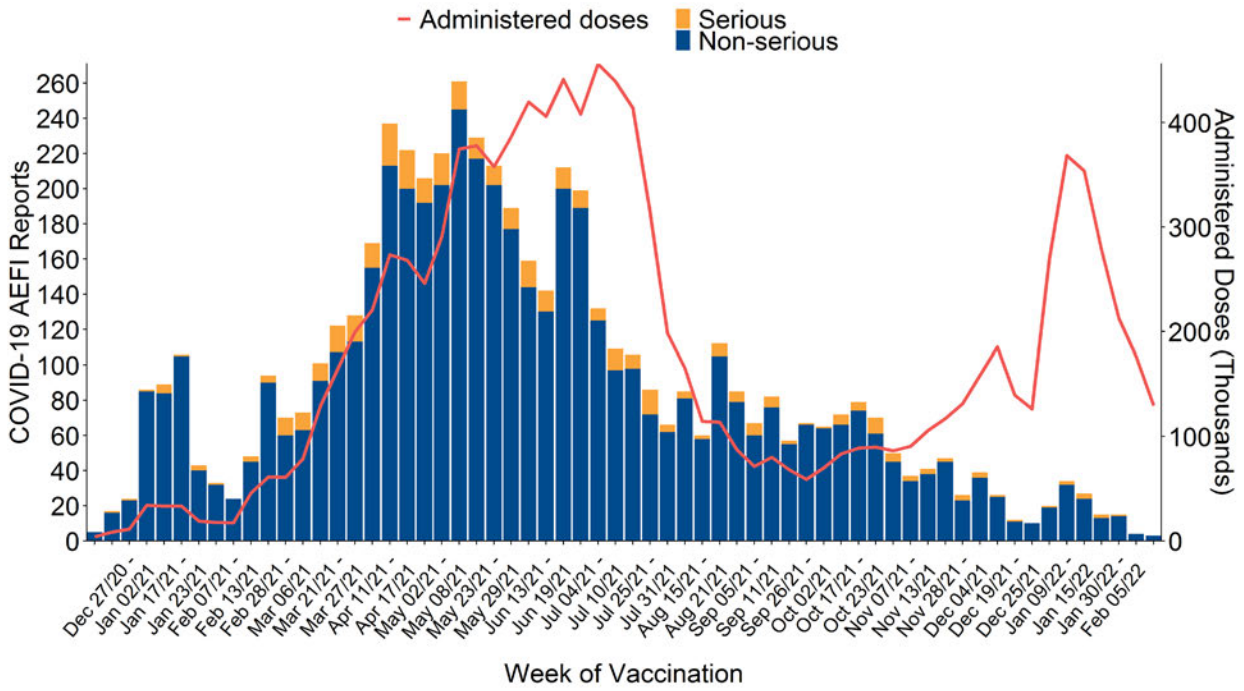
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of February 19, 2022, there have been 11,232,980 COVID-19 vaccine doses administered in BC and 5,527 COVID-19 AEFI reports (49.2 reports per 100,000 doses administered)
- 403 reports (7.3%) met the serious definition, for a rate of 3.6 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Feb. 19, 2022 **(N=5,527)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including February 19, 2022, a total of 11,232,980 doses have been administered. During this period, there have been 5,527 AEFI reports following a COVID-19 vaccine, for a reporting rate of 49.2 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second and third doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Feb. 19, 2022 **(N=5,527)**

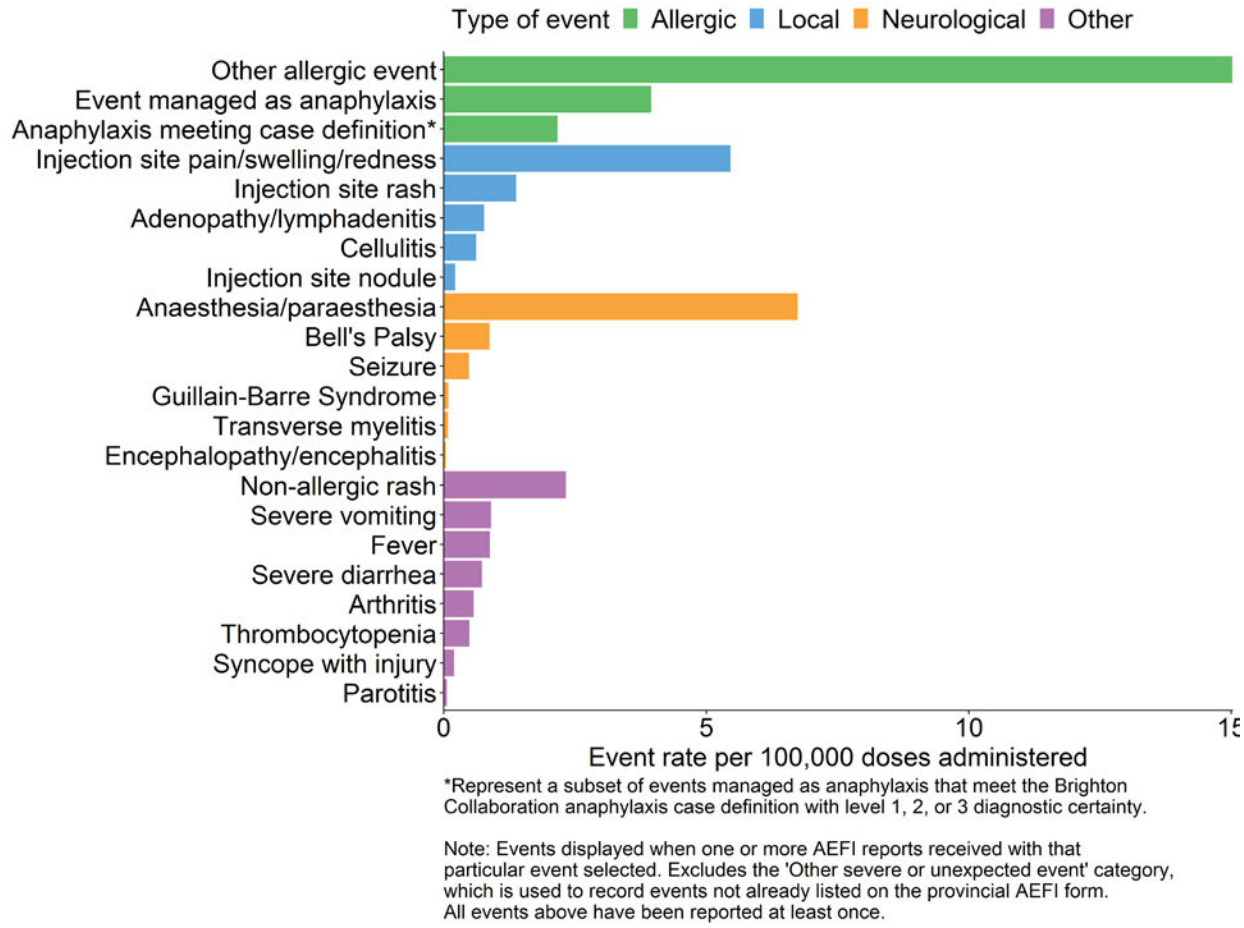
		COVID-19 Vaccine*					
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5527**	**282**	**71**	**9**	**1943**	**3200**	**22**
Non-serious reports	5124	247	65	8	1815	2969	20
Serious reports	403	35	6	1	128	231	2
Proportion serious	7.3%	12.4%	8.5%	11.1%	6.6%	7.2%	9.1%
Dose 1 reports	3962	252	69	7	1277	2335	22
Dose 2 reports	1337	29	2	2	512	792	0
Total doses administered	**11,232,980**	**339,296**	**84,334**	**10,596**	**3,504,428**	**7,024,890**	**269,436**
Dose 1 administered	4,471,758	230,772	68,046	10,046	927,538	3,042,169	193,187
Dose 2 administered	4,234,724	108,228	16,246	410	1,180,136	2,853,471	76,233
Total reporting rate	**49.2**	**83.1**	**84.2**	**84.9**	**55.4**	**45.6**	**8.2**
Serious rate	3.6	10.3	7.1	9.4	3.7	3.3	0.7
Dose 1 rate	88.6	109.2	101.4	69.7	137.7	76.8	11.4
Dose 2 rate	31.6	26.8	12.3	487.8	43.4	27.8	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,527 AEFI reports received up to February 19, 2022 contained a total of 7,023 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Feb. 19, 2022 **(N=7,023)**



Event Descriptions

Four hundred forty-four reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 244 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Seventy reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred three reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 383 individuals were admitted to hospital, including 2.9% of cases reported as anaphylaxis.

One hundred and eighty-three reports contained a diagnosed neurological event. Ninety-eight individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Fifty-four individuals were reported with seizures (18.5% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were ten reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine, 5 followed Pfizer-BioNTech Comirnaty, and 1 followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 54 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were sixteen reports of immune thrombocytopenia purpura: seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases were associated with 27 hospitalizations (50.9% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals (median age: 76.5 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 168 were for various thrombotic/ thromboembolic conditions. These included 35 strokes (94.3% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 24 myocardial infarctions (95.8% hospitalized), 47 pulmonary emboli (55.3% hospitalized), 53 deep vein thromboses, and eight superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Two serious AEFI reports in the 5-11 year age group has been reported. One was of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[23] The second was a report of hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital.

There have been 195 reports of myocarditis/pericarditis. Fifty-four individuals were diagnosed with myocarditis, 89 with pericarditis, and 52 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.8 years, and 124 (63.6%) were male. Seventy-five had received Moderna Spikevax, 113 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Ninety-four of these events occurred after a second dose (42 Moderna Spikevax and 51 Pfizer-BioNTech Comirnaty) and ten occurred after a third dose (8 Moderna Spikevax and 2 Pfizer-BioNTech Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Forty-nine (out of 54) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty (out of 89) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-two (out of 52) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[24] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Feb. 19, 2022 **(N=188)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**17 (9%)**	**18 (9.6%)**	**16 (8.5%)**	**24 (12.8%)**	**75 (39.9%)**
Dose 1	N (% Total)	0 (0%)	4 (2.1%)	8 (4.3%)	6 (3.2%)	7 (3.7%)	25 (13.3%)
Dose 2	N (% Total)	0 (0%)	12 (6.4%)	8 (4.3%)	10 (5.3%)	12 (6.4%)	42 (22.3%)
Dose 3	N (% Total)	0 (0%)	1 (0.5%)	2 (1.1%)	0 (0%)	5 (2.7%)	8 (4.3%)
Pfizer-BioNTech Comirnaty	**N (% Total)**	**17 (9%)**	**22 (11.7%)**	**6 (3.2%)**	**24 (12.8%)**	**44 (23.4%)**	**113 (60.1%)**
Dose 1	N (% Total)	7 (3.7%)	6 (3.2%)	2 (1.1%)	18 (9.6%)	27 (14.4%)	60 (31.9%)
Dose 2	N (% Total)	10 (5.3%)	15 (8%)	4 (2.1%)	6 (3.2%)	16 (8.5%)	51 (27.1%)
Dose 3	N (% Total)	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)	2 (1.1%)
mRNA Vaccines	**N (% Total)**	**17 (9%)**	**39 (20.7%)**	**24 (12.9%)**	**40 (21.3%)**	**68 (36.2%)**	**188 (100%)**

Total = 188 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including February 19, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Feb. 19, 2022. Stratified by sex, age groups, vaccine trade name, and dose **(N=188)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	56.1 (20.4-135.1)	**206.1 (116.2-344.6)**	89.5 (21.7-330.1)	**127.1 (77.5-199)**	21 (5.1-77.3)	20.1 (4.9-74)	0 (0-0)	17.4 (5.4-48.5)
25-29	**120.7 (56.6-234.7)**	**156.8 (80.7-282.7)**	144.7 (44.8-403.1)	**139.7 (86.4-216)**	47.3 (14.6-131.8)	0 (0-0)	0 (0-0)	18.4 (5.7-51.4)
30-39	41.4 (16.8-90.6)	46.1 (20.3-94.5)	0 (0-0)	30.4 (16.2-53.2)	23.3 (7.2-64.8)	50.8 (22.4-104.1)	0 (0-0)	24.3 (12-45.3)
40+	14.7 (6-32.2)	13 (5.7-26.7)	3.7 (1.2-10.4)	9.2 (5.2-15.4)	10.9 (4-26.3)	18.1 (8.9-33.8)	5 (1.8-12)	10.3 (6.1-16.6)
All Ages	35.8 (22.5-54.8)	**48.5 (33.8-67.7)**	7.7 (3.4-15.7)	29.5 (22.5-38.2)	17.7 (9.1-31.8)	22.3 (13.2-36)	4 (1.5-9.7)	13.5 (9.1-19.4)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	45 (21.1-87.6)	54.7 (27-102)	0 (0-0)	43.7 (25.8-70.5)	7.8 (1.9-28.6)	24.1 (8.8-58.1)	0 (0-0)	13.7 (5.6-30.1)
18-24	27.4 (11.1-60.2)	**65 (34.7-113.9)**	20.3 (4.9-74.9)	**42 (25.2-66.7)**	13.4 (4.2-37.4)	42.3 (19.8-82.3)	0 (0-0)	22.6 (11.6-40.7)
25-29	**8.3 (2-30.7)**	**17.6 (5.4-49)**	0 (0-0)	**10.7 (3.9-25.7)**	8.1 (2-29.7)	17 (5.2-47.3)	0 (0-0)	10.1 (3.7-24.3)
30-39	65.2 (39.7-102)	18.3 (7.4-40.2)	0 (0-0)	37.3 (24-55.8)	12.2 (4.4-29.5)	8.6 (2.7-23.9)	0 (0-0)	9.1 (4-18.6)
40+	13.5 (7.6-22.5)	11.9 (6.3-20.8)	3 (0.7-11.2)	11 (7.2-16.2)	16.9 (10.4-26.1)	7.9 (3.9-14.8)	0 (0-0)	10.4 (6.9-15)
All Ages	25.6 (18.6-34.5)	**22.9 (16.2-31.6)**	3.8 (1.2-10.6)	21.1 (16.7-26.3)	14.4 (9.6-20.9)	13.3 (8.7-19.8)	0 (0-0)	11.6 (8.6-15.3)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	43.6 (20.5-84.8)	53.7 (26.5-100.2)	0 (0-0)	42.7 (25.1-68.8)	7.5 (1.8-27.7)	23.7 (8.6-57)	0 (0-0)	13.4 (5.4-29.4)
18-24	35.1 (17.3-65.6)	104.3 (67.8-154.7)	33.1 (10.2-92.2)	64.2 (44.8-89.6)	15.3 (5.5-36.7)	36.5 (18-68.1)	0 (0-0)	21.3 (11.7-36.4)
25-29	41.2 (20.3-76.8)	60.7 (33.3-103.7)	33.1 (10.2-92.2)	48.1 (30.9-72)	18 (6.5-43.4)	12.2 (3.8-34.1)	0 (0-0)	12.3 (5.4-25.2)
30-39	58.1 (37.4-87)	27.6 (14.7-48.3)	0 (0-0)	34.8 (24.1-48.8)	15.1 (6.7-30.9)	21.1 (10.4-39.4)	0 (0-0)	14.3 (8.3-23.5)
40+	13.8 (8.4-21.6)	12.3 (7.4-19.5)	3.5 (1.3-8.3)	10.3 (7.3-14.2)	15.5 (10-23.3)	11 (6.6-17.5)	3 (1.1-7.3)	10.3 (7.5-14)
All Ages	26.7 (20.5-34.3)	30.1 (23.4-38.2)	5.9 (2.9-11.1)	23.3 (19.5-27.6)	14.5 (10.2-20)	15.6 (11.1-21.3)	2.2 (0.8-5.3)	11.9 (9.4-14.9)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including February 19, 2021. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age groups.

Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following dose and age groups:

Males:

- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 only

Females:

- None showed a statistically significant difference between products.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on February 23, 2022. Only AEFIs reported and doses administered up to February 19, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to February 19, 2022

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including February 19, 2022. Please refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Please refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

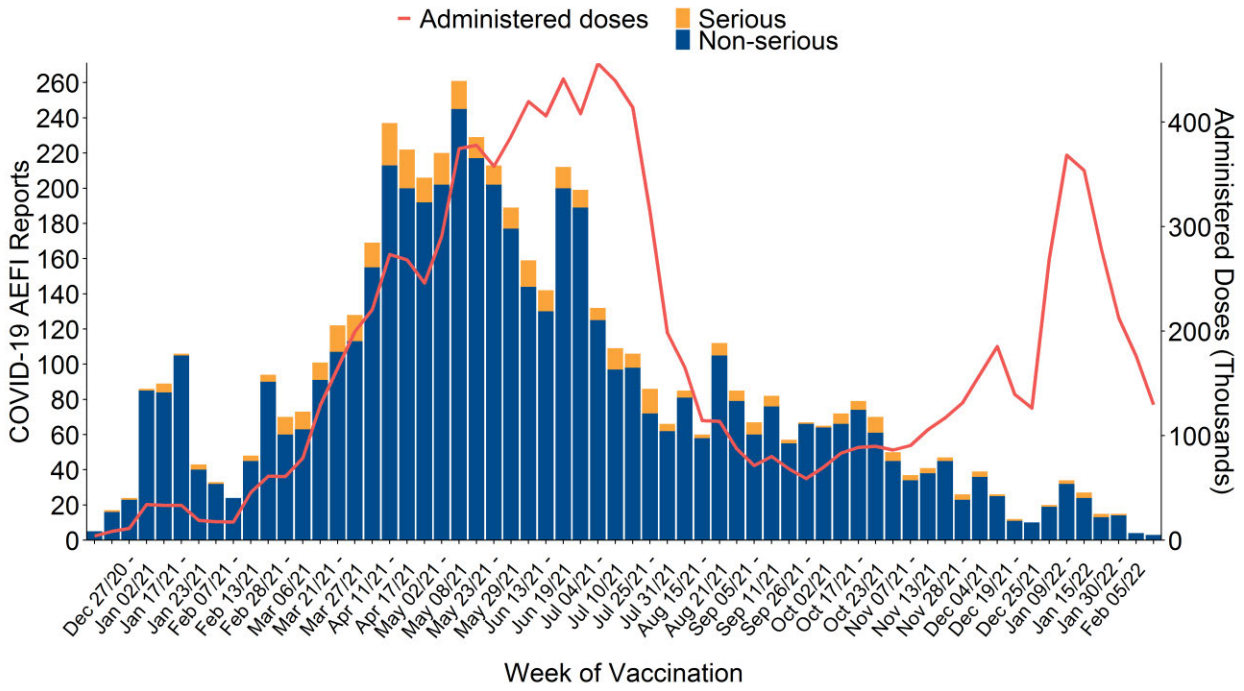
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of February 19, 2022, there have been 11,232,980 COVID-19 vaccine doses administered in BC and 5,527 COVID-19 AEFI reports (49.2 reports per 100,000 doses administered)
- 403 reports (7.3%) met the serious definition, for a rate of 3.6 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Feb. 19, 2022 **(N=5,527)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including February 19, 2022, a total of 11,232,980 doses have been administered. During this period, there have been 5,527 AEFI reports following a COVID-19 vaccine, for a reporting rate of 49.2 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second and third doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Feb. 19, 2022 **(N=5,527)**

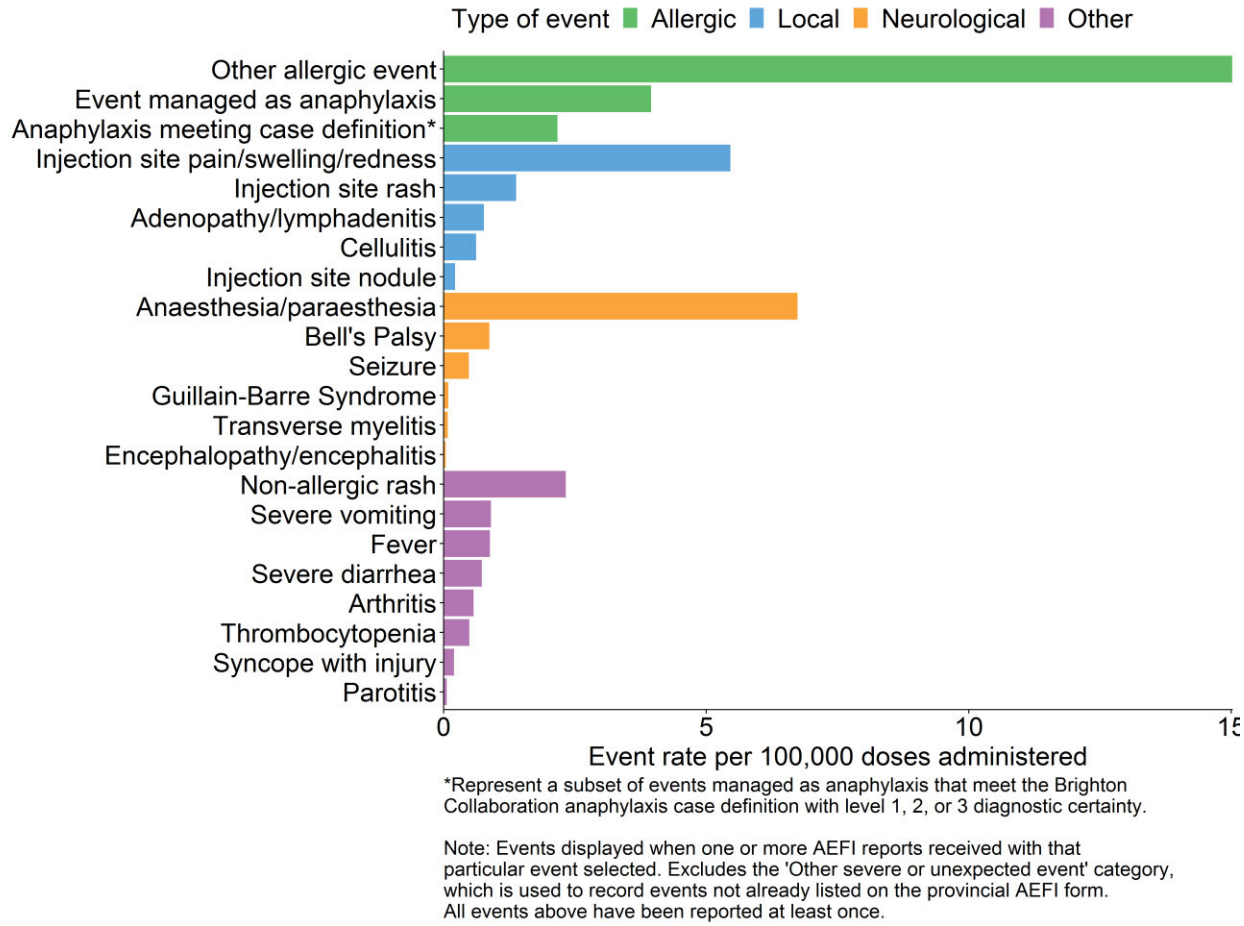
	COVID-19 Vaccine*						
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5527**	**282**	**71**	**9**	**1943**	**3200**	**22**
Non-serious reports	5124	247	65	8	1815	2969	20
Serious reports	403	35	6	1	128	231	2
Proportion serious	7.3%	12.4%	8.5%	11.1%	6.6%	7.2%	9.1%
Dose 1 reports	3962	252	69	7	1277	2335	22
Dose 2 reports	1337	29	2	2	512	792	0
Total doses administered	**11,232,980**	**339,296**	**84,334**	**10,596**	**3,504,428**	**7,024,890**	**269,436**
Dose 1 administered	4,471,758	230,772	68,046	10,046	927,538	3,042,169	193,187
Dose 2 administered	4,234,724	108,228	16,246	410	1,180,136	2,853,471	76,233
Total reporting rate	**49.2**	**83.1**	**84.2**	**84.9**	**55.4**	**45.6**	**8.2**
Serious rate	3.6	10.3	7.1	9.4	3.7	3.3	0.7
Dose 1 rate	88.6	109.2	101.4	69.7	137.7	76.8	11.4
Dose 2 rate	31.6	26.8	12.3	487.8	43.4	27.8	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,527 AEFI reports received up to February 19, 2022 contained a total of 7,023 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Feb. 19, 2022 **(N=7,023)**



Event Descriptions

Four hundred forty-four reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 244 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Seventy reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred three reports (7.3%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 383 individuals were admitted to hospital, including 2.9% of cases reported as anaphylaxis.

One hundred and eighty-three reports contained a diagnosed neurological event. Ninety-eight individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Fifty-four individuals were reported with seizures (18.5% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were ten reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine, 5 followed Pfizer-BioNTech Comirnaty, and 1 followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 54 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were sixteen reports of immune thrombocytopenia purpura: seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases were associated with 27 hospitalizations (50.9% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals (median age: 76.5 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 168 were for various thrombotic/ thromboembolic conditions. These included 35 strokes (94.3% of which were hospitalized) and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), 24 myocardial infarctions (95.8% hospitalized), 47 pulmonary emboli (55.3% hospitalized), 53 deep vein thromboses, and eight superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Two serious AEFI reports in the 5-11 year age group has been reported. One was of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[23] The second was a report of hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital.

There have been 195 reports of myocarditis/pericarditis. Fifty-four individuals were diagnosed with myocarditis, 89 with pericarditis, and 52 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.8 years, and 124 (63.6%) were male. Seventy-five had received Moderna Spikevax, 113 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Ninety-four of these events occurred after a second dose (42 Moderna Spikevax and 51 Pfizer-BioNTech Comirnaty) and ten occurred after a third dose (8 Moderna Spikevax and 2 Pfizer-BioNTech Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Forty-nine (out of 54) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty (out of 89) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-two (out of 52) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[24] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Feb. 19, 2022 **(N=188)**

Vaccine / Dose		Age (years)					
		12-17	18-24	25-29	30-39	40+	All Ages
Moderna Spikevax	**N (% Total)**	**0 (0%)**	**17 (9%)**	**18 (9.6%)**	**16 (8.5%)**	**24 (12.8%)**	**75 (39.9%)**
Dose 1	N (% Total)	0 (0%)	4 (2.1%)	8 (4.3%)	6 (3.2%)	7 (3.7%)	25 (13.3%)
Dose 2	N (% Total)	0 (0%)	12 (6.4%)	8 (4.3%)	10 (5.3%)	12 (6.4%)	42 (22.3%)
Dose 3	N (% Total)	0 (0%)	1 (0.5%)	2 (1.1%)	0 (0%)	5 (2.7%)	8 (4.3%)
Pfizer-BioNTech Comirnaty	**N (% Total)**	**17 (9%)**	**22 (11.7%)**	**6 (3.2%)**	**24 (12.8%)**	**44 (23.4%)**	**113 (60.1%)**
Dose 1	N (% Total)	7 (3.7%)	6 (3.2%)	2 (1.1%)	18 (9.6%)	27 (14.4%)	60 (31.9%)
Dose 2	N (% Total)	10 (5.3%)	15 (8%)	4 (2.1%)	6 (3.2%)	16 (8.5%)	51 (27.1%)
Dose 3	N (% Total)	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)	2 (1.1%)
mRNA Vaccines	**N (% Total)**	**17 (9%)**	**39 (20.7%)**	**24 (12.9%)**	**40 (21.3%)**	**68 (36.2%)**	**188 (100%)**

Total = 188 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including February 19, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Feb. 19, 2022. Stratified by sex, age groups, vaccine trade name, and dose **(N=188)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	56.1 (20.4-135.1)	**206.1 (116.2-344.6)**	89.5 (21.7-330.1)	**127.1 (77.5-199)**	21 (5.1-77.3)	20.1 (4.9-74)	0 (0-0)	17.4 (5.4-48.5)
25-29	**120.7 (56.6-234.7)**	**156.8 (80.7-282.7)**	144.7 (44.8-403.1)	**139.7 (86.4-216)**	47.3 (14.6-131.8)	0 (0-0)	0 (0-0)	18.4 (5.7-51.4)
30-39	41.4 (16.8-90.6)	46.1 (20.3-94.5)	0 (0-0)	30.4 (16.2-53.2)	23.3 (7.2-64.8)	50.8 (22.4-104.1)	0 (0-0)	24.3 (12-45.3)
40+	14.7 (6-32.2)	13 (5.7-26.7)	3.7 (1.2-10.4)	9.2 (5.2-15.4)	10.9 (4-26.3)	18.1 (8.9-33.8)	5 (1.8-12)	10.3 (6.1-16.6)
All Ages	35.8 (22.5-54.8)	**48.5 (33.8-67.7)**	7.7 (3.4-15.7)	29.5 (22.5-38.2)	17.7 (9.1-31.8)	22.3 (13.2-36)	4 (1.5-9.7)	13.5 (9.1-19.4)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	45 (21.1-87.6)	54.7 (27-102)	0 (0-0)	43.7 (25.8-70.5)	7.8 (1.9-28.6)	24.1 (8.8-58.1)	0 (0-0)	13.7 (5.6-30.1)
18-24	27.4 (11.1-60.2)	**65 (34.7-113.9)**	20.3 (4.9-74.9)	**42 (25.2-66.7)**	13.4 (4.2-37.4)	42.3 (19.8-82.3)	0 (0-0)	22.6 (11.6-40.7)
25-29	**8.3 (2-30.7)**	**17.6 (5.4-49)**	0 (0-0)	**10.7 (3.9-25.7)**	8.1 (2-29.7)	17 (5.2-47.3)	0 (0-0)	10.1 (3.7-24.3)
30-39	65.2 (39.7-102)	18.3 (7.4-40.2)	0 (0-0)	37.3 (24-55.8)	12.2 (4.4-29.5)	8.6 (2.7-23.9)	0 (0-0)	9.1 (4-18.6)
40+	13.5 (7.6-22.5)	11.9 (6.3-20.8)	3 (0.7-11.2)	11 (7.2-16.2)	16.9 (10.4-26.1)	7.9 (3.9-14.8)	0 (0-0)	10.4 (6.9-15)
All Ages	25.6 (18.6-34.5)	**22.9 (16.2-31.6)**	3.8 (1.2-10.6)	21.1 (16.7-26.3)	14.4 (9.6-20.9)	13.3 (8.7-19.8)	0 (0-0)	11.6 (8.6-15.3)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	43.6 (20.5-84.8)	53.7 (26.5-100.2)	0 (0-0)	42.7 (25.1-68.8)	7.5 (1.8-27.7)	23.7 (8.6-57)	0 (0-0)	13.4 (5.4-29.4)
18-24	35.1 (17.3-65.6)	104.3 (67.8-154.7)	33.1 (10.2-92.2)	64.2 (44.8-89.6)	15.3 (5.5-36.7)	36.5 (18-68.1)	0 (0-0)	21.3 (11.7-36.4)
25-29	41.2 (20.3-76.8)	60.7 (33.3-103.7)	33.1 (10.2-92.2)	48.1 (30.9-72)	18 (6.5-43.4)	12.2 (3.8-34.1)	0 (0-0)	12.3 (5.4-25.2)
30-39	58.1 (37.4-87)	27.6 (14.7-48.3)	0 (0-0)	34.8 (24.1-48.8)	15.1 (6.7-30.9)	21.1 (10.4-39.4)	0 (0-0)	14.3 (8.3-23.5)
40+	13.8 (8.4-21.6)	12.3 (7.4-19.5)	3.5 (1.3-8.3)	10.3 (7.3-14.2)	15.5 (10-23.3)	11 (6.6-17.5)	3 (1.1-7.3)	10.3 (7.5-14)
All Ages	26.7 (20.5-34.3)	30.1 (23.4-38.2)	5.9 (2.9-11.1)	23.3 (19.5-27.6)	14.5 (10.2-20)	15.6 (11.1-21.3)	2.2 (0.8-5.3)	11.9 (9.4-14.9)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including February 19, 2021. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age groups.

Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following dose and age groups:

Males:

- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 only

Females:

- None showed a statistically significant difference between products.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on February 23, 2022. Only AEFIs reported and doses administered up to February 19, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Fortnightly COVID-19 AEFI Report
Date: Thursday, March 10, 2022 2:32:08 PM
Attachments: COVID19_AEFI_Fortnightly_Report_2022-03-10.docx
COVID19_AEFI_Fortnightly_Report_2022-03-10.pdf

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to March 5, 2022

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including March 5, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

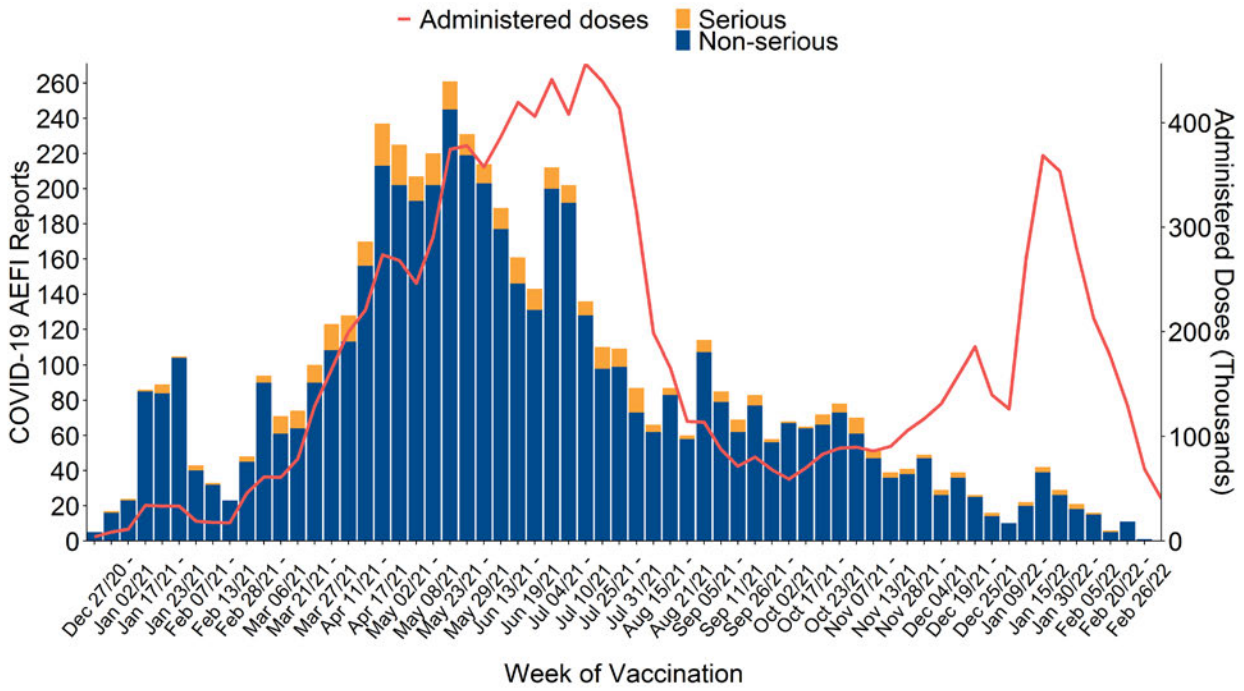
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of March 5, 2022, there have been 11,347,655 COVID-19 vaccine doses administered in BC and 5,600 COVID-19 AEFI reports (49.3 reports per 100,000 doses administered)
- 412 reports (7.4%) met the serious definition, for a rate of 3.6 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Mar. 5, 2022 **(N=5,600)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including March 5, 2022, a total of 11,347,655 doses have been administered. During this period, there have been 5,600 AEFI reports following a COVID-19 vaccine, for a reporting rate of 49.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second and third doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Mar. 5, 2022 **(N=5,600)**

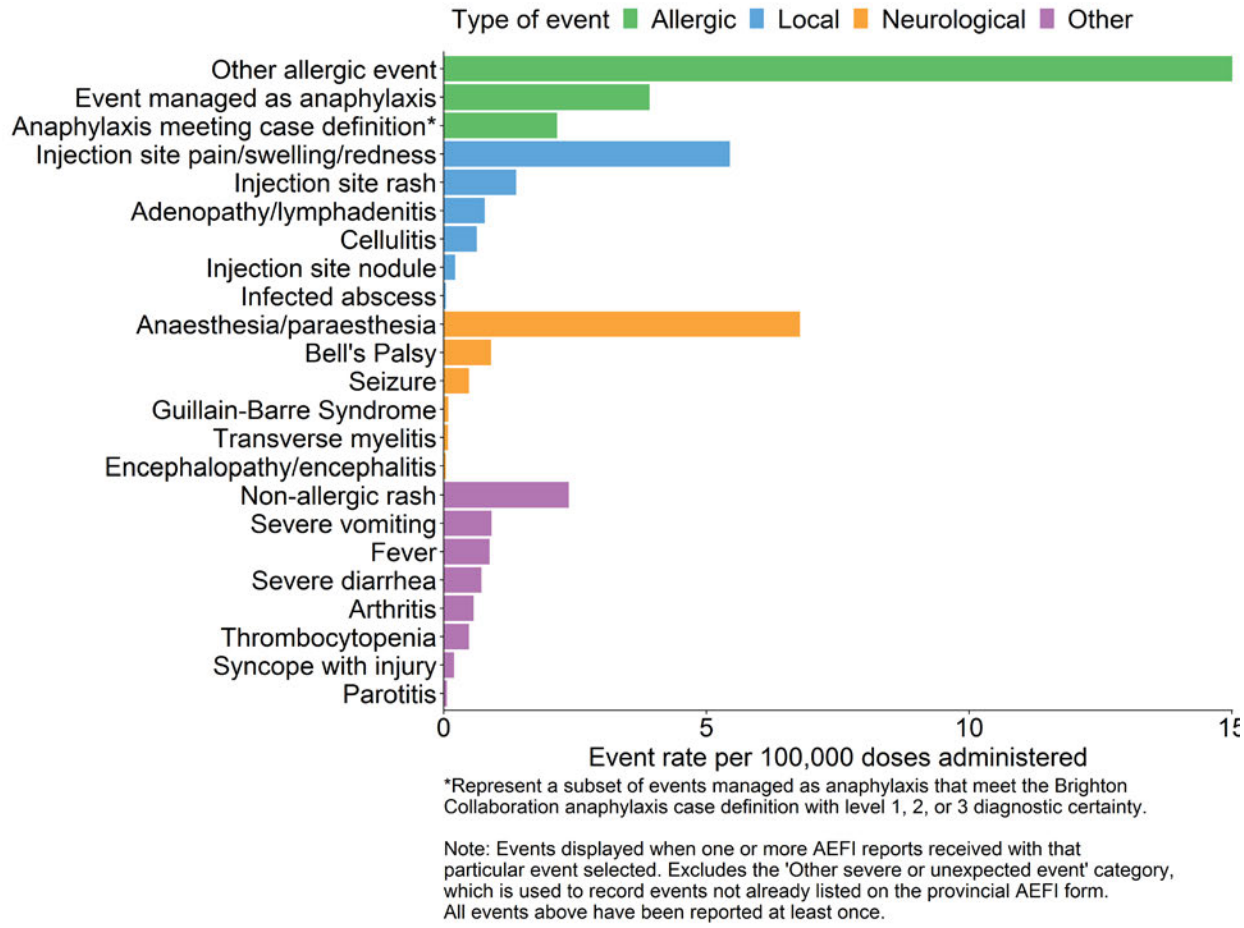
	COVID-19 Vaccine*						
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5600**	**285**	**71**	**11**	**1971**	**3235**	**27**
Non-serious reports	5188	249	65	9	1840	3000	25
Serious reports	412	36	6	2	131	235	2
Proportion serious	7.4%	12.6%	8.5%	18.2%	6.6%	7.3%	7.4%
Dose 1 reports	3983	255	69	9	1280	2346	24
Dose 2 reports	1367	29	2	2	524	807	3
Total doses administered	**11,347,655**	**340,041**	**85,156**	**11,064**	**3,526,960**	**7,088,900**	**295,534**
Dose 1 administered	4,479,520	231,156	68,462	10,487	928,478	3,045,437	195,500
Dose 2 administered	4,267,767	108,554	16,651	433	1,181,932	2,860,194	100,003
Total reporting rate	**49.3**	**83.8**	**83.4**	**99.4**	**55.9**	**45.6**	**9.1**
Serious rate	3.6	10.6	7.0	18.1	3.7	3.3	0.7
Dose 1 rate	88.9	110.3	100.8	85.8	137.9	77.0	12.3
Dose 2 rate	32.0	26.7	12.0	461.9	44.3	28.2	3.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,600 AEFI reports received up to March 5, 2022 contained a total of 7,116 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Mar. 5, 2022 **(N=7,116)**



Event Descriptions

Four hundred forty-five reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 245 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Seventy-one reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred twelve reports (7.4%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 392 individuals were admitted to hospital, including 2.9% of cases reported as anaphylaxis.

One hundred and eighty-four reports contained a diagnosed neurological event. One hundred two individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Fifty-four individuals were reported with seizures (18.5% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were ten reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine, 5 followed Pfizer-BioNTech Comirnaty, and 1 followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 55 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were sixteen reports of immune thrombocytopenia purpura: seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases were associated with 28 hospitalizations (50.9% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals (median age: 76.5 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 171 were for various thrombotic/ thromboembolic conditions. These included 37 strokes (91.9% of which were hospitalized), two cerebral venous sinus thromboses, 26 myocardial infarctions (96.2% hospitalized), 47 pulmonary emboli (55.3% hospitalized), 53 deep vein thromboses, and eight superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Two serious AEFI reports in the 5-11 year age group has been reported. One was of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[23] The second was a report of hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital.

There have been 203 reports of myocarditis/pericarditis. Fifty-eight individuals were diagnosed with myocarditis, 92 with pericarditis, and 53 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.8 years, and 124 (64.0%) were male. Eighty had received Moderna Spikevax, 116 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Ninety-seven of these events occurred after a second dose (44 Moderna Spikevax and 52 Pfizer-BioNTech Comirnaty) and twelve occurred after a third dose (9 Moderna Spikevax and 3 Pfizer-BioNTech Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Fifty-two (out of 58) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty (out of 92) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-two (out of 53) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[24] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Mar. 5, 2022 **(N=195)**

Vaccine / Age Group	Counts (% Total)			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18-24	4 (2.1%)	12 (6.2%)	1 (0.5%)	17 (8.7%)
25-29	9 (4.6%)	9 (4.6%)	2 (1%)	20 (10.3%)
30-39	6 (3.1%)	10 (5.1%)	1 (0.5%)	17 (8.7%)
40+	8 (4.1%)	13 (6.7%)	5 (2.6%)	26 (13.3%)
All Ages	27 (13.8%)	44 (22.6%)	9 (4.6%)	80 (41%)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	7 (3.6%)	10 (5.1%)	1 (0.5%)	18 (9.2%)
18-24	6 (3.1%)	15 (7.7%)	1 (0.5%)	22 (11.3%)
25-29	2 (1%)	4 (2.1%)	0 (0%)	6 (3.1%)
30-39	18 (9.2%)	6 (3.1%)	0 (0%)	24 (12.3%)
40+	27 (13.8%)	17 (8.7%)	1 (0.5%)	45 (23.1%)
All Ages	60 (30.8%)	52 (26.7%)	3 (1.5%)	115 (59%)
mRNA Vaccines	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	7 (3.6%)	10 (5.1%)	1 (0.5%)	18 (9.2%)
18-24	10 (5.1%)	27 (13.8%)	2 (1%)	39 (20%)
25-29	11 (5.6%)	13 (6.7%)	2 (1%)	26 (13.3%)
30-39	24 (12.3%)	16 (8.2%)	1 (0.5%)	41 (21%)
40+	35 (17.9%)	30 (15.4%)	6 (3.1%)	71 (36.4%)
All Ages	87 (44.6%)	96 (49.2%)	12 (6.2%)	195 (100%)

Total = 195 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including March 05, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Mar. 5, 2022. Stratified by sex, age groups, vaccine trade name, and dose **(N=195)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	56.4 (20.5-135.9)	**207.1 (116.7-346.2)**	86.7 (21-319.8)	**127.3 (77.6-199.3)**	21 (5.1-77.6)	20.1 (4.9-74.2)	0 (0-0)	17.4 (5.4-48.5)
25-29	**140.8 (69.4-262.6)**	**156.7 (80.6-282.5)**	140.4 (43.4-391)	**147.8 (92.7-225.9)**	47.3 (14.6-131.7)	22 (5.3-81)	0 (0-0)	27.5 (10-66.3)
30-39	41.3 (16.7-90.4)	46 (20.2-94.2)	10.8 (2.6-39.7)	33.5 (18.4-57.2)	23.2 (7.2-64.8)	50.7 (22.3-103.9)	0 (0-0)	24.1 (11.9-45)
40+	18.3 (8.1-37.5)	15.6 (7.3-30.4)	3.7 (1.1-10.3)	10.8 (6.4-17.5)	10.9 (4-26.3)	18.1 (8.9-33.7)	4.9 (1.8-11.8)	10.2 (6-16.5)
All Ages	40 (25.7-59.9)	**50.1 (35.2-69.5)**	9.1 (4.3-17.6)	31.7 (24.4-40.6)	17.7 (9.1-31.8)	24 (14.4-38.1)	4 (1.4-9.6)	14 (9.5-19.9)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	45.3 (21.2-88)	54.7 (27-102.1)	23.9 (5.8-88.1)	46.3 (27.8-73.5)	7.8 (1.9-28.7)	24.1 (8.8-58.2)	0 (0-0)	13.5 (5.5-29.6)
18-24	27.4 (11.1-60)	**64.7 (34.5-113.3)**	18.9 (4.6-69.8)	**41.4 (24.8-65.7)**	13.4 (4.1-37.3)	42.1 (19.8-81.9)	0 (0-0)	22.3 (11.5-40.1)
25-29	**8.3 (2-30.6)**	**17.5 (5.4-48.8)**	0 (0-0)	**10.6 (3.8-25.5)**	8 (1.9-29.7)	16.9 (5.2-47.2)	0 (0-0)	10 (3.6-24)
30-39	65 (39.7-101.8)	18.3 (7.4-40.1)	0 (0-0)	37 (23.8-55.3)	12.2 (4.4-29.4)	8.5 (2.6-23.8)	0 (0-0)	9 (4-18.4)
40+	13.5 (7.6-22.5)	11.9 (6.3-20.8)	3 (0.7-10.9)	11 (7.2-16.1)	16.9 (10.4-26.1)	9.1 (4.7-16.3)	0 (0-0)	10.8 (7.3-15.5)
All Ages	25.6 (18.6-34.4)	**22.8 (16.1-31.5)**	5.5 (2-13.2)	21.2 (16.8-26.4)	14.4 (9.6-20.9)	14 (9.2-20.6)	0 (0-0)	11.8 (8.8-15.5)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	43.6 (20.5-84.9)	53.6 (26.5-100.1)	23.4 (5.7-86.1)	45 (27-71.5)	7.5 (1.8-27.7)	23.6 (8.6-56.9)	0 (0-0)	13.1 (5.3-28.7)
18-24	35.1 (17.3-65.5)	104 (67.6-154.4)	31.1 (9.6-86.6)	63.6 (44.4-88.7)	15.2 (5.5-36.7)	36.4 (18-68)	0 (0-0)	21.1 (11.6-36)
25-29	47 (24.2-84.8)	60.6 (33.3-103.5)	31.6 (9.8-88)	50.2 (32.6-74.4)	18 (6.5-43.4)	18.3 (6.7-44.2)	0 (0-0)	14.6 (6.9-28.5)
30-39	58 (37.3-86.8)	27.5 (14.6-48.1)	6.3 (1.5-23.4)	35.7 (24.9-49.8)	15.1 (6.6-30.9)	21 (10.4-39.3)	0 (0-0)	14.2 (8.2-23.3)
40+	14.7 (9.1-22.7)	13.1 (8-20.6)	3.4 (1.2-8.2)	10.9 (7.8-14.9)	15.5 (10-23.2)	11.8 (7.2-18.5)	3 (1.1-7.2)	10.6 (7.7-14.2)
All Ages	27.7 (21.3-35.4)	30.4 (23.7-38.5)	7.5 (4-13)	24 (20.2-28.4)	14.4 (10.2-20)	16.4 (11.8-22.3)	2.2 (0.8-5.2)	12.2 (9.6-15.2)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including March 05, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age groups.

Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following dose and age groups:

Males:

- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 only

Females:

- None showed a statistically significant difference between products.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on March 9, 2022. Only AEFIs reported and doses administered up to March 5, 2022 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to March 5, 2022

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including March 5, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for use and in worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, Canada and BC are monitoring the occurrence of myocarditis and pericarditis. This association was first recognized in Israel and the USA in young adults and adolescents, and has now also been seen in other countries.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is reviewed and reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

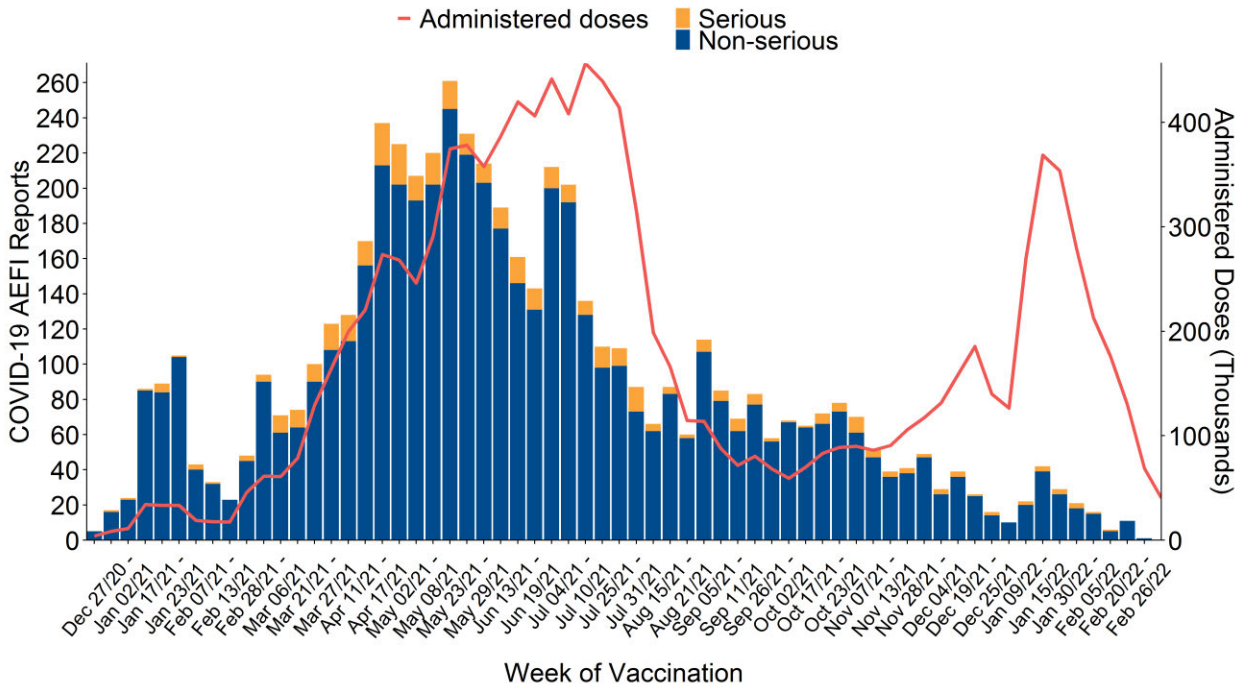
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of March 5, 2022, there have been 11,347,655 COVID-19 vaccine doses administered in BC and 5,600 COVID-19 AEFI reports (49.3 reports per 100,000 doses administered)
- 412 reports (7.4%) met the serious definition, for a rate of 3.6 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Mar. 5, 2022 **(N=5,600)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including March 5, 2022, a total of 11,347,655 doses have been administered. During this period, there have been 5,600 AEFI reports following a COVID-19 vaccine, for a reporting rate of 49.3 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second and third doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Mar. 5, 2022 **(N=5,600)**

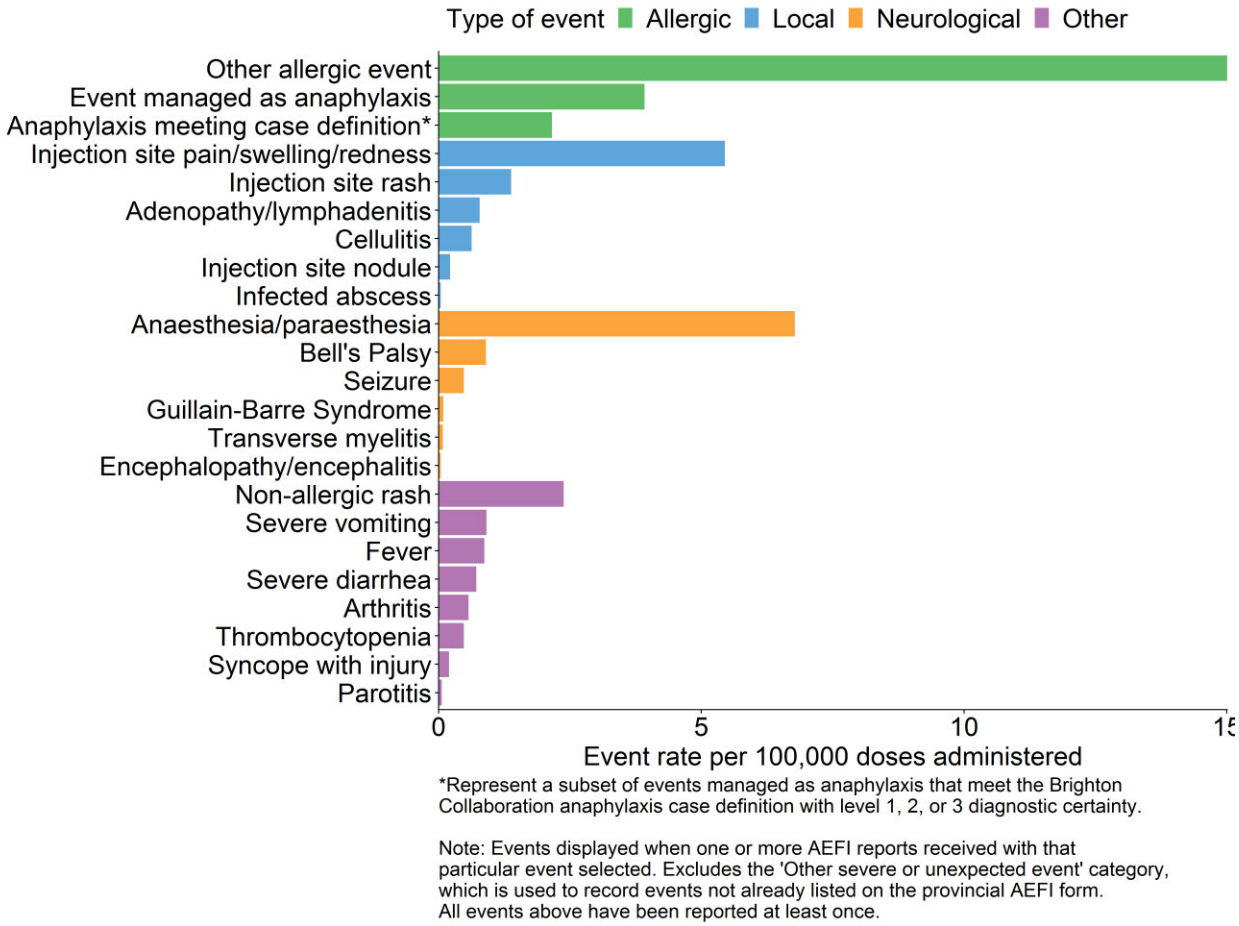
	COVID-19 Vaccine*						
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5600**	**285**	**71**	**11**	**1971**	**3235**	**27**
Non-serious reports	5188	249	65	9	1840	3000	25
Serious reports	412	36	6	2	131	235	2
Proportion serious	7.4%	12.6%	8.5%	18.2%	6.6%	7.3%	7.4%
Dose 1 reports	3983	255	69	9	1280	2346	24
Dose 2 reports	1367	29	2	2	524	807	3
Total doses administered	**11,347,655**	**340,041**	**85,156**	**11,064**	**3,526,960**	**7,088,900**	**295,534**
Dose 1 administered	4,479,520	231,156	68,462	10,487	928,478	3,045,437	195,500
Dose 2 administered	4,267,767	108,554	16,651	433	1,181,932	2,860,194	100,003
Total reporting rate	**49.3**	**83.8**	**83.4**	**99.4**	**55.9**	**45.6**	**9.1**
Serious rate	3.6	10.6	7.0	18.1	3.7	3.3	0.7
Dose 1 rate	88.9	110.3	100.8	85.8	137.9	77.0	12.3
Dose 2 rate	32.0	26.7	12.0	461.9	44.3	28.2	3.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,600 AEFI reports received up to March 5, 2022 contained a total of 7,116 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Mar. 5, 2022 **(N=7,116)**



Event Descriptions

Four hundred forty-five reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 245 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Seventy-one reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred twelve reports (7.4%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 392 individuals were admitted to hospital, including 2.9% of cases reported as anaphylaxis.

One hundred and eighty-four reports contained a diagnosed neurological event. One hundred two individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional three individuals were reported as having transverse myelitis, however, one had a clinical diagnosis unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and the last one is currently being investigated for several differential diagnoses other than transverse myelitis. Fifty-four individuals were reported with seizures (18.5% of which were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, one of whom experienced encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one developed encephalitis presumed to be viral in nature; one developed encephalopathy attributed to a workplace toxin exposure and was hospitalized (this event was reported because of its coincidental temporal association to COVID-19 vaccine receipt); one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities was hospitalized for encephalopathy and made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were ten reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Four of these reports followed AstraZeneca vaccine, 5 followed Pfizer-BioNTech Comirnaty, and 1 followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but followed an illness compatible with recent infection of unknown cause for the other two cases. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19] Finally, there have been three reports of sudden hearing loss verified by audiology testing. Two individuals had a sensorineural hearing loss (SNHL), and the other had either sensorineural or conductive hearing loss. Two individuals recovered their hearing with treatment and the third individual's hearing was still improving at the time of this report. One U.S. study has looked at an association between COVID-19 vaccines and SNHL and found rates after vaccination did not exceed background rates in the general population.[20]

There were 55 reports of thrombocytopenia without concurrent thrombosis. Two occurred in individuals with a single low platelet count followed subsequently by normal results; in both the low platelet counts were assessed as due to laboratory error. The majority of reports were in individuals who had a previous history of thrombocytopenia or who had a concurrent condition (e.g., known infection, sepsis, cancer) or medication associated with thrombocytopenia. There were sixteen reports of immune thrombocytopenia purpura: seven of these were following the AstraZeneca vaccine, and in one case, the individual tested positive for the anti-platelet factor 4 antibody often observed with TTS. This individual did not meet the TTS definition as they had no signs or symptoms of thrombosis, and all imaging studies for a thrombus/thromboembolism were negative. Collectively, thrombocytopenia cases were associated with 28 hospitalizations (50.9% of cases).

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Death may also be recorded as the outcome of a specific reportable event. Sixteen serious AEFI reports were received for individuals (median age: 76.5 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider or coroner who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions, one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities, with completion of a coroner's investigation pending.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.

'Other serious' events:
Some events may be reported as an "other serious" event when they do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 171 were for various thrombotic/ thromboembolic conditions. These included 37 strokes (91.9% of which were hospitalized), two cerebral venous sinus thromboses, 26 myocardial infarctions (96.2% hospitalized), 47 pulmonary emboli (55.3% hospitalized), 53 deep vein thromboses, and eight superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[21] Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[22]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults in their 30s or 40s and two were in their 60s. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia, this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Two serious AEFI reports in the 5-11 year age group has been reported. One was of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[23] The second was a report of hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital.

There have been 203 reports of myocarditis/pericarditis. Fifty-eight individuals were diagnosed with myocarditis, 92 with pericarditis, and 53 with myopericarditis. Ages ranged from 14 to 95 with a median of 37.8 years, and 124 (64.0%) were male. Eighty had received Moderna Spikevax, 116 received Pfizer-BioNTech Comirnaty, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. Ninety-seven of these events occurred after a second dose (44 Moderna Spikevax and 52 Pfizer-BioNTech Comirnaty) and twelve occurred after a third dose (9 Moderna Spikevax and 3 Pfizer-BioNTech Comirnaty). Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Fifty-two (out of 58) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty (out of 92) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-two (out of 53) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[24] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Mar. 5, 2022 **(N=195)**

Vaccine / Age Group	Counts (% Total)			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	0 (0%)	0 (0%)	0 (0%)	0 (0%)
18-24	4 (2.1%)	12 (6.2%)	1 (0.5%)	17 (8.7%)
25-29	9 (4.6%)	9 (4.6%)	2 (1%)	20 (10.3%)
30-39	6 (3.1%)	10 (5.1%)	1 (0.5%)	17 (8.7%)
40+	8 (4.1%)	13 (6.7%)	5 (2.6%)	26 (13.3%)
All Ages	27 (13.8%)	44 (22.6%)	9 (4.6%)	80 (41%)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	7 (3.6%)	10 (5.1%)	1 (0.5%)	18 (9.2%)
18-24	6 (3.1%)	15 (7.7%)	1 (0.5%)	22 (11.3%)
25-29	2 (1%)	4 (2.1%)	0 (0%)	6 (3.1%)
30-39	18 (9.2%)	6 (3.1%)	0 (0%)	24 (12.3%)
40+	27 (13.8%)	17 (8.7%)	1 (0.5%)	45 (23.1%)
All Ages	60 (30.8%)	52 (26.7%)	3 (1.5%)	115 (59%)
mRNA Vaccines	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	7 (3.6%)	10 (5.1%)	1 (0.5%)	18 (9.2%)
18-24	10 (5.1%)	27 (13.8%)	2 (1%)	39 (20%)
25-29	11 (5.6%)	13 (6.7%)	2 (1%)	26 (13.3%)
30-39	24 (12.3%)	16 (8.2%)	1 (0.5%)	41 (21%)
40+	35 (17.9%)	30 (15.4%)	6 (3.1%)	71 (36.4%)
All Ages	87 (44.6%)	96 (49.2%)	12 (6.2%)	195 (100%)

Total = 195 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including March 05, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Mar. 5, 2022. Stratified by sex, age groups, vaccine trade name, and dose **(N=195)**

Vaccine / Age Group	Reporting Rate* (95% CI)							
	Males				Females			
Moderna Spikevax	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All Doses**
12-17	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	56.4 (20.5-135.9)	**207.1 (116.7-346.2)**	86.7 (21-319.8)	**127.3 (77.6-199.3)**	21 (5.1-77.6)	20.1 (4.9-74.2)	0 (0-0)	17.4 (5.4-48.5)
25-29	**140.8 (69.4-262.6)**	**156.7 (80.6-282.5)**	140.4 (43.4-391)	**147.8 (92.7-225.9)**	47.3 (14.6-131.7)	22 (5.3-81)	0 (0-0)	27.5 (10-66.3)
30-39	41.3 (16.7-90.4)	46 (20.2-94.2)	10.8 (2.6-39.7)	33.5 (18.4-57.2)	23.2 (7.2-64.8)	50.7 (22.3-103.9)	0 (0-0)	24.1 (11.9-45)
40+	18.3 (8.1-37.5)	15.6 (7.3-30.4)	3.7 (1.1-10.3)	10.8 (6.4-17.5)	10.9 (4-26.3)	18.1 (8.9-33.7)	4.9 (1.8-11.8)	10.2 (6-16.5)
All Ages	40 (25.7-59.9)	**50.1 (35.2-69.5)**	9.1 (4.3-17.6)	31.7 (24.4-40.6)	17.7 (9.1-31.8)	24 (14.4-38.1)	4 (1.4-9.6)	14 (9.5-19.9)
Pfizer-BioNTech Comirnaty	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**	**Dose 1**	**Dose 2**	**Dose 3**	**All doses**
12-17	45.3 (21.2-88)	54.7 (27-102.1)	23.9 (5.8-88.1)	46.3 (27.8-73.5)	7.8 (1.9-28.7)	24.1 (8.8-58.2)	0 (0-0)	13.5 (5.5-29.6)
18-24	27.4 (11.1-60)	**64.7 (34.5-113.3)**	18.9 (4.6-69.8)	**41.4 (24.8-65.7)**	13.4 (4.1-37.3)	42.1 (19.8-81.9)	0 (0-0)	22.3 (11.5-40.1)
25-29	**8.3 (2-30.6)**	**17.5 (5.4-48.8)**	0 (0-0)	**10.6 (3.8-25.5)**	8 (1.9-29.7)	16.9 (5.2-47.2)	0 (0-0)	10 (3.6-24)
30-39	65 (39.7-101.8)	18.3 (7.4-40.1)	0 (0-0)	37 (23.8-55.3)	12.2 (4.4-29.4)	8.5 (2.6-23.8)	0 (0-0)	9 (4-18.4)
40+	13.5 (7.6-22.5)	11.9 (6.3-20.8)	3 (0.7-10.9)	11 (7.2-16.1)	16.9 (10.4-26.1)	9.1 (4.7-16.3)	0 (0-0)	10.8 (7.3-15.5)
All Ages	25.6 (18.6-34.4)	**22.8 (16.1-31.5)**	5.5 (2-13.2)	21.2 (16.8-26.4)	14.4 (9.6-20.9)	14 (9.2-20.6)	0 (0-0)	11.8 (8.8-15.5)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	All doses	Dose 1	Dose 2	Dose 3	All doses
12-17	43.6 (20.5-84.9)	53.6 (26.5-100.1)	23.4 (5.7-86.1)	45 (27-71.5)	7.5 (1.8-27.7)	23.6 (8.6-56.9)	0 (0-0)	13.1 (5.3-28.7)
18-24	35.1 (17.3-65.5)	104 (67.6-154.4)	31.1 (9.6-86.6)	63.6 (44.4-88.7)	15.2 (5.5-36.7)	36.4 (18-68)	0 (0-0)	21.1 (11.6-36)
25-29	47 (24.2-84.8)	60.6 (33.3-103.5)	31.6 (9.8-88)	50.2 (32.6-74.4)	18 (6.5-43.4)	18.3 (6.7-44.2)	0 (0-0)	14.6 (6.9-28.5)
30-39	58 (37.3-86.8)	27.5 (14.6-48.1)	6.3 (1.5-23.4)	35.7 (24.9-49.8)	15.1 (6.6-30.9)	21 (10.4-39.3)	0 (0-0)	14.2 (8.2-23.3)
40+	14.7 (9.1-22.7)	13.1 (8-20.6)	3.4 (1.2-8.2)	10.9 (7.8-14.9)	15.5 (10-23.2)	11.8 (7.2-18.5)	3 (1.1-7.2)	10.6 (7.7-14.2)
All Ages	27.7 (21.3-35.4)	30.4 (23.7-38.5)	7.5 (4-13)	24 (20.2-28.4)	14.4 (10.2-20)	16.4 (11.8-22.3)	2.2 (0.8-5.2)	12.2 (9.6-15.2)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including March 05, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition.
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age groups.

Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following dose and age groups:

Males:

- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 only

Females:

- None showed a statistically significant difference between products.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on March 9, 2022. Only AEFIs reported and doses administered up to March 5, 2022 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From: Minhas, Sableen
To: Dalati, Hadi [BCCDC]; Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: Fortnightly COVID-19 AEFI Report
Date: Thursday, March 10, 2022 2:50:26 PM

Thanks Hadi!

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, March 10, 2022 2:32 PM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Fortnightly COVID-19 AEFI Report

Hello all,

Please find attached the latest fortnightly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ílwətaʔ/Selilwitulh (TsleilWaututh) Nations.

From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: RE: Adverse events summary report
Date: Thursday, June 16, 2022 12:51:28 PM

Correct!
Hadi

From: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Sent: Thursday, June 16, 2022 12:35 PM
To: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: RE: Adverse events summary report

Thanks – that's good to know. Why is it starting up again? Is it in preparation for the 0-4 campaign?

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, June 16, 2022 12:24 PM
To: Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: RE: Adverse events summary report

Hello Sableen,

Thank you for reaching out. The public COVID AEFI report is set to start back up again on **a monthly basis starting next week** (on Thursdays)**.**

Thank you,
Hadi

From: Minhas, Sableen <sableen.minhas@phsa.ca>
Sent: Thursday, June 16, 2022 12:05 PM
To: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Cc: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Subject: Adverse events summary report

Hi Hadi and Monika,

We still have a note up on our website that a summary report on adverse events will be published in the coming months. What would the timeline be for it?

Sableen Minhas
Communications Specialist
BC Centre for Disease Control
Provincial Health Services Authority

From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Monthly COVID-19 AEFI Report
Date: Thursday, August 04, 2022 1:48:43 PM
Attachments: COVID19_AEFI_Monthly_Report_2022-08-04.docx
COVID19_AEFI_Monthly_Report_2022-08-04.pdf

Hello all,

Please find attached the latest monthly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

Provincial Health Services Authority

Tel (604)707-2537

Fax (604)707-2515

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to July 30, 2022

This report summarizes COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including July 30, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Among reports in BC, anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, myocarditis and pericarditis were first recognized in Israel and the USA in young adults and adolescents, and have now also been seen in other countries including Canada and in BC reports.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is further reviewed and investigated, and then reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

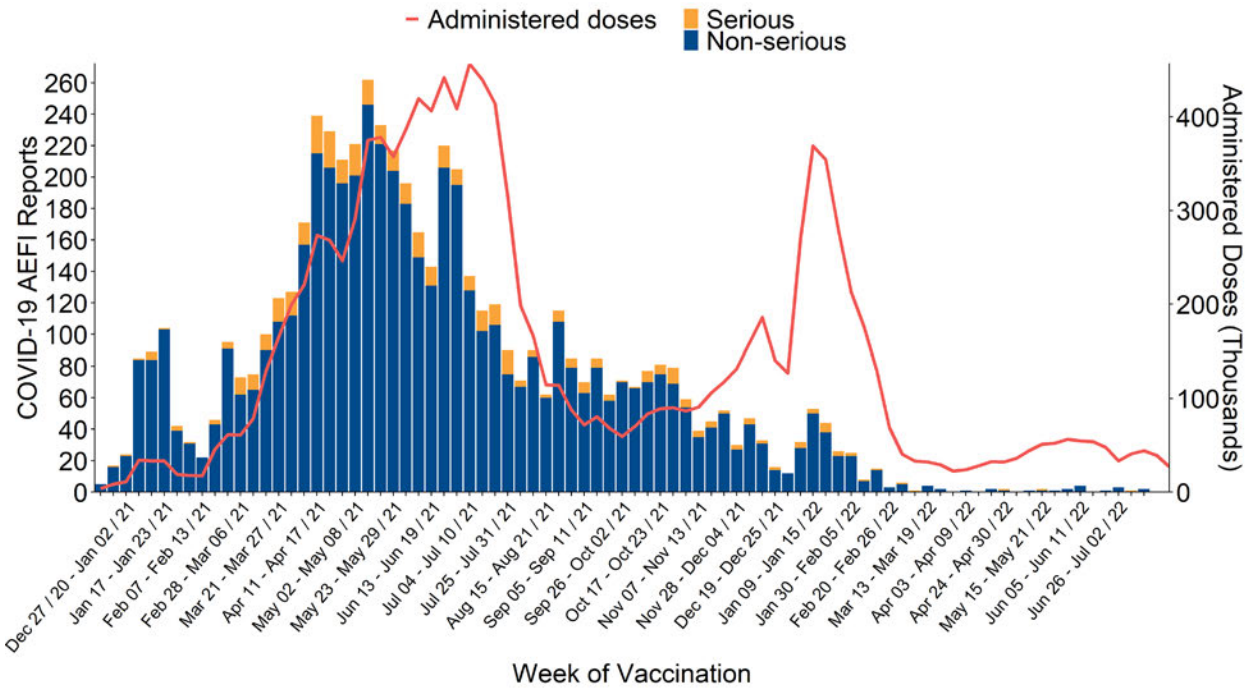
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of July 30, 2022, there have been 12,177,643 COVID-19 vaccine doses administered in BC and 5,821 COVID-19 AEFI reports (47.8 reports per 100,000 doses administered)
- 449 reports (7.7%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/ paraesthesia, and injection site pain/swelling/redness
- Other events have been less frequently reported and are detailed below

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jul. 30, 2022 **(N=5,821)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including July 30, 2022, a total of 12,177,643 doses have been administered. During this period, there have been 5,821 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.8 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second, third, and fourth doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jul. 30, 2022 **(N=5,821)**

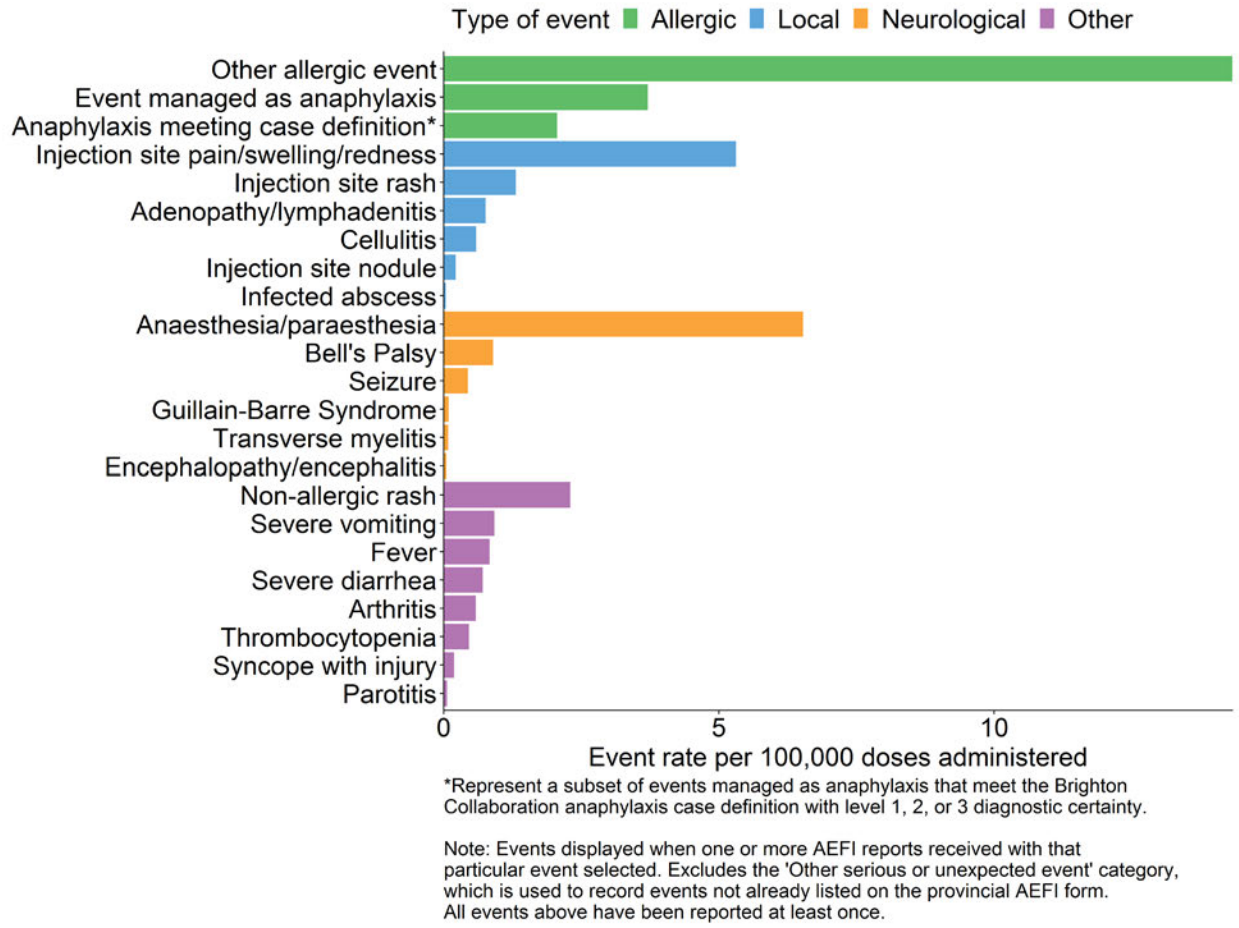
	COVID-19 Vaccine*							
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Novavax NUVAXOVID**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5821**	**287**	**71**	**15**	**2081**	**1**	**3327**	**39**
Non-serious reports	5372	251	65	13	1933	1	3073	36
Serious reports	449	36	6	2	148	0	254	3
Proportion serious	7.7%	12.5%	8.5%	13.3%	7.1%	0%	7.6%	7.7%
Dose 1 reports	4046	256	69	12	1299	1	2380	29
Dose 2 reports	1428	30	2	2	549	0	836	9
Dose 3 reports	314	0	0	1	217	0	96	0
Dose 4 reports	14	0	0	0	10	0	4	0
Total doses administered	**12,177,643**	**342,912**	**88,305**	**12,514**	**3,885,688**	**4,340**	**7,479,535**	**364,349**
Dose 1 administered	4,510,137	232,495	70,090	11,816	932,065	1,874	3,055,261	206,536
Dose 2 administered	4,355,150	109,760	18,112	514	1,187,516	1,588	2,880,043	157,617
Dose 3 administered	2,795,280	642	100	181	1,471,615	477	1,322,070	195
Dose 4 administered	516,916	15	3	3	294,411	401	222,082	1
Total reporting rate	**47.8**	**83.7**	**80.4**	**119.9**	**53.6**	**23.0**	**44.5**	**10.7**
Serious rate	3.7	10.5	6.8	16.0	3.8	0.0	3.4	0.8
Dose 1 rate	89.7	110.1	98.4	101.6	139.4	53.4	77.9	14.0
Dose 2 rate	32.8	27.3	11.0	389.1	46.2	0.0	29.0	5.7
Dose 3 rate	11.2	0.0	0.0	552.5	14.7	0.0	7.3	0.0
Dose 4 rate	2.7	0.0	0.0	0.0	3.4	0.0	1.8	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,821 AEFI reports received up to July 30, 2022 contained a total of 7,418 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 30, 2022 **(N=7,418)**



Event Descriptions

Four hundred fifty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 251 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Many events managed as anaphylaxis have features more compatible with anxiety or vasovagal syncope/pre-syncopal (fainting) events.

Seventy-two reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred forty-nine reports (7.7%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 422 individuals were admitted to hospital, including 2.90% of cases reported as anaphylaxis.

One hundred and ninety-two reports contained a diagnosed neurological event. One hundred and nine individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional four individuals were reported as having transverse myelitis, however, one was unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and another was referred to a specialist for further investigation. Fifty-four individuals were reported with seizures (18.5% of whom were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, including one with encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one encephalitis was presumed to be viral in nature; one encephalopathy was attributed to a workplace toxin exposure; one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities and encephalopathy made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were eleven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Five of these reports followed AstraZeneca vaccine, five followed Pfizer-BioNTech Comirnaty, and one followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but in two cases followed an illness compatible with recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19]

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Readers will note that some of the reported deaths described below appear to have a clear cause of death unrelated to the vaccine. Death may also be recorded as the outcome of a specific reportable event. Eighteen serious AEFI reports were received for individuals (median age: 76.5 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions; one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities. Investigation revealed the death was due to natural causes unrelated to the vaccine, but occurring in temporal association with vaccine receipt.

- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.
- One death occurred in an individual due to septic shock unrelated to the vaccine, but occurring in temporal association with vaccine receipt.
- One death occurred in an elderly individual due to an underlying cardiac compromise unrelated to the vaccine, but occurring in temporal association with vaccine receipt.

'Other serious or unexpected' events:
Some events may be reported as an "other serious or unexpected" event when these do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 175 were for various thrombotic/ thromboembolic conditions. These included 39 strokes (89.7% of which were hospitalized), two cerebral venous sinus thromboses, 27 myocardial infarctions (92.6% hospitalized), 50 pulmonary emboli (58.0% hospitalized), 57 deep vein thromboses, and eight superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[20] Health Canada issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[21]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults aged 30-49 and two were aged 60-69 years. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia; this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Three serious AEFI reports in the 5-11 year age group have been reported. One was of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[22] The second was a report of hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital. The third was a report of hospitalization following myo/pericarditis; this child was discharged with full resolution of symptoms.

There have been 222 reports of myocarditis/pericarditis. Sixty-six individuals were diagnosed with myocarditis, 99 with pericarditis, and 57 with myopericarditis. Ages ranged from 10 to 95 with a median of 34 years, and 145 (65%) were male. Ninety-two had received Moderna Spikevax, 122 received Pfizer-BioNTech Comirnaty, one received Pfizer-BioNTech Comirnaty Pediatric, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. One hundred and three of these events occurred after a second dose (47 Moderna Spikevax, 54 Pfizer-BioNTech Comirnaty, 1 Pfizer-BioNTech Comirnaty Pediatric, and 1 AstraZeneca Vaxzevria/Verity COVISHIELD). Seventeen occurred after a third dose (14 Moderna Spikevax and 3 Pfizer-BioNTech Comirnaty), and one occurred after a fourth dose of Moderna. Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Fifty-eight (out of 66) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-three (out of 99) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 57) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14,24]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jul. 30, 2022 **(N=215)**

Vaccine/Age Groups	*Dose 1*	*Dose 2*	*Done 3*	*Dose 4*	*All Doses*
Moderna Spikevax					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12-17	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.5%)
18-24	5 (2.3%)	14 (6.5%)	1 (0.5%)	0 (0%)	20 (9.3%)
25-29	10 (4.7%)	9 (4.2%)	2 (0.9%)	0 (0%)	21 (9.8%)
30-39	7 (3.3%)	10 (4.7%)	1 (0.5%)	0 (0%)	18 (8.4%)
40+	8 (3.7%)	14 (6.5%)	9 (4.2%)	1 (0.5%)	32 (14.9%)
All ages	30 (14%)	47 (21.9%)	14 (6.5%)	1 (0.5%)	92 (42.8%)
Pfizer-BioNTech Comirnaty					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.3%)	10 (4.7%)	1 (0.5%)	0 (0%)	18 (8.4%)
18-24	7 (3.3%)	15 (7%)	1 (0.5%)	0 (0%)	23 (10.7%)
25-29	4 (1.9%)	4 (1.9%)	0 (0%)	0 (0%)	8 (3.7%)
30-39	19 (8.8%)	6 (2.8%)	0 (0%)	0 (0%)	25 (11.6%)
40+	28 (13%)	19 (8.8%)	1 (0.5%)	0 (0%)	48 (22.3%)
All ages	65 (30.2%)	55 (25.6%)	3 (1.4%)	0 (0%)	123 (57.2%)
mRNA Vaccines					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.3%)	10 (4.7%)	2 (0.9%)	0 (0%)	19 (8.8%)
18-24	12 (5.6%)	29 (13.5%)	2 (0.9%)	0 (0%)	43 (20%)
25-29	14 (6.5%)	13 (6%)	2 (0.9%)	0 (0%)	29 (13.5%)
30-39	26 (12.1%)	16 (7.4%)	1 (0.5%)	0 (0%)	43 (20%)
40+	36 (16.7%)	33 (15.3%)	10 (4.7%)	1 (0.5%)	80 (37.2%)
All ages	95 (44.2%)	102 (47.4%)	17 (7.9%)	1 (0.5%)	215 (100%)

Total = 215 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including July 30, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jul. 30, 2022. Stratified by sex, age group, vaccine trade name, and dose **(N=215)**

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Moderna Spikevax	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	0 (0-0)	0 (0-0)	**900.1 (218-3320.3)**	0 (0-0)	204.5 (49.5-754.4)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	80.6 (32.7-176.6)	**262.3 (154.5-423)**	84.5 (20.5-311.7)	0 (0-0)	**161.9 (102.9-244.8)**	22.5 (5.4-82.8)	21.5 (5.2-79.3)	0 (0-0)	0 (0-0)	18.3 (5.7-51.1)
25-29	160.5 (82.6-289.4)	**156.5 (80.5-282.1)**	132.5 (41-369.1)	0 (0-0)	**154.8 (98.4-234)**	47.3 (14.6-131.9)	22 (5.3-81.1)	0 (0-0)	0 (0-0)	27.2 (9.9-65.6)
30-39	40.8 (16.6-89.5)	45.6 (20.1-93.4)	10.4 (2.5-38.4)	0 (0-0)	32.8 (18-56)	34.6 (12.6-83.2)	50.4 (22.2-103.2)	0 (0-0)	0 (0-0)	26.9 (13.8-48.5)
40+	18 (7.9-36.9)	18 (8.9-33.5)	7.1 (2.9-15.5)	7.6 (1.8-27.9)	12.5 (7.8-19.1)	10.7 (3.9-25.9)	17.9 (8.8-33.3)	7.9 (3.5-16.2)	0 (0-0)	10.3 (6.3-16.1)
All ages	44 (28.9-64.8)	**54.8 (39.1-75)**	13.1 (7-22.9)	7.5 (1.8-27.6)	**33.7 (26.4-42.4)**	19.8 (10.5-34.7)	23.9 (14.3-38)	6.4 (2.8-13.1)	0 (0-0)	14.1 (9.8-19.8)

Pfizer-BioNTech Comirnaty	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.3-49.6)	0 (0-0)	0 (0-0)	5.9 (1.4-21.6)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	45.1 (21.2-87.7)	54.9 (27.1-102.4)	**19.6 (4.7-72.3)**	0 (0-0)	44.9 (26.9-71.3)	7.8 (1.9-28.8)	24.3 (8.8-58.6)	0 (0-0)	0 (0-0)	13.1 (5.3-28.8)
18-24	34 (15-69.7)	**63.9 (34.1-111.9)**	16.2 (3.9-59.9)	0 (0-0)	**42.9 (26.1-67.2)**	13.3 (4.1-37.2)	41.8 (19.6-81.2)	0 (0-0)	0 (0-0)	21.6 (11.1-38.9)
25-29	24.9 (9-59.9)	**17.5 (5.4-48.6)**	0 (0-0)	0 (0-0)	**17.2 (7.6-35.2)**	8.1 (2-29.8)	17 (5.2-47.2)	0 (0-0)	0 (0-0)	9.8 (3.5-23.5)
30-39	68.7 (42.5-106.2)	18.1 (7.3-39.6)	0 (0-0)	0 (0-0)	37.6 (24.4-55.7)	12.1 (4.4-29.2)	8.4 (2.6-23.5)	0 (0-0)	0 (0-0)	8.7 (3.8-17.8)
40+	14.5 (8.3-23.7)	13 (7.1-22.2)	2.7 (0.7-10.1)	0 (0-0)	11.1 (7.4-16.1)	16.6 (10.3-25.7)	10 (5.4-17.6)	0 (0-0)	0 (0-0)	10.4 (7.1-14.9)
All ages	26.9 (20-35.7)	**22.8 (16.3-31.2)**	4.9 (1.8-11.8)	0 (0-0)	**21 (16.8-25.9)**	13.5 (9-19.6)	13.8 (9.2-20.2)	0 (0-0)	0 (0-0)	10.9 (8.2-14.3)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.3-49.6)	0 (0-0)	0 (0-0)	5.9 (1.4-21.6)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	44.4 (20.8-86.4)	54.1 (26.7-101)	38.4 (11.9-106.9)	0 (0-0)	47.4 (28.9-74.2)	7.7 (1.9-28.3)	24 (8.7-57.7)	0 (0-0)	0 (0-0)	12.9 (5.2-28.3)
18-24	45.8 (24.4-80.2)	115.6 (76.6-168.6)	27.2 (8.4-75.9)	0 (0-0)	71.6 (51.1-98)	15.4 (5.6-37.2)	36.8 (18.2-68.7)	0 (0-0)	0 (0-0)	20.8 (11.4-35.6)
25-29	64.6 (36.4-108)	60.4 (33.1-103.1)	28.4 (8.8-79.2)	0 (0-0)	56.5 (37.8-81.9)	18.1 (6.6-43.5)	18.4 (6.7-44.2)	0 (0-0)	0 (0-0)	14.4 (6.7-28)
30-39	60.4 (39.3-89.6)	27.2 (14.5-47.6)	5.8 (1.4-21.3)	0 (0-0)	35.8 (25.2-49.7)	18 (8.4-34.9)	20.8 (10.3-38.9)	0 (0-0)	0 (0-0)	14.9 (8.8-24)
40+	15.4 (9.6-23.5)	14.7 (9.2-22.4)	5.4 (2.4-11)	4.3 (1-16)	11.7 (8.6-15.6)	15.3 (9.8-22.9)	12.4 (7.7-19.2)	4.7 (2.1-9.7)	0 (0-0)	10.3 (7.6-13.8)
All ages	30.9 (24.2-39)	32.2 (25.3-40.4)	9.2 (5.3-15.1)	4.3 (1-15.7)	25.3 (21.4-29.6)	14.8 (10.5-20.4)	16.6 (12-22.4)	3.3 (1.5-6.9)	0 (0-0)	12 (9.5-14.8)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including July 30, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from the calculation of rates in this table).
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age group.

Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following sex, dose and age groups:

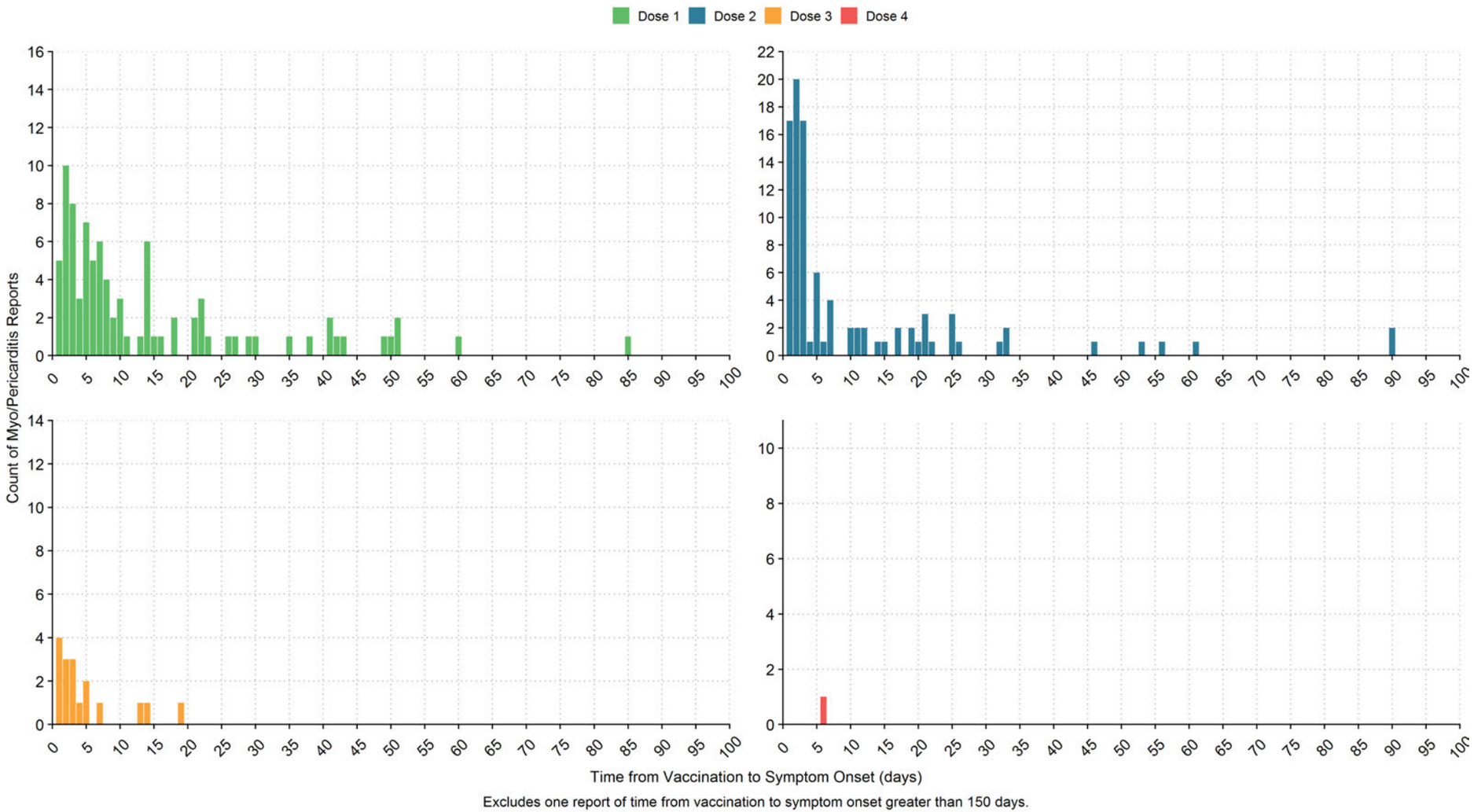
Males:

- 12-17 year olds: Dose 3 - However this is based on 1 report in relation to only 1088 doses administered. This rate should be interpreted with caution.
- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 2 and all doses combined
- All ages combined: Dose 2 and all doses combined

Females:

None showed a statistically significant difference between products.

Figure 3: Time from Vaccination to Symptom Onset of Myo/Pericarditis Reports, British Columbia, Dec. 13 2020 – Jul. 30, 2022 **(N=215)**



Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on August 3, 2022. Only AEFIs reported and doses administered up to July 30, 2022 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to July 30, 2022

This report summarizes COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including July 30, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Among reports in BC, anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, myocarditis and pericarditis were first recognized in Israel and the USA in young adults and adolescents, and have now also been seen in other countries including Canada and in BC reports.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is further reviewed and investigated, and then reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

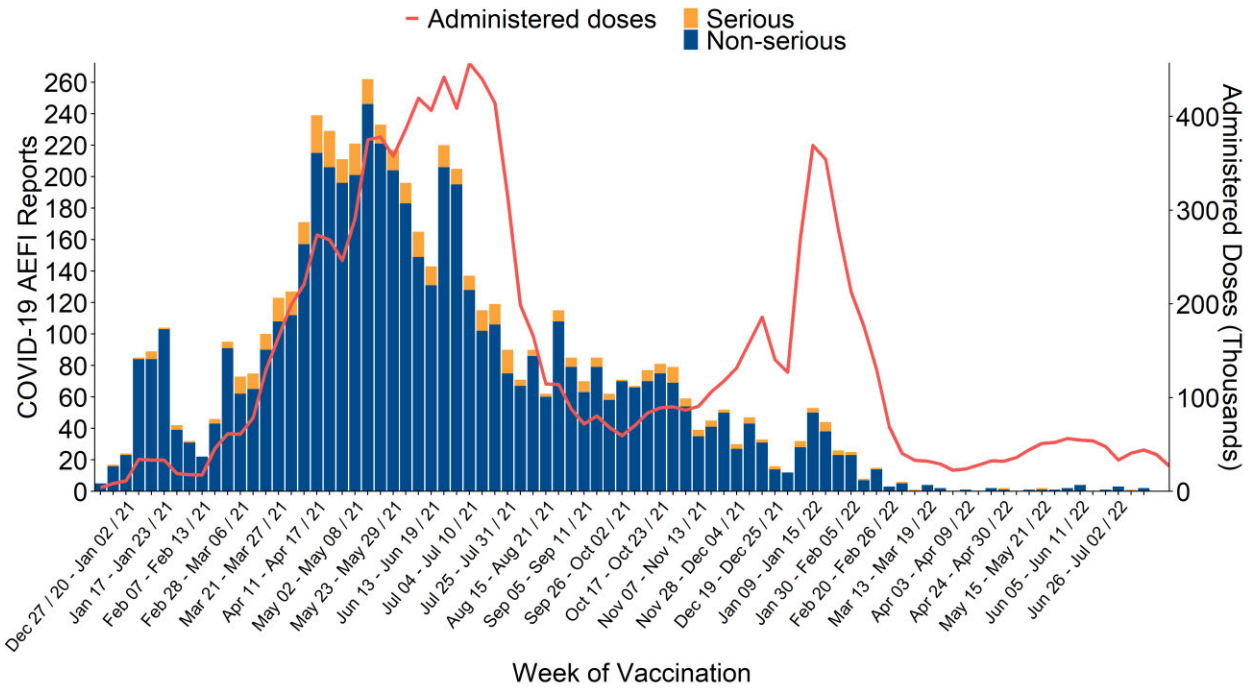
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of July 30, 2022, there have been 12,177,643 COVID-19 vaccine doses administered in BC and 5,821 COVID-19 AEFI reports (47.8 reports per 100,000 doses administered)
- 449 reports (7.7%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/ paraesthesia, and injection site pain/swelling/redness
- Other events have been less frequently reported and are detailed below

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jul. 30, 2022 **(N=5,821)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including July 30, 2022, a total of 12,177,643 doses have been administered. During this period, there have been 5,821 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.8 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second, third, and fourth doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jul. 30, 2022 **(N=5,821)**

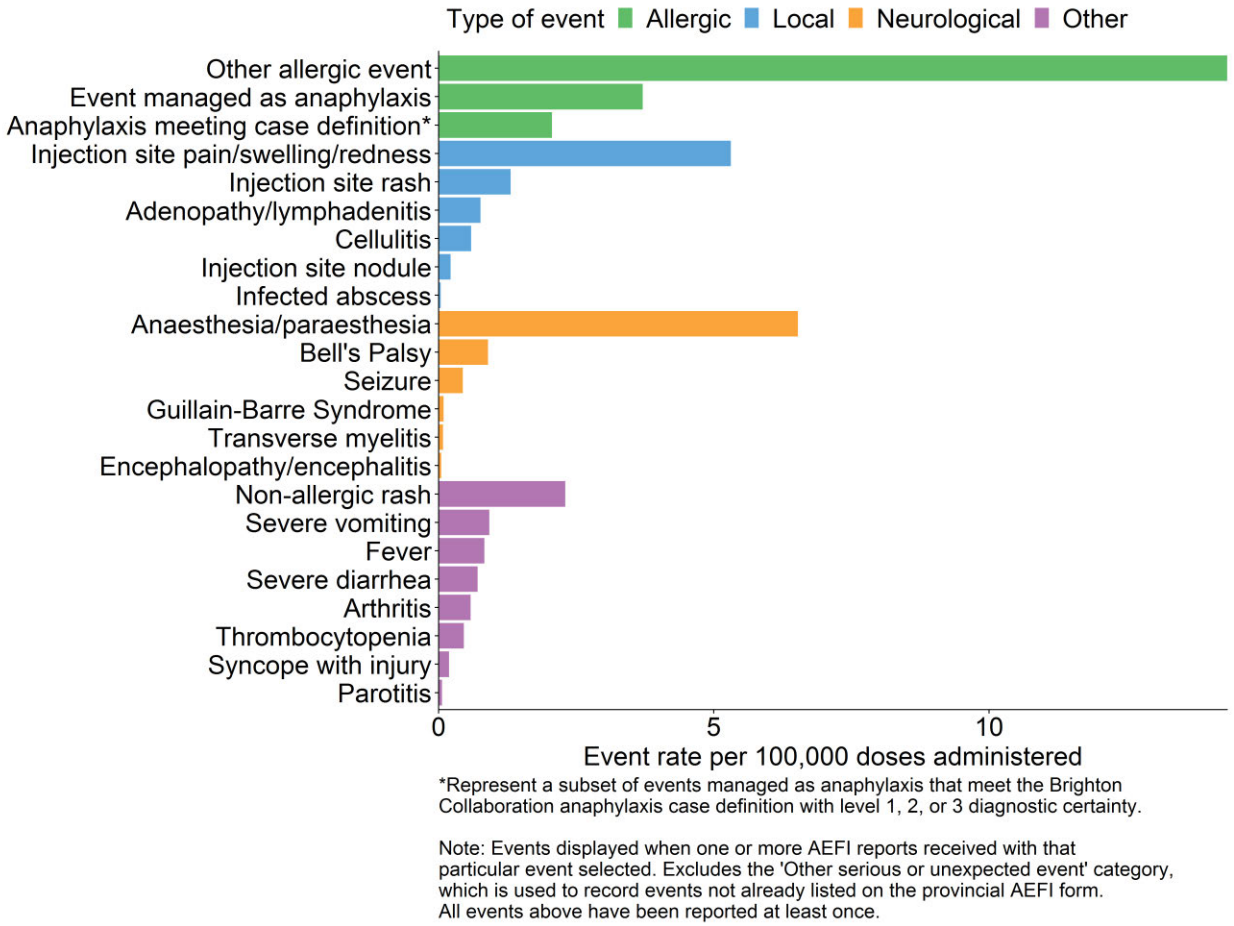
	COVID-19 Vaccine*							
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Novavax NUVAXOVID**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5821**	**287**	**71**	**15**	**2081**	**1**	**3327**	**39**
Non-serious reports	5372	251	65	13	1933	1	3073	36
Serious reports	449	36	6	2	148	0	254	3
Proportion serious	7.7%	12.5%	8.5%	13.3%	7.1%	0%	7.6%	7.7%
Dose 1 reports	4046	256	69	12	1299	1	2380	29
Dose 2 reports	1428	30	2	2	549	0	836	9
Dose 3 reports	314	0	0	1	217	0	96	0
Dose 4 reports	14	0	0	0	10	0	4	0
Total doses administered	**12,177,643**	**342,912**	**88,305**	**12,514**	**3,885,688**	**4,340**	**7,479,535**	**364,349**
Dose 1 administered	4,510,137	232,495	70,090	11,816	932,065	1,874	3,055,261	206,536
Dose 2 administered	4,355,150	109,760	18,112	514	1,187,516	1,588	2,880,043	157,617
Dose 3 administered	2,795,280	642	100	181	1,471,615	477	1,322,070	195
Dose 4 administered	516,916	15	3	3	294,411	401	222,082	1
Total reporting rate	**47.8**	**83.7**	**80.4**	**119.9**	**53.6**	**23.0**	**44.5**	**10.7**
Serious rate	3.7	10.5	6.8	16.0	3.8	0.0	3.4	0.8
Dose 1 rate	89.7	110.1	98.4	101.6	139.4	53.4	77.9	14.0
Dose 2 rate	32.8	27.3	11.0	389.1	46.2	0.0	29.0	5.7
Dose 3 rate	11.2	0.0	0.0	552.5	14.7	0.0	7.3	0.0
Dose 4 rate	2.7	0.0	0.0	0.0	3.4	0.0	1.8	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,821 AEFI reports received up to July 30, 2022 contained a total of 7,418 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Jul. 30, 2022 **(N=7,418)**



Event Descriptions

Four hundred fifty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 251 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Many events managed as anaphylaxis have features more compatible with anxiety or vasovagal syncope/pre-syncopal (fainting) events.

Seventy-two reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred forty-nine reports (7.7%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 422 individuals were admitted to hospital, including 2.90% of cases reported as anaphylaxis.

One hundred and ninety-two reports contained a diagnosed neurological event. One hundred and nine individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional four individuals were reported as having transverse myelitis, however, one was unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and another was referred to a specialist for further investigation. Fifty-four individuals were reported with seizures (18.5% of whom were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, including one with encephalopathy. Four additional individuals were hospitalized for encephalitis or encephalopathy: one encephalitis was presumed to be viral in nature; one encephalopathy was attributed to a workplace toxin exposure; one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; one individual with several comorbidities and encephalopathy made a spontaneous and full recovery within days, without a specific cause identified. One individual was hospitalized for aseptic meningitis. There were eleven reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Five of these reports followed AstraZeneca vaccine, five followed Pfizer-BioNTech Comirnaty, and one followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but in two cases followed an illness compatible with recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19]

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Readers will note that some of the reported deaths described below appear to have a clear cause of death unrelated to the vaccine. Death may also be recorded as the outcome of a specific reportable event. Eighteen serious AEFI reports were received for individuals (median age: 76.5 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions; one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.
- One death occurred in an elderly individual who suffered from multiple serious comorbidities. Investigation revealed the death was due to natural causes unrelated to the vaccine, but occurring in temporal association with vaccine receipt.

- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.
- One death occurred in an individual due to septic shock unrelated to the vaccine, but occurring in temporal association with vaccine receipt.
- One death occurred in an elderly individual due to an underlying cardiac compromise unrelated to the vaccine, but occurring in temporal association with vaccine receipt.

'Other serious or unexpected' events:
Some events may be reported as an "other serious or unexpected" event when these do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 175 were for various thrombotic/ thromboembolic conditions. These included 39 strokes (89.7% of which were hospitalized), two cerebral venous sinus thromboses, 27 myocardial infarctions (92.6% hospitalized), 50 pulmonary emboli (58.0% hospitalized), 57 deep vein thromboses, and eight superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[20] Health Canada issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[21]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults aged 30-49 and two were aged 60-69 years. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia; this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Three serious AEFI reports in the 5-11 year age group have been reported. One was of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[22] The second was a report of hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital. The third was a report of hospitalization following myo/pericarditis; this child was discharged with full resolution of symptoms.

There have been 222 reports of myocarditis/pericarditis. Sixty-six individuals were diagnosed with myocarditis, 99 with pericarditis, and 57 with myopericarditis. Ages ranged from 10 to 95 with a median of 34 years, and 145 (65%) were male. Ninety-two had received Moderna Spikevax, 122 received Pfizer-BioNTech Comirnaty, one received Pfizer-BioNTech Comirnaty Pediatric, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. One hundred and three of these events occurred after a second dose (47 Moderna Spikevax, 54 Pfizer-BioNTech Comirnaty, 1 Pfizer-BioNTech Comirnaty Pediatric, and 1 AstraZeneca Vaxzevria/Verity COVISHIELD). Seventeen occurred after a third dose (14 Moderna Spikevax and 3 Pfizer-BioNTech Comirnaty), and one occurred after a fourth dose of Moderna. Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Fifty-eight (out of 66) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-three (out of 99) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 57) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14,24]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jul. 30, 2022 **(N=215)**

Vaccine/Age Groups	*Dose 1*	*Dose 2*	*Done 3*	*Dose 4*	*All Doses*
Moderna Spikevax					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12-17	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.5%)
18-24	5 (2.3%)	14 (6.5%)	1 (0.5%)	0 (0%)	20 (9.3%)
25-29	10 (4.7%)	9 (4.2%)	2 (0.9%)	0 (0%)	21 (9.8%)
30-39	7 (3.3%)	10 (4.7%)	1 (0.5%)	0 (0%)	18 (8.4%)
40+	8 (3.7%)	14 (6.5%)	9 (4.2%)	1 (0.5%)	32 (14.9%)
All ages	30 (14%)	47 (21.9%)	14 (6.5%)	1 (0.5%)	92 (42.8%)
Pfizer-BioNTech Comirnaty					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.3%)	10 (4.7%)	1 (0.5%)	0 (0%)	18 (8.4%)
18-24	7 (3.3%)	15 (7%)	1 (0.5%)	0 (0%)	23 (10.7%)
25-29	4 (1.9%)	4 (1.9%)	0 (0%)	0 (0%)	8 (3.7%)
30-39	19 (8.8%)	6 (2.8%)	0 (0%)	0 (0%)	25 (11.6%)
40+	28 (13%)	19 (8.8%)	1 (0.5%)	0 (0%)	48 (22.3%)
All ages	65 (30.2%)	55 (25.6%)	3 (1.4%)	0 (0%)	123 (57.2%)
mRNA Vaccines					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.3%)	10 (4.7%)	2 (0.9%)	0 (0%)	19 (8.8%)
18-24	12 (5.6%)	29 (13.5%)	2 (0.9%)	0 (0%)	43 (20%)
25-29	14 (6.5%)	13 (6%)	2 (0.9%)	0 (0%)	29 (13.5%)
30-39	26 (12.1%)	16 (7.4%)	1 (0.5%)	0 (0%)	43 (20%)
40+	36 (16.7%)	33 (15.3%)	10 (4.7%)	1 (0.5%)	80 (37.2%)
All ages	95 (44.2%)	102 (47.4%)	17 (7.9%)	1 (0.5%)	215 (100%)

Total = 215 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including July 30, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec.13, 2020 - Jul. 30, 2022. Stratified by sex, age group, vaccine trade name, and dose **(N=215)**

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Moderna Spikevax	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	0 (0-0)	0 (0-0)	**900.1 (218-3320.3)**	0 (0-0)	204.5 (49.5-754.4)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	80.6 (32.7-176.6)	**262.3 (154.5-423)**	84.5 (20.5-311.7)	0 (0-0)	**161.9 (102.9-244.8)**	22.5 (5.4-82.8)	21.5 (5.2-79.3)	0 (0-0)	0 (0-0)	18.3 (5.7-51.1)
25-29	160.5 (82.6-289.4)	**156.5 (80.5-282.1)**	132.5 (41-369.1)	0 (0-0)	**154.8 (98.4-234)**	47.3 (14.6-131.9)	22 (5.3-81.1)	0 (0-0)	0 (0-0)	27.2 (9.9-65.6)
30-39	40.8 (16.6-89.5)	45.6 (20.1-93.4)	10.4 (2.5-38.4)	0 (0-0)	32.8 (18-56)	34.6 (12.6-83.2)	50.4 (22.2-103.2)	0 (0-0)	0 (0-0)	26.9 (13.8-48.5)
40+	18 (7.9-36.9)	18 (8.9-33.5)	7.1 (2.9-15.5)	7.6 (1.8-27.9)	12.5 (7.8-19.1)	10.7 (3.9-25.9)	17.9 (8.8-33.3)	7.9 (3.5-16.2)	0 (0-0)	10.3 (6.3-16.1)
All ages	44 (28.9-64.8)	**54.8 (39.1-75)**	13.1 (7-22.9)	7.5 (1.8-27.6)	**33.7 (26.4-42.4)**	19.8 (10.5-34.7)	23.9 (14.3-38)	6.4 (2.8-13.1)	0 (0-0)	14.1 (9.8-19.8)

Pfizer-BioNTech Comirnaty	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.3-49.6)	0 (0-0)	0 (0-0)	5.9 (1.4-21.6)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	45.1 (21.2-87.7)	54.9 (27.1-102.4)	**19.6 (4.7-72.3)**	0 (0-0)	44.9 (26.9-71.3)	7.8 (1.9-28.8)	24.3 (8.8-58.6)	0 (0-0)	0 (0-0)	13.1 (5.3-28.8)
18-24	34 (15-69.7)	**63.9 (34.1-111.9)**	16.2 (3.9-59.9)	0 (0-0)	**42.9 (26.1-67.2)**	13.3 (4.1-37.2)	41.8 (19.6-81.2)	0 (0-0)	0 (0-0)	21.6 (11.1-38.9)
25-29	24.9 (9-59.9)	**17.5 (5.4-48.6)**	0 (0-0)	0 (0-0)	**17.2 (7.6-35.2)**	8.1 (2-29.8)	17 (5.2-47.2)	0 (0-0)	0 (0-0)	9.8 (3.5-23.5)
30-39	68.7 (42.5-106.2)	18.1 (7.3-39.6)	0 (0-0)	0 (0-0)	37.6 (24.4-55.7)	12.1 (4.4-29.2)	8.4 (2.6-23.5)	0 (0-0)	0 (0-0)	8.7 (3.8-17.8)
40+	14.5 (8.3-23.7)	13 (7.1-22.2)	2.7 (0.7-10.1)	0 (0-0)	11.1 (7.4-16.1)	16.6 (10.3-25.7)	10 (5.4-17.6)	0 (0-0)	0 (0-0)	10.4 (7.1-14.9)
All ages	26.9 (20-35.7)	**22.8 (16.3-31.2)**	4.9 (1.8-11.8)	0 (0-0)	**21 (16.8-25.9)**	13.5 (9-19.6)	13.8 (9.2-20.2)	0 (0-0)	0 (0-0)	10.9 (8.2-14.3)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.3-49.6)	0 (0-0)	0 (0-0)	5.9 (1.4-21.6)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	44.4 (20.8-86.4)	54.1 (26.7-101)	38.4 (11.9-106.9)	0 (0-0)	47.4 (28.9-74.2)	7.7 (1.9-28.3)	24 (8.7-57.7)	0 (0-0)	0 (0-0)	12.9 (5.2-28.3)
18-24	45.8 (24.4-80.2)	115.6 (76.6-168.6)	27.2 (8.4-75.9)	0 (0-0)	71.6 (51.1-98)	15.4 (5.6-37.2)	36.8 (18.2-68.7)	0 (0-0)	0 (0-0)	20.8 (11.4-35.6)
25-29	64.6 (36.4-108)	60.4 (33.1-103.1)	28.4 (8.8-79.2)	0 (0-0)	56.5 (37.8-81.9)	18.1 (6.6-43.5)	18.4 (6.7-44.2)	0 (0-0)	0 (0-0)	14.4 (6.7-28)
30-39	60.4 (39.3-89.6)	27.2 (14.5-47.6)	5.8 (1.4-21.3)	0 (0-0)	35.8 (25.2-49.7)	18 (8.4-34.9)	20.8 (10.3-38.9)	0 (0-0)	0 (0-0)	14.9 (8.8-24)
40+	15.4 (9.6-23.5)	14.7 (9.2-22.4)	5.4 (2.4-11)	4.3 (1-16)	11.7 (8.6-15.6)	15.3 (9.8-22.9)	12.4 (7.7-19.2)	4.7 (2.1-9.7)	0 (0-0)	10.3 (7.6-13.8)
All ages	30.9 (24.2-39)	32.2 (25.3-40.4)	9.2 (5.3-15.1)	4.3 (1-15.7)	25.3 (21.4-29.6)	14.8 (10.5-20.4)	16.6 (12-22.4)	3.3 (1.5-6.9)	0 (0-0)	12 (9.5-14.8)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including July 30, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from the calculation of rates in this table).
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age group.

Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following sex, dose and age groups:

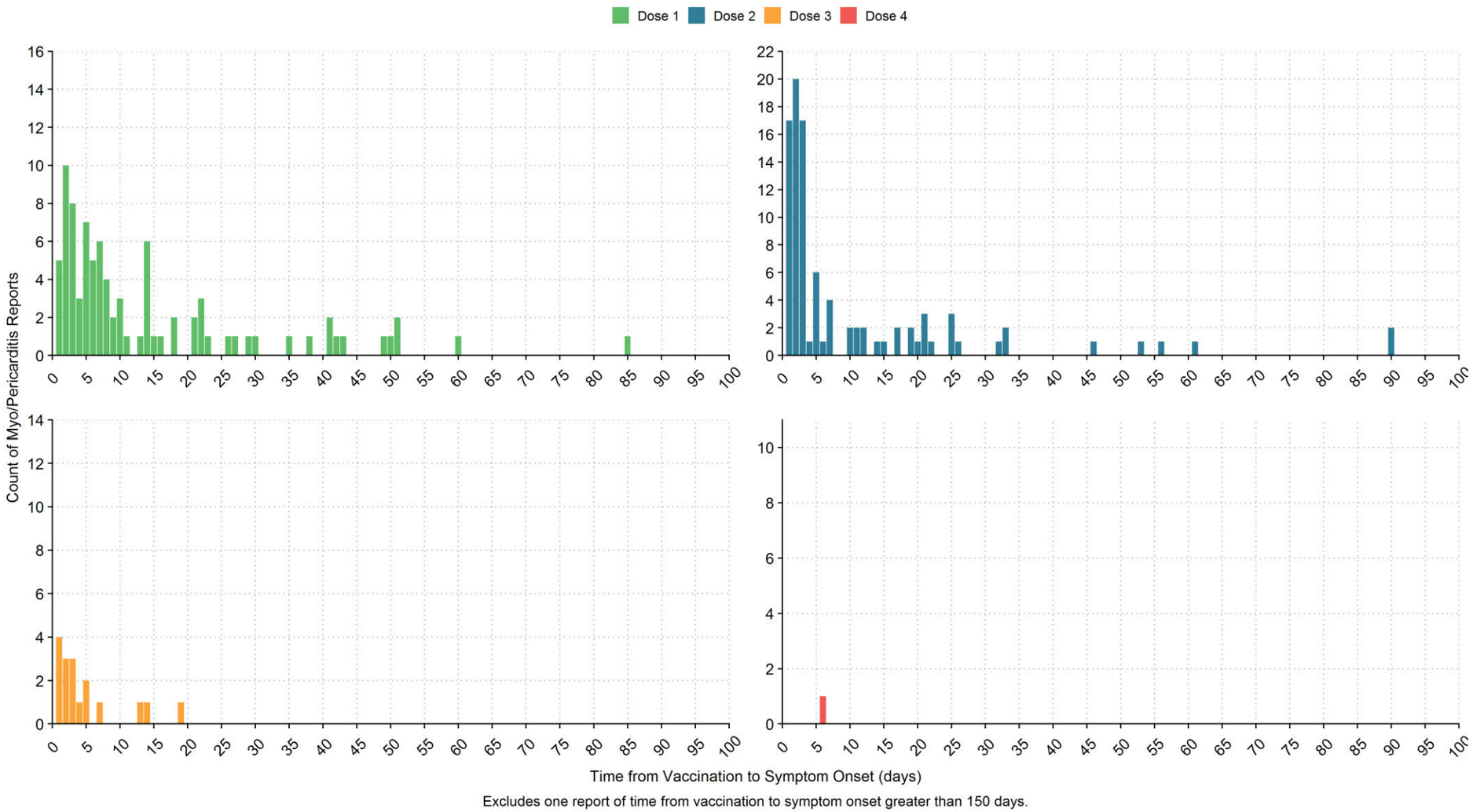
Males:

- 12-17 year olds: Dose 3 - However this is based on 1 report in relation to only 1088 doses administered. This rate should be interpreted with caution.
- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 2 and all doses combined
- All ages combined: Dose 2 and all doses combined

Females:

None showed a statistically significant difference between products.

Figure 3: Time from Vaccination to Symptom Onset of Myo/Pericarditis Reports, British Columbia, Dec. 13 2020 – Jul. 30, 2022 **(N=215)**



Excludes one report of time from vaccination to symptom onset greater than 150 days.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on August 3, 2022. Only AEFIs reported and doses administered up to July 30, 2022 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From: Minhas, Sableen
To: Dalati, Hadi [BCCDC]; Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: Monthly COVID-19 AEFI Report
Date: Thursday, August 04, 2022 1:54:57 PM

Thanks Hadi! It's posted.

Sableen Minhas
Communications Specialist
BC Centre for Disease Control
Provincial Health Services Authority

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, August 04, 2022 1:49 PM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Monthly COVID-19 AEFI Report

Hello all,

Please find attached the latest monthly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515

I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaɁ/Selilwitulh (TsleilWaututh) Nations.

From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Monthly COVID-19 AEFI Report
Date: Friday, September 02, 2022 4:14:27 PM
Attachments: COVID19_AEFI_Monthly_Report_2022-09-01.docx
COVID19_AEFI_Monthly_Report_2022-09-01.pdf

Hello all,

Please find attached the latest monthly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to August 27, 2022

This report summarizes COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including August 27, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Among reports in BC, anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, myocarditis and pericarditis were first recognized in Israel and the USA in young adults and adolescents, and have now also been seen in other countries including Canada and in BC reports.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is further reviewed and investigated, and then reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

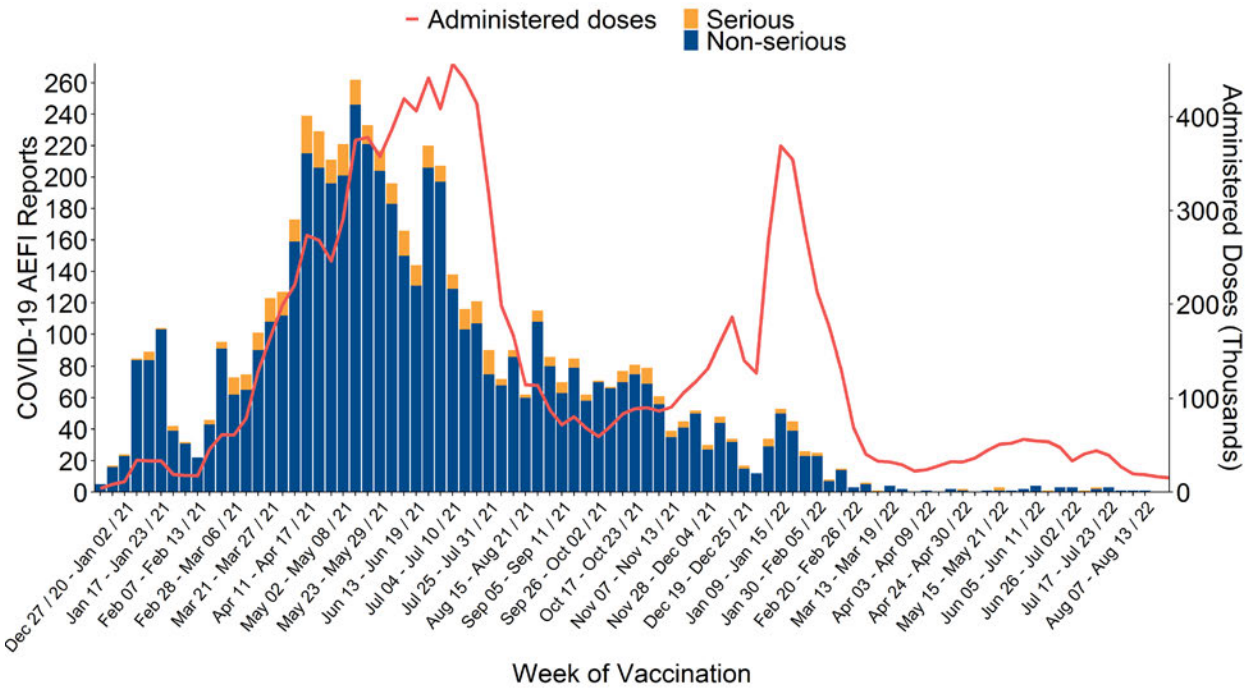
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of August 27, 2022, there have been 12,249,299 COVID-19 vaccine doses administered in BC and 5,853 COVID-19 AEFI reports (47.8 reports per 100,000 doses administered)
- 456 reports (7.8%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness
- Other events have been less frequently reported and are detailed below

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Aug. 27, 2022 **(N=5,853)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including August 27, 2022, a total of 12,249,299 doses have been administered. During this period, there have been 5,853 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.8 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second, third, and fourth doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Aug. 27, 2022 **(N=5,853)**

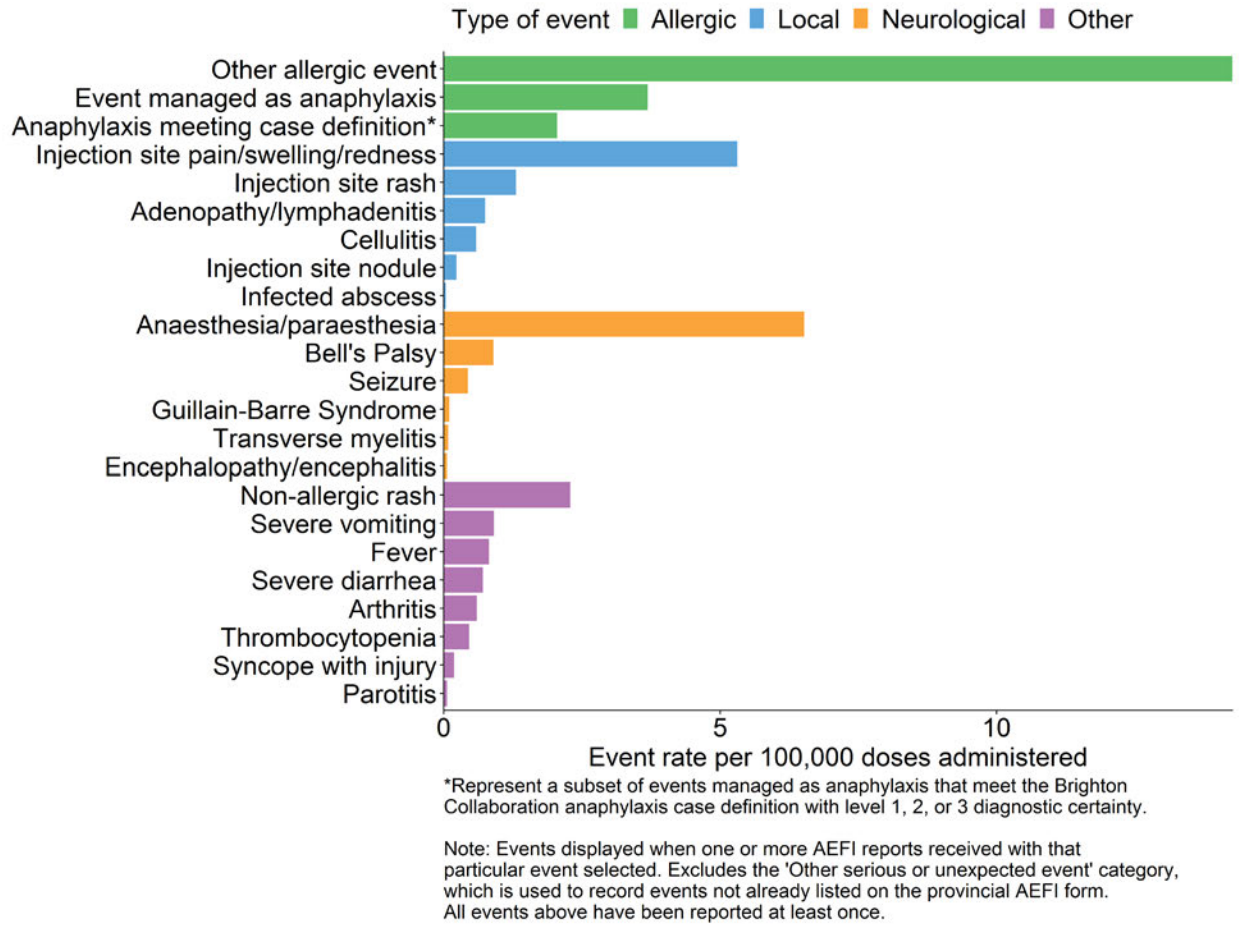
		COVID-19 Vaccine*						
	All COVID-19 Vaccines	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**	**Verity COVISHIELD**	**AstraZeneca Vaxzevria**	**J&J Janssen**	**Novavax NUVAXOVID**
Total reports	**5853**	**2095**	**3344**	**39**	**71**	**287**	**15**	**2**
Non-serious reports	5397	1944	3086	36	65	251	13	2
Serious reports	456	151	258	3	6	36	2	0
Proportion serious	7.8%	7.2%	7.7%	7.7%	8.5%	12.5%	13.3%	0%
Dose 1 reports	4054	1302	2384	29	69	256	12	2
Dose 2 reports	1436	552	841	9	2	30	2	0
Dose 3 reports	324	221	102	0	0	0	1	0
Dose 4 reports	20	14	6	0	0	0	0	0
Total doses administered	**12,249,299**	**3,914,510**	**7,516,096**	**369,085**	**88,730**	**343,279**	**12,627**	**4,972**
Dose 1 administered	4,514,604	932,530	3,056,576	208,627	70,300	232,633	11,915	2,023
Dose 2 administered	4,359,926	1,187,913	2,881,228	160,207	18,303	109,908	523	1,844
Dose 3 administered	2,810,615	1,475,212	1,333,578	250	123	721	186	545
Dose 4 administered	563,930	318,744	244,603	1	4	17	3	558
Total reporting rate	**47.8**	**53.5**	**44.5**	**10.6**	**80.0**	**83.6**	**118.8**	**40.2**
Serious rate	3.7	3.9	3.4	0.8	6.8	10.5	15.8	0.0
Dose 1 rate	89.8	139.6	78.0	13.9	98.2	110.0	100.7	98.9
Dose 2 rate	32.9	46.5	29.2	5.6	10.9	27.3	382.4	0.0
Dose 3 rate	11.5	15.0	7.6	0.0	0.0	0.0	537.6	0.0
Dose 4 rate	3.5	4.4	2.5	0.0	0.0	0.0	0.0	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,853 AEFI reports received up to August 27, 2022 contained a total of 7,455 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 27, 2022 **(N=7,455)**



Event Descriptions

Four hundred fifty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 251 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Many events managed as anaphylaxis have features more compatible with anxiety or vasovagal syncope/pre-syncopal (fainting) events.

Seventy-two reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred fifty-six reports (7.8%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 427 individuals were admitted to hospital, including 2.9% of cases reported as anaphylaxis.

One hundred and ninety-seven reports contained a diagnosed neurological event. One hundred and ten individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional four individuals were reported as having transverse myelitis, however, one was unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and another was referred to a specialist for further investigation. Fifty-four individuals were reported with seizures (18.5% hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, including one with encephalopathy. Six additional individuals developed encephalitis or encephalopathy: one encephalitis was presumed to be viral in nature; one encephalopathy was attributed to a workplace toxin exposure; one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; two individual with several comorbidities and encephalopathy made a spontaneous and full recovery within days, without a specific cause identified; one encephalitis was attributed to a new onset autoimmune condition diagnosed after receipt of vaccine. One individual was hospitalized for aseptic meningitis. There were twelve reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Five of these reports followed AstraZeneca vaccine, five followed Pfizer-BioNTech Comirnaty, and two followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but in two cases followed an illness compatible with recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19]

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Readers will note that some of the reported deaths described below appear to have a clear cause of death unrelated to the vaccine. Death may also be recorded as the outcome of a specific reportable event. Nineteen serious AEFI reports were received for individuals (median age: 76.5 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions; one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

- One death occurred in an elderly individual who suffered from multiple serious comorbidities. Investigation revealed the death was due to natural causes unrelated to the vaccine, but occurring in temporal association with vaccine receipt.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.
- One death occurred in an individual due to septic shock unrelated to the vaccine.
- Two deaths occurred in elderly individuals due to an underlying cardiac compromise unrelated to the vaccine.

'Other serious or unexpected' events:
Some events may be reported as an "other serious or unexpected" event when these do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 186 were for various thrombotic/ thromboembolic conditions. These included 39 strokes (89.7% hospitalized) two cerebral venous sinus thromboses, 28 myocardial infarctions (92.9% hospitalized), 51 pulmonary emboli (58.9% hospitalized), 57 deep vein thromboses, and nine superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[20] Health Canada issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[21]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults aged 30-49 and two were aged 60-69 years. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia; this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Three serious AEFI reports in the 5-11 year age group have been reported. One was of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[22] The second was a report of hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital. The third was a report of hospitalization following myo/pericarditis; this child was discharged with full resolution of symptoms.

There have been 222 reports of myocarditis/pericarditis. Sixty-six individuals were diagnosed with myocarditis, 99 with pericarditis, and 57 with myopericarditis. Ages ranged from 10 to 95 with a median of 34 years, and 145 (65%) were male. Ninety-two had received Moderna Spikevax, 122 received Pfizer-BioNTech Comirnaty, one received Pfizer-BioNTech Comirnaty Pediatric, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. One hundred and three of these events occurred after a second dose (47 Moderna Spikevax, 54 Pfizer-BioNTech Comirnaty, 1 Pfizer-BioNTech Comirnaty Pediatric, and 1 AstraZeneca Vaxzevria/Verity COVISHIELD). Seventeen occurred after a third dose (14 Moderna Spikevax and 3 Pfizer-BioNTech Comirnaty), and one occurred after a fourth dose of Moderna. Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Fifty-eight (out of 66) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-three (out of 99) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 57) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14,24]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 27, 2022 **(N=215)**

Vaccine/Age Groups	*Dose 1*	*Dose 2*	*Done 3*	*Dose 4*	*All Doses*
Moderna Spikevax					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12-17	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.5%)
18-24	5 (2.3%)	14 (6.5%)	1 (0.5%)	0 (0%)	20 (9.3%)
25-29	10 (4.7%)	9 (4.2%)	2 (0.9%)	0 (0%)	21 (9.8%)
30-39	7 (3.3%)	10 (4.7%)	1 (0.5%)	0 (0%)	18 (8.4%)
40+	8 (3.7%)	14 (6.5%)	9 (4.2%)	1 (0.5%)	32 (14.9%)
All ages	30 (14%)	47 (21.9%)	14 (6.5%)	1 (0.5%)	92 (42.8%)
Pfizer-BioNTech Comirnaty					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.3%)	10 (4.7%)	1 (0.5%)	0 (0%)	18 (8.4%)
18-24	7 (3.3%)	15 (7%)	1 (0.5%)	0 (0%)	23 (10.7%)
25-29	4 (1.9%)	4 (1.9%)	0 (0%)	0 (0%)	8 (3.7%)
30-39	19 (8.8%)	6 (2.8%)	0 (0%)	0 (0%)	25 (11.6%)
40+	28 (13%)	19 (8.8%)	1 (0.5%)	0 (0%)	48 (22.3%)
All ages	65 (30.2%)	55 (25.6%)	3 (1.4%)	0 (0%)	123 (57.2%)
mRNA Vaccines					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.3%)	10 (4.7%)	2 (0.9%)	0 (0%)	19 (8.8%)
18-24	12 (5.6%)	29 (13.5%)	2 (0.9%)	0 (0%)	43 (20%)
25-29	14 (6.5%)	13 (6%)	2 (0.9%)	0 (0%)	29 (13.5%)
30-39	26 (12.1%)	16 (7.4%)	1 (0.5%)	0 (0%)	43 (20%)
40+	36 (16.7%)	33 (15.3%)	10 (4.7%)	1 (0.5%)	80 (37.2%)
All ages	95 (44.2%)	102 (47.4%)	17 (7.9%)	1 (0.5%)	215 (100%)

Total = 215 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including August 27, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 27, 2022. Stratified by sex, age group, vaccine trade name, and dose **(N=215)**

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Moderna Spikevax	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	0 (0-0)	0 (0-0)	**899.3 (217.8-3317.3)**	0 (0-0)	207.7 (50.3-766.3)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	81.8 (33.2-179.2)	**266.3 (156.8-429.5)**	84.8 (20.5-312.9)	0 (0-0)	**164 (104.2-248)**	22.8 (5.5-84)	21.8 (5.3-80.4)	0 (0-0)	0 (0-0)	18.6 (5.7-51.7)
25-29	160.5 (82.6-289.4)	**156.5 (80.5-282.1)**	132.2 (40.9-368.3)	0 (0-0)	**154.7 (98.3-233.9)**	47.4 (14.7-131.9)	22 (5.3-81.2)	0 (0-0)	0 (0-0)	27.2 (9.9-65.6)
30-39	40.8 (16.5-89.3)	45.6 (20.1-93.4)	10.4 (2.5-38.4)	0 (0-0)	32.7 (18-55.9)	34.5 (12.5-83.1)	50.3 (22.2-103.1)	0 (0-0)	0 (0-0)	26.8 (13.8-48.4)
40+	18 (7.9-36.8)	17.9 (8.8-33.4)	7.1 (2.9-15.5)	7 (1.7-26)	12.3 (7.7-18.9)	10.7 (3.9-25.8)	17.8 (8.8-33.2)	7.9 (3.5-16.1)	0 (0-0)	10.1 (6.2-15.9)
All ages	43.2 (28.4-63.6)	**54.8 (39.1-75)**	13 (7-22.9)	6.9 (1.7-25.6)	**33.3 (26.1-41.9)**	19.4 (10.4-34)	23.9 (14.3-38)	6.4 (2.8-13)	0 (0-0)	13.9 (9.7-19.6)

Pfizer-BioNTech Comirnaty	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.4)	0 (0-0)	0 (0-0)	5.9 (1.4-21.6)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	45.2 (21.2-88)	55.1 (27.2-102.9)	**19.2 (4.6-70.7)**	0 (0-0)	44.9 (26.9-71.3)	7.8 (1.9-28.9)	24.5 (8.9-58.9)	0 (0-0)	0 (0-0)	13.1 (5.3-28.8)
18-24	34 (15-69.6)	**63.8 (34-111.8)**	16 (3.9-59.2)	0 (0-0)	**42.7 (26.1-66.9)**	13.3 (4.1-37.2)	41.8 (19.6-81.2)	0 (0-0)	0 (0-0)	21.5 (11.1-38.8)
25-29	24.9 (9-60)	**17.5 (5.4-48.7)**	0 (0-0)	0 (0-0)	**17.2 (7.6-35.2)**	8.1 (2-29.8)	17 (5.2-47.3)	0 (0-0)	0 (0-0)	9.7 (3.5-23.5)
30-39	68.6 (42.4-106)	18 (7.3-39.5)	0 (0-0)	0 (0-0)	37.4 (24.3-55.5)	12.1 (4.4-29.2)	8.4 (2.6-23.5)	0 (0-0)	0 (0-0)	8.7 (3.8-17.7)
40+	14.4 (8.3-23.7)	13 (7.1-22.1)	2.7 (0.7-10)	0 (0-0)	11.1 (7.4-16)	16.6 (10.3-25.7)	10 (5.3-17.6)	0 (0-0)	0 (0-0)	10.3 (7-14.7)
All ages	26.9 (19.9-35.6)	**22.8 (16.2-31.1)**	4.9 (1.8-11.7)	0 (0-0)	**20.9 (16.7-25.7)**	13.5 (9-19.5)	13.8 (9.2-20.2)	0 (0-0)	0 (0-0)	10.9 (8.1-14.2)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.4)	0 (0-0)	0 (0-0)	5.9 (1.4-21.6)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	44.6 (20.9-86.7)	54.4 (26.8-101.4)	37.5 (11.6-104.6)	0 (0-0)	47.4 (28.9-74.2)	7.7 (1.9-28.5)	24.1 (8.8-58)	0 (0-0)	0 (0-0)	12.9 (5.2-28.3)
18-24	45.9 (24.5-80.4)	115.9 (76.8-169.1)	27 (8.3-75.2)	0 (0-0)	71.6 (51.1-98)	15.5 (5.6-37.3)	36.9 (18.2-68.9)	0 (0-0)	0 (0-0)	20.9 (11.4-35.6)
25-29	64.6 (36.4-108)	60.4 (33.2-103.2)	28.3 (8.7-78.8)	0 (0-0)	56.4 (37.7-81.7)	18.1 (6.6-43.5)	18.4 (6.7-44.2)	0 (0-0)	0 (0-0)	14.3 (6.7-27.9)
30-39	60.3 (39.2-89.5)	27.1 (14.5-47.5)	5.8 (1.4-21.2)	0 (0-0)	35.7 (25.1-49.6)	17.9 (8.4-34.9)	20.8 (10.3-38.8)	0 (0-0)	0 (0-0)	14.8 (8.7-23.9)
40+	15.3 (9.6-23.4)	14.6 (9.2-22.4)	5.3 (2.4-11)	4 (1-14.8)	11.6 (8.5-15.4)	15.3 (9.8-22.9)	12.4 (7.7-19.2)	4.7 (2.1-9.6)	0 (0-0)	10.3 (7.5-13.7)
All ages	30.8 (24.1-38.8)	32.2 (25.3-40.4)	9.2 (5.3-15.1)	3.9 (1-14.5)	25.1 (21.3-29.4)	14.8 (10.5-20.3)	16.5 (12-22.4)	3.3 (1.5-6.8)	0 (0-0)	11.9 (9.4-14.7)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including August 27, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from the calculation of rates in this table).
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age group.

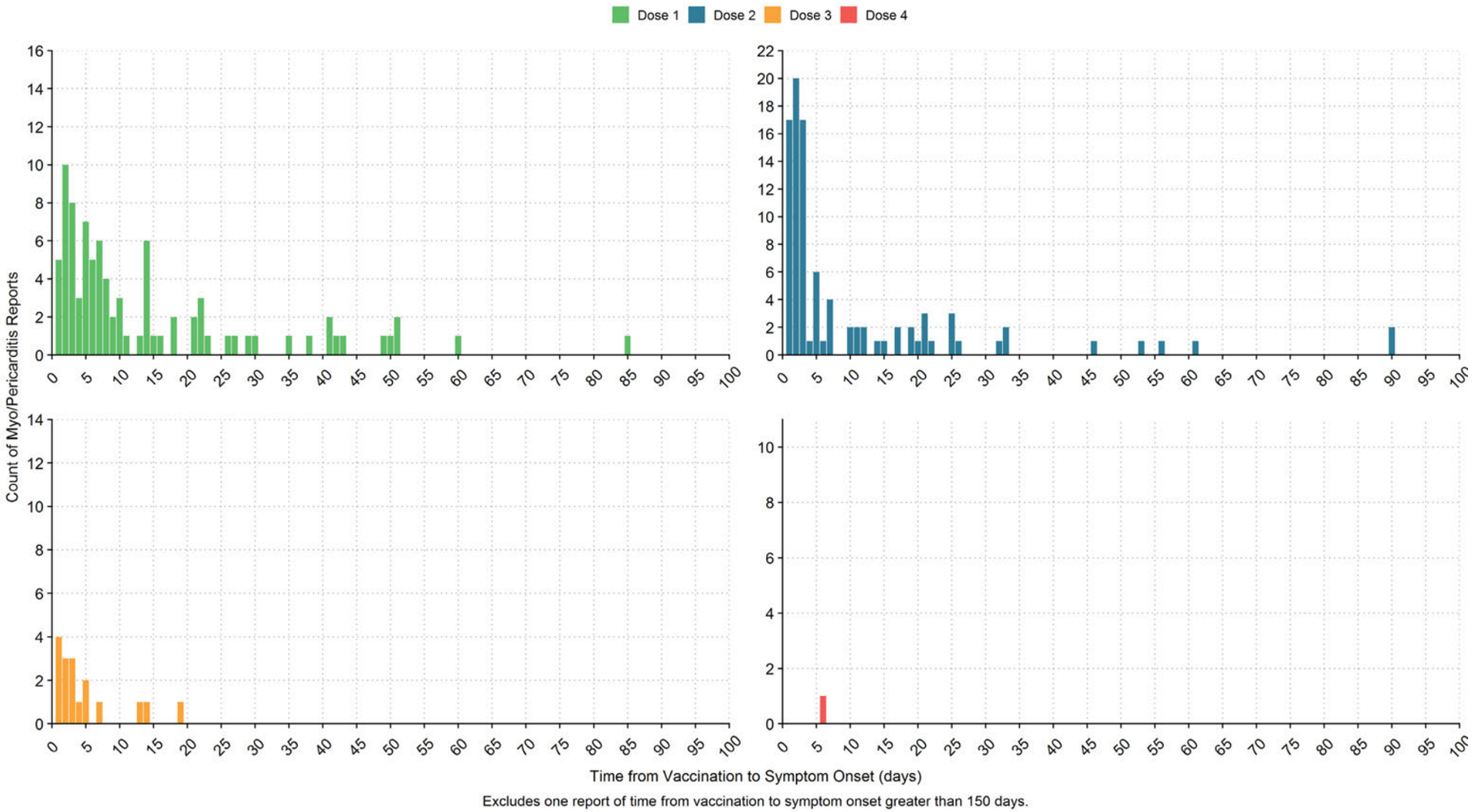
Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following sex, dose, and age groups:

Males:

- 12-17 year olds: Dose 3 - However this is based on a single report in relation to only 1112 doses administered. This rate should be interpreted with caution.
- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 2 and all doses combined
- All ages combined: Dose 2 and all doses combined

Females:
None showed a statistically significant difference between products.

Figure 3: Time from Vaccination to Symptom Onset of Myo/Pericarditis Reports, British Columbia, Dec. 13, 2020 - Aug. 27, 2022 **(N=215)**



Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on August 31, 2022. Only AEFIs reported and doses administered up to August 27, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to August 27, 2022

This report summarizes COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including August 27, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Among reports in BC, anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, myocarditis and pericarditis were first recognized in Israel and the USA in young adults and adolescents, and have now also been seen in other countries including Canada and in BC reports.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is further reviewed and investigated, and then reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

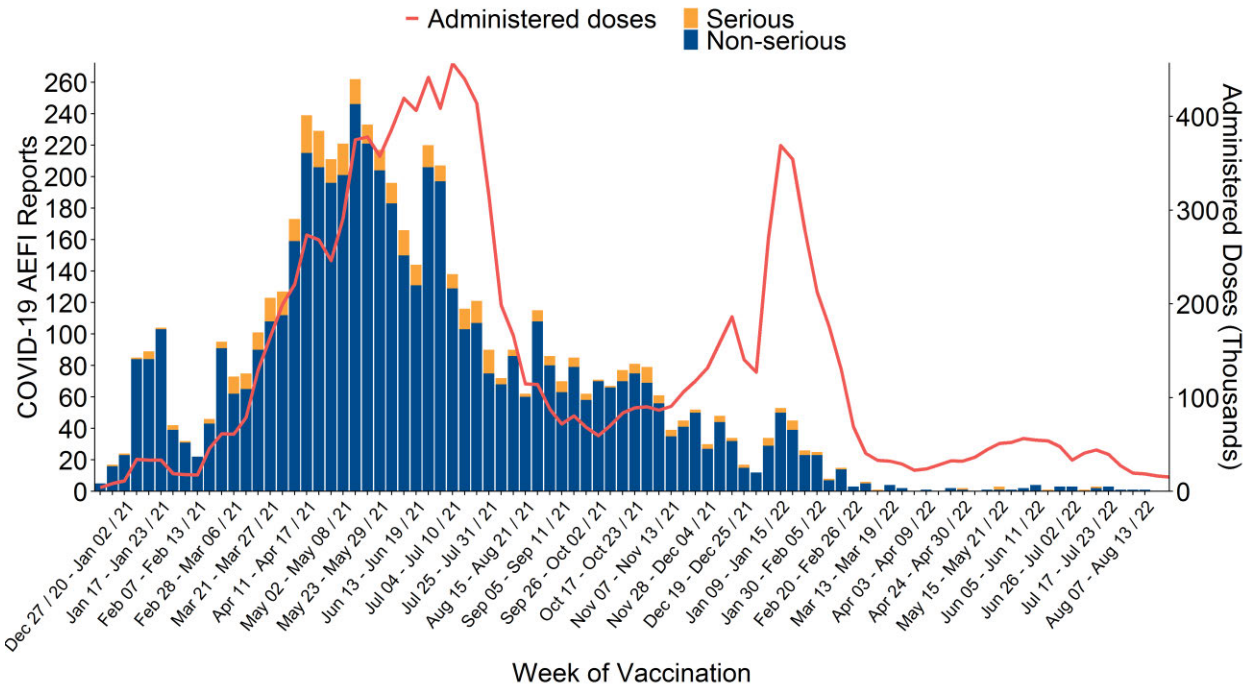
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of August 27, 2022, there have been 12,249,299 COVID-19 vaccine doses administered in BC and 5,853 COVID-19 AEFI reports (47.8 reports per 100,000 doses administered)
- 456 reports (7.8%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness
- Other events have been less frequently reported and are detailed below

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Aug. 27, 2022 **(N=5,853)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including August 27, 2022, a total of 12,249,299 doses have been administered. During this period, there have been 5,853 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.8 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second, third, and fourth doses of all COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Aug. 27, 2022 **(N=5,853)**

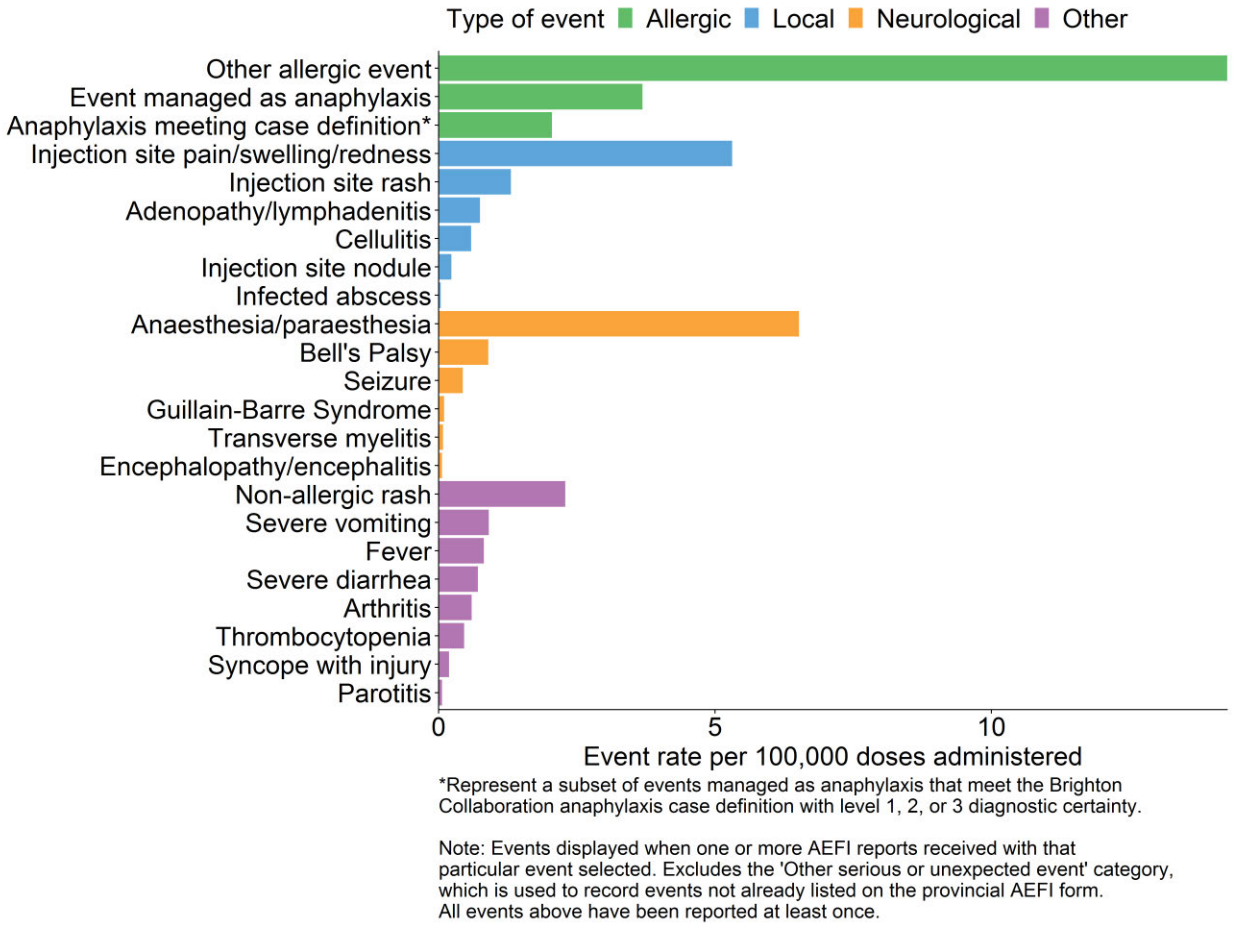
	COVID-19 Vaccine*							
	All COVID-19 Vaccines	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**	**Verity COVISHIELD**	**AstraZeneca Vaxzevria**	**J&J Janssen**	**Novavax NUVAXOVID**
Total reports	**5853**	**2095**	**3344**	**39**	**71**	**287**	**15**	**2**
Non-serious reports	5397	1944	3086	36	65	251	13	2
Serious reports	456	151	258	3	6	36	2	0
Proportion serious	7.8%	7.2%	7.7%	7.7%	8.5%	12.5%	13.3%	0%
Dose 1 reports	4054	1302	2384	29	69	256	12	2
Dose 2 reports	1436	552	841	9	2	30	2	0
Dose 3 reports	324	221	102	0	0	0	1	0
Dose 4 reports	20	14	6	0	0	0	0	0
Total doses administered	**12,249,299**	**3,914,510**	**7,516,096**	**369,085**	**88,730**	**343,279**	**12,627**	**4,972**
Dose 1 administered	4,514,604	932,530	3,056,576	208,627	70,300	232,633	11,915	2,023
Dose 2 administered	4,359,926	1,187,913	2,881,228	160,207	18,303	109,908	523	1,844
Dose 3 administered	2,810,615	1,475,212	1,333,578	250	123	721	186	545
Dose 4 administered	563,930	318,744	244,603	1	4	17	3	558
Total reporting rate	**47.8**	**53.5**	**44.5**	**10.6**	**80.0**	**83.6**	**118.8**	**40.2**
Serious rate	3.7	3.9	3.4	0.8	6.8	10.5	15.8	0.0
Dose 1 rate	89.8	139.6	78.0	13.9	98.2	110.0	100.7	98.9
Dose 2 rate	32.9	46.5	29.2	5.6	10.9	27.3	382.4	0.0
Dose 3 rate	11.5	15.0	7.6	0.0	0.0	0.0	537.6	0.0
Dose 4 rate	3.5	4.4	2.5	0.0	0.0	0.0	0.0	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,853 AEFI reports received up to August 27, 2022 contained a total of 7,455 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 27, 2022 **(N=7,455)**



Event Descriptions

Four hundred fifty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 251 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Many events managed as anaphylaxis have features more compatible with anxiety or vasovagal syncope/pre-syncopal (fainting) events.

Seventy-two reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred fifty-six reports (7.8%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 427 individuals were admitted to hospital, including 2.9% of cases reported as anaphylaxis.

One hundred and ninety-seven reports contained a diagnosed neurological event. One hundred and ten individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional four individuals were reported as having transverse myelitis, however, one was unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and another was referred to a specialist for further investigation. Fifty-four individuals were reported with seizures (18.5% hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, including one with encephalopathy. Six additional individuals developed encephalitis or encephalopathy: one encephalitis was presumed to be viral in nature; one encephalopathy was attributed to a workplace toxin exposure; one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; two individual with several comorbidities and encephalopathy made a spontaneous and full recovery within days, without a specific cause identified; one encephalitis was attributed to a new onset autoimmune condition diagnosed after receipt of vaccine. One individual was hospitalized for aseptic meningitis. There were twelve reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Five of these reports followed AstraZeneca vaccine, five followed Pfizer-BioNTech Comirnaty, and two followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but in two cases followed an illness compatible with recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19]

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Readers will note that some of the reported deaths described below appear to have a clear cause of death unrelated to the vaccine. Death may also be recorded as the outcome of a specific reportable event. Nineteen serious AEFI reports were received for individuals (median age: 76.5 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions; one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

- One death occurred in an elderly individual who suffered from multiple serious comorbidities. Investigation revealed the death was due to natural causes unrelated to the vaccine, but occurring in temporal association with vaccine receipt.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.
- One death occurred in an individual due to septic shock unrelated to the vaccine.
- Two deaths occurred in elderly individuals due to an underlying cardiac compromise unrelated to the vaccine.

'Other serious or unexpected' events:
Some events may be reported as an "other serious or unexpected" event when these do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 186 were for various thrombotic/ thromboembolic conditions. These included 39 strokes (89.7% hospitalized) two cerebral venous sinus thromboses, 28 myocardial infarctions (92.9% hospitalized), 51 pulmonary emboli (58.9% hospitalized), 57 deep vein thromboses, and nine superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[20] Health Canada issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[21]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults aged 30-49 and two were aged 60-69 years. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia; this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Three serious AEFI reports in the 5-11 year age group have been reported. One was of new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[22] The second was a report of hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital. The third was a report of hospitalization following myo/pericarditis; this child was discharged with full resolution of symptoms.

There have been 222 reports of myocarditis/pericarditis. Sixty-six individuals were diagnosed with myocarditis, 99 with pericarditis, and 57 with myopericarditis. Ages ranged from 10 to 95 with a median of 34 years, and 145 (65%) were male. Ninety-two had received Moderna Spikevax, 122 received Pfizer-BioNTech Comirnaty, one received Pfizer-BioNTech Comirnaty Pediatric, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. One hundred and three of these events occurred after a second dose (47 Moderna Spikevax, 54 Pfizer-BioNTech Comirnaty, 1 Pfizer-BioNTech Comirnaty Pediatric, and 1 AstraZeneca Vaxzevria/Verity COVISHIELD). Seventeen occurred after a third dose (14 Moderna Spikevax and 3 Pfizer-BioNTech Comirnaty), and one occurred after a fourth dose of Moderna. Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Fifty-eight (out of 66) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-three (out of 99) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 57) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14,24]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 27, 2022 **(N=215)**

Vaccine/Age Groups	*Dose 1*	*Dose 2*	*Done 3*	*Dose 4*	*All Doses*
Moderna Spikevax					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12-17	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.5%)
18-24	5 (2.3%)	14 (6.5%)	1 (0.5%)	0 (0%)	20 (9.3%)
25-29	10 (4.7%)	9 (4.2%)	2 (0.9%)	0 (0%)	21 (9.8%)
30-39	7 (3.3%)	10 (4.7%)	1 (0.5%)	0 (0%)	18 (8.4%)
40+	8 (3.7%)	14 (6.5%)	9 (4.2%)	1 (0.5%)	32 (14.9%)
All ages	30 (14%)	47 (21.9%)	14 (6.5%)	1 (0.5%)	92 (42.8%)
Pfizer-BioNTech Comirnaty					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.3%)	10 (4.7%)	1 (0.5%)	0 (0%)	18 (8.4%)
18-24	7 (3.3%)	15 (7%)	1 (0.5%)	0 (0%)	23 (10.7%)
25-29	4 (1.9%)	4 (1.9%)	0 (0%)	0 (0%)	8 (3.7%)
30-39	19 (8.8%)	6 (2.8%)	0 (0%)	0 (0%)	25 (11.6%)
40+	28 (13%)	19 (8.8%)	1 (0.5%)	0 (0%)	48 (22.3%)
All ages	65 (30.2%)	55 (25.6%)	3 (1.4%)	0 (0%)	123 (57.2%)
mRNA Vaccines					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.3%)	10 (4.7%)	2 (0.9%)	0 (0%)	19 (8.8%)
18-24	12 (5.6%)	29 (13.5%)	2 (0.9%)	0 (0%)	43 (20%)
25-29	14 (6.5%)	13 (6%)	2 (0.9%)	0 (0%)	29 (13.5%)
30-39	26 (12.1%)	16 (7.4%)	1 (0.5%)	0 (0%)	43 (20%)
40+	36 (16.7%)	33 (15.3%)	10 (4.7%)	1 (0.5%)	80 (37.2%)
All ages	95 (44.2%)	102 (47.4%)	17 (7.9%)	1 (0.5%)	215 (100%)

Total = 215 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including August 27, 2022

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Aug. 27, 2022. Stratified by sex, age group, vaccine trade name, and dose **(N=215)**

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Moderna Spikevax	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	0 (0-0)	0 (0-0)	**899.3 (217.8-3317.3)**	0 (0-0)	207.7 (50.3-766.3)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	81.8 (33.2-179.2)	**266.3 (156.8-429.5)**	84.8 (20.5-312.9)	0 (0-0)	**164 (104.2-248)**	22.8 (5.5-84)	21.8 (5.3-80.4)	0 (0-0)	0 (0-0)	18.6 (5.7-51.7)
25-29	160.5 (82.6-289.4)	**156.5 (80.5-282.1)**	132.2 (40.9-368.3)	0 (0-0)	**154.7 (98.3-233.9)**	47.4 (14.7-131.9)	22 (5.3-81.2)	0 (0-0)	0 (0-0)	27.2 (9.9-65.6)
30-39	40.8 (16.5-89.3)	45.6 (20.1-93.4)	10.4 (2.5-38.4)	0 (0-0)	32.7 (18-55.9)	34.5 (12.5-83.1)	50.3 (22.2-103.1)	0 (0-0)	0 (0-0)	26.8 (13.8-48.4)
40+	18 (7.9-36.8)	17.9 (8.8-33.4)	7.1 (2.9-15.5)	7 (1.7-26)	12.3 (7.7-18.9)	10.7 (3.9-25.8)	17.8 (8.8-33.2)	7.9 (3.5-16.1)	0 (0-0)	10.1 (6.2-15.9)
All ages	43.2 (28.4-63.6)	**54.8 (39.1-75)**	13 (7-22.9)	6.9 (1.7-25.6)	**33.3 (26.1-41.9)**	19.4 (10.4-34)	23.9 (14.3-38)	6.4 (2.8-13)	0 (0-0)	13.9 (9.7-19.6)

Pfizer-BioNTech Comirnaty	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.4)	0 (0-0)	0 (0-0)	5.9 (1.4-21.6)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	45.2 (21.2-88)	55.1 (27.2-102.9)	**19.2 (4.6-70.7)**	0 (0-0)	44.9 (26.9-71.3)	7.8 (1.9-28.9)	24.5 (8.9-58.9)	0 (0-0)	0 (0-0)	13.1 (5.3-28.8)
18-24	34 (15-69.6)	**63.8 (34-111.8)**	16 (3.9-59.2)	0 (0-0)	**42.7 (26.1-66.9)**	13.3 (4.1-37.2)	41.8 (19.6-81.2)	0 (0-0)	0 (0-0)	21.5 (11.1-38.8)
25-29	24.9 (9-60)	**17.5 (5.4-48.7)**	0 (0-0)	0 (0-0)	**17.2 (7.6-35.2)**	8.1 (2-29.8)	17 (5.2-47.3)	0 (0-0)	0 (0-0)	9.7 (3.5-23.5)
30-39	68.6 (42.4-106)	18 (7.3-39.5)	0 (0-0)	0 (0-0)	37.4 (24.3-55.5)	12.1 (4.4-29.2)	8.4 (2.6-23.5)	0 (0-0)	0 (0-0)	8.7 (3.8-17.7)
40+	14.4 (8.3-23.7)	13 (7.1-22.1)	2.7 (0.7-10)	0 (0-0)	11.1 (7.4-16)	16.6 (10.3-25.7)	10 (5.3-17.6)	0 (0-0)	0 (0-0)	10.3 (7-14.7)
All ages	26.9 (19.9-35.6)	**22.8 (16.2-31.1)**	4.9 (1.8-11.7)	0 (0-0)	**20.9 (16.7-25.7)**	13.5 (9-19.5)	13.8 (9.2-20.2)	0 (0-0)	0 (0-0)	10.9 (8.1-14.2)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.4)	0 (0-0)	0 (0-0)	5.9 (1.4-21.6)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	44.6 (20.9-86.7)	54.4 (26.8-101.4)	37.5 (11.6-104.6)	0 (0-0)	47.4 (28.9-74.2)	7.7 (1.9-28.5)	24.1 (8.8-58)	0 (0-0)	0 (0-0)	12.9 (5.2-28.3)
18-24	45.9 (24.5-80.4)	115.9 (76.8-169.1)	27 (8.3-75.2)	0 (0-0)	71.6 (51.1-98)	15.5 (5.6-37.3)	36.9 (18.2-68.9)	0 (0-0)	0 (0-0)	20.9 (11.4-35.6)
25-29	64.6 (36.4-108)	60.4 (33.2-103.2)	28.3 (8.7-78.8)	0 (0-0)	56.4 (37.7-81.7)	18.1 (6.6-43.5)	18.4 (6.7-44.2)	0 (0-0)	0 (0-0)	14.3 (6.7-27.9)
30-39	60.3 (39.2-89.5)	27.1 (14.5-47.5)	5.8 (1.4-21.2)	0 (0-0)	35.7 (25.1-49.6)	17.9 (8.4-34.9)	20.8 (10.3-38.8)	0 (0-0)	0 (0-0)	14.8 (8.7-23.9)
40+	15.3 (9.6-23.4)	14.6 (9.2-22.4)	5.3 (2.4-11)	4 (1-14.8)	11.6 (8.5-15.4)	15.3 (9.8-22.9)	12.4 (7.7-19.2)	4.7 (2.1-9.6)	0 (0-0)	10.3 (7.5-13.7)
All ages	30.8 (24.1-38.8)	32.2 (25.3-40.4)	9.2 (5.3-15.1)	3.9 (1-14.5)	25.1 (21.3-29.4)	14.8 (10.5-20.3)	16.5 (12-22.4)	3.3 (1.5-6.8)	0 (0-0)	11.9 (9.4-14.7)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including August 27, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from the calculation of rates in this table).
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age group.

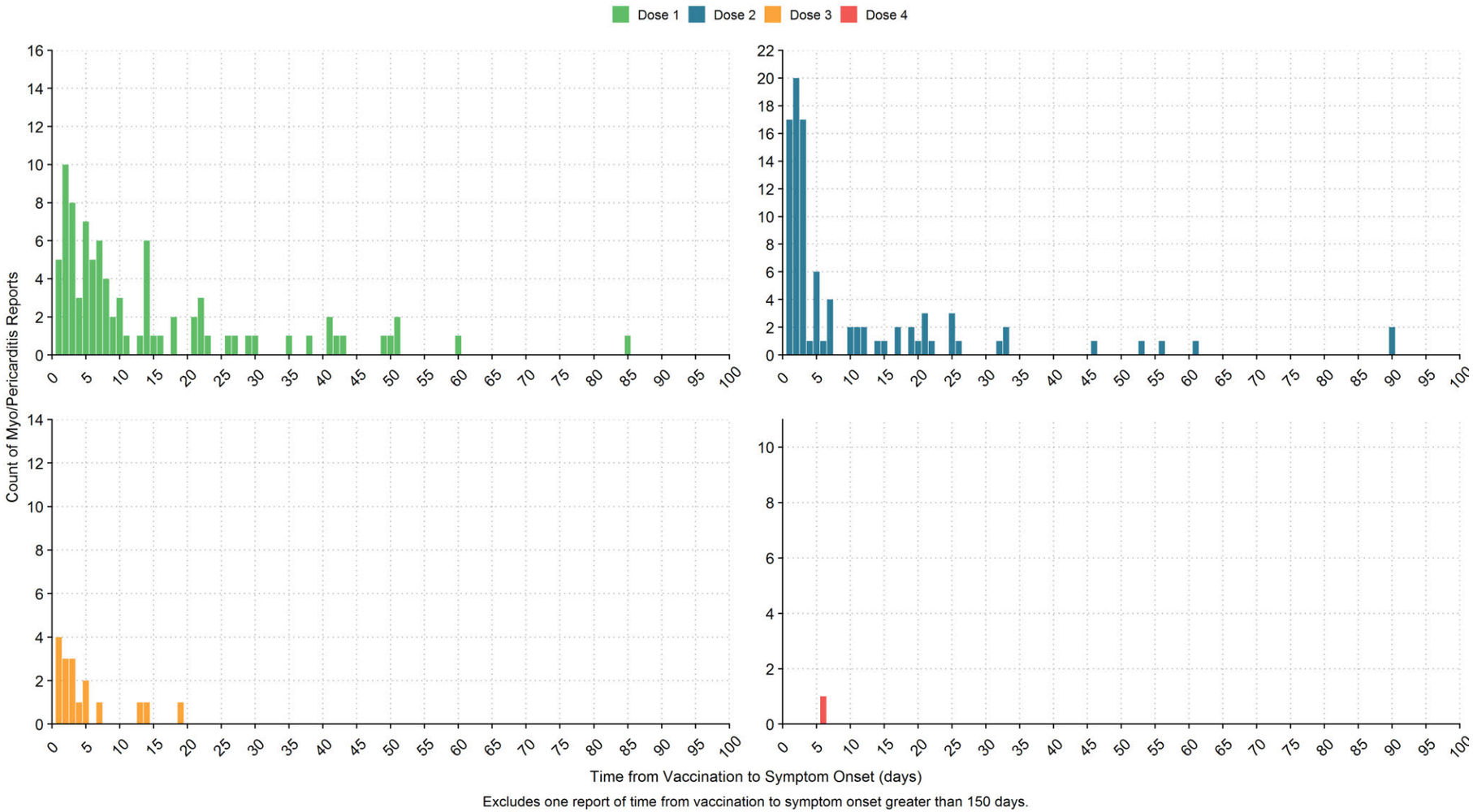
Table 3 interpretation: the rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following sex, dose, and age groups:

Males:

- 12-17 year olds: Dose 3 - However this is based on a single report in relation to only 1112 doses administered. This rate should be interpreted with caution.
- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 2 and all doses combined
- All ages combined: Dose 2 and all doses combined

Females:
None showed a statistically significant difference between products.

Figure 3: Time from Vaccination to Symptom Onset of Myo/Pericarditis Reports, British Columbia, Dec. 13, 2020 - Aug. 27, 2022 **(N=215)**



Excludes one report of time from vaccination to symptom onset greater than 150 days.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on August 31, 2022. Only AEFIs reported and doses administered up to August 27, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From: Minhas, Sableen
To: Dalati, Hadi [BCCDC]; Amos, Heather [BCCDC]
Cc: Naus, Monika [BCCDC]
Subject: RE: Monthly COVID-19 AEFI Report
Date: Friday, September 02, 2022 4:30:15 PM

It's up! Thanks Hadi.

Have a great long weekend,

Sableen Minhas
Communications Specialist
BC Centre for Disease Control
Provincial Health Services Authority

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Friday, September 02, 2022 4:14 PM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Monthly COVID-19 AEFI Report

Hello all,

Please find attached the latest monthly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515

I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaɁ/Selilwitulh (TsleilWaututh) Nations.

From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: Monthly COVID-19 AEFI Report
Date: Thursday, September 29, 2022 2:42:56 PM
Attachments: COVID19_AEFI_Monthly_Report_2022-09-29.docx
COVID19_AEFI_Monthly_Report_2022-09-29.pdf

Hello all,

Please find attached the latest monthly COVID-19 AEFI report for posting.

As always, thank you for all your hard work.

Best,

Hadi Dalati, MPH

Communicable Disease Epidemiologist

Communicable Diseases and Immunization Service (CDIS)

BC Centre for Disease Control

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to September 24, 2022

This report summarizes COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including September 24, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Among reports in BC, anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, myocarditis and pericarditis were first recognized in Israel and the USA in young adults and adolescents, and have now also been seen in other countries including Canada and in BC reports.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is further reviewed and investigated, and then reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

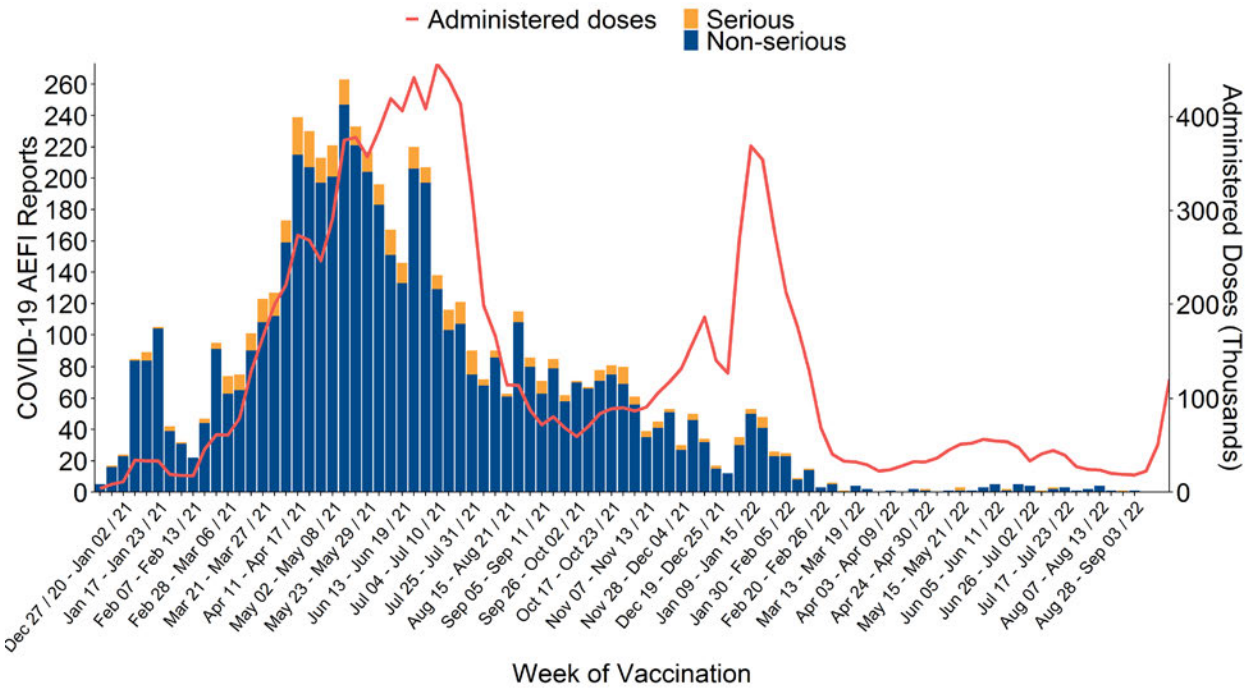
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of September 24, 2022, there have been 12,477,702 COVID-19 vaccine doses administered in BC and 5,888 COVID-19 AEFI reports (47.2 reports per 100,000 doses administered)
- 461 reports (7.8%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness
- Other events have been less frequently reported and are detailed below

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including September 24, 2022, a total of 12,477,702 doses have been administered. During this period, there have been 5,888 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.2 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second, third, and fourth doses of COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**

		COVID-19 Vaccine*				
	All COVID-19 Vaccines	**Moderna Spikevax**	**Moderna Spikevax Pediatric**	**Moderna Spikevax Bivalent**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5888**	**2104**	**6**	**0**	**3362**	**41**
Non-serious reports	5427	1952	5	0	3101	38
Serious reports	461	152	1	0	261	3
Proportion serious	7.8%	7.2%	16.7%	0.0%	7.8%	7.3%
Dose 1 reports	4076	1306	6	0	2394	31
Dose 2 reports	1440	552	0	0	845	9
Dose 3 reports	333	226	0	0	106	0
Dose 4 reports	25	16	0	0	9	0
Total doses administered	**12,477,702**	**3,924,397**	**21,263**	**143,476**	**7,539,697**	**398,189**
Dose 1 administered	4,537,878	932,612	21,189	1	3,056,949	209,887
Dose 2 administered	4,363,176	1,188,090	43	9	2,881,923	162,179
Dose 3 administered	2,848,835	1,476,493	23	4,178	1,340,307	26,119
Dose 4 administered	726,548	327,069	8	138,309	260,369	4
Total reporting rate	**47.2**	**53.6**	**28.2**	**0.0**	**44.6**	**10.3**
Serious rate	3.7	3.9	4.7	0.0	3.5	0.8
Dose 1 rate	89.8	140.0	28.3	0.0	78.3	14.8
Dose 2 rate	33.0	46.5	0.0	0.0	29.3	5.5
Dose 3 rate	11.7	15.3	0.0	0.0	7.9	0.0
Dose 4 rate	3.4	4.9	0.0	0.0	3.5	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Table 1 (continued): Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**

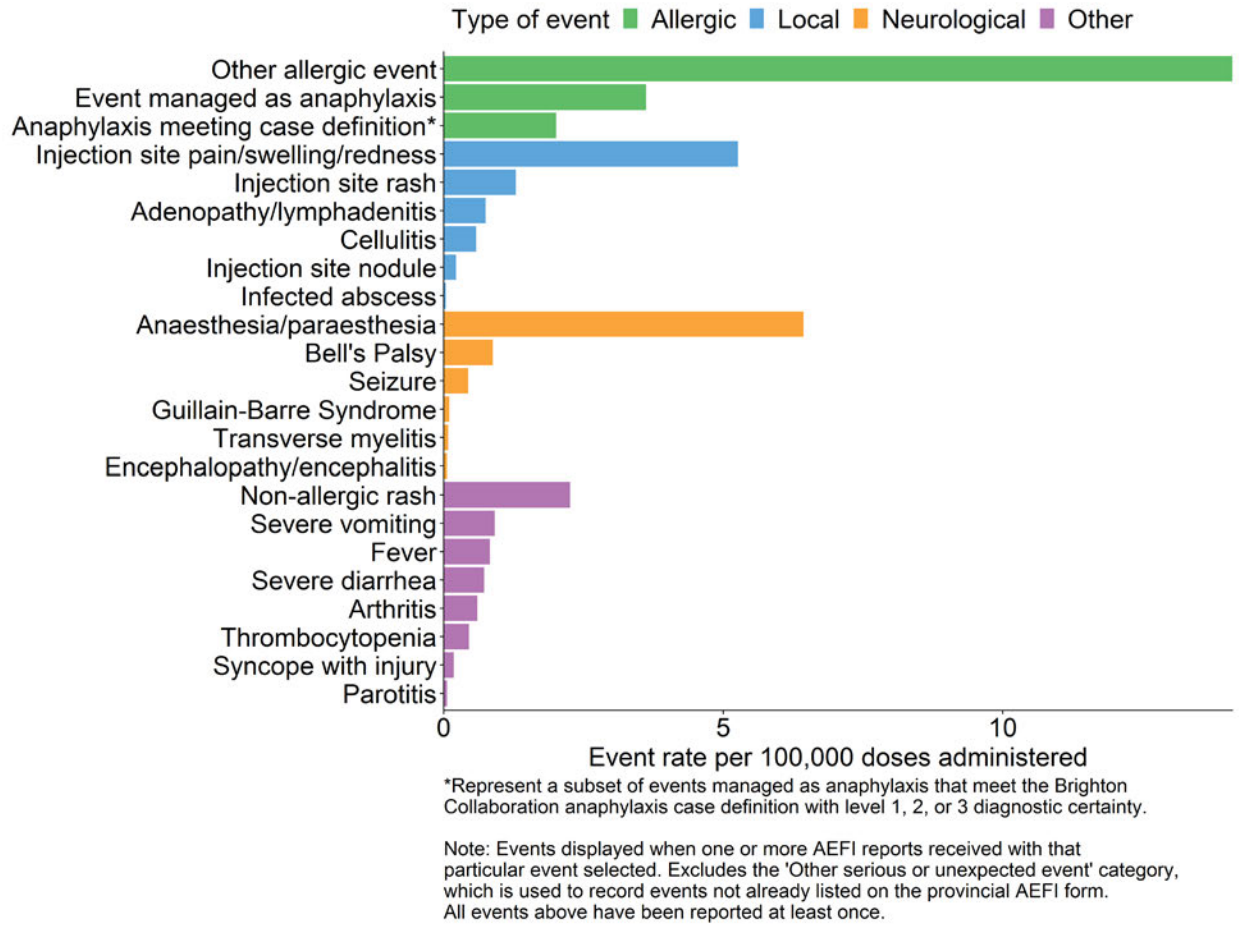
	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**Verity COVISHIELD**	**AstraZeneca Vaxzevria**	**J&J Janssen**	**Novavax NUVAXOVID**
Total reports	**5888**	**71**	**287**	**15**	**2**
Non-serious reports	5427	65	251	13	2
Serious reports	461	6	36	2	0
Proportion serious	7.8%	8.5%	12.5%	13.3%	0%
Dose 1 reports	4076	69	256	12	2
Dose 2 reports	1440	2	30	2	0
Dose 3 reports	333	0	0	1	0
Dose 4 reports	25	0	0	0	0
Total doses administered	**12,477,702**	**89,032**	**343,477**	**12,730**	**5,441**
Dose 1 administered	4,537,878	70,443	232,693	12,000	2,104
Dose 2 administered	4,363,176	18,443	109,975	534	1,980
Dose 3 administered	2,848,835	142	793	190	590
Dose 4 administered	726,548	4	16	6	763
Total reporting rate	**47.2**	**79.7**	**83.6**	**117.8**	**36.8**
Serious rate	3.7	6.7	10.5	15.7	0.0
Dose 1 rate	89.8	98.0	110.0	100.0	95.1
Dose 2 rate	33.0	10.8	27.3	374.5	0.0
Dose 3 rate	11.7	0.0	0.0	526.3	0.0
Dose 4 rate	3.4	0.0	0.0	0.0	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,888 AEFI reports received up to September 24, 2022 contained a total of 7,508 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=7,508)**



Event Descriptions

Four hundred fifty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 251 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Many events managed as anaphylaxis have features more compatible with anxiety or vasovagal syncope/pre-syncopal (fainting) events.

Seventy-two reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred sixty-one reports (7.8%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 432 individuals were admitted to hospital, including 2.9% of cases reported as anaphylaxis.

One hundred and ninety-eight reports contained a diagnosed neurological event. One hundred and ten individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional four individuals were reported as having transverse myelitis, however, one was unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and another was referred to a specialist for further investigation. Fifty-five individuals were reported with seizures (20% hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, including one with encephalopathy. Six additional individuals developed encephalitis or encephalopathy: one encephalitis was presumed to be viral in nature; one encephalopathy was attributed to a workplace toxin exposure; one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; two individuals with several comorbidities and encephalopathy made a spontaneous and full recovery within days, without a specific cause identified; one encephalitis was attributed to a new onset autoimmune condition diagnosed after receipt of vaccine. One individual was hospitalized for aseptic meningitis. There were twelve reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Five of these reports followed AstraZeneca vaccine, five followed Pfizer-BioNTech Comirnaty, and two followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but in two cases followed an illness compatible with recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19]

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Readers will note that some of the reported deaths described below appear to have a clear cause of death unrelated to the vaccine. Death may also be recorded as the outcome of a specific reportable event. Nineteen serious AEFI reports were received for individuals (median age: 76.5 years who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions; one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

- One death occurred in an elderly individual who suffered from multiple serious comorbidities. Investigation revealed the death was due to natural causes unrelated to the vaccine, but occurring in temporal association with vaccine receipt.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.
- One death occurred in an individual due to septic shock unrelated to the vaccine.
- Two deaths occurred in elderly individuals due to underlying cardiac compromise unrelated to the vaccine.

'Other serious or unexpected' events:
Some events may be reported as an "other serious or unexpected" event when these do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 188 were for various thrombotic/ thromboembolic conditions. These included 39 strokes (89.7% hospitalized) two cerebral venous sinus thromboses, 28 myocardial infarctions (92.9% hospitalized), 51 pulmonary emboli (58.9% hospitalized), 59 deep vein thromboses, and nine superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[20] Health Canada issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[21]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults aged 30-49 and two were aged 60-69 years. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia; this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Four serious AEFI reports in the 5-11 year age group have been reported. The first was for a new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[22] The second was for hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital. The third was for hospitalization following myo/pericarditis; this child was discharged with full resolution of symptoms. The fourth was for hospitalization following febrile seizures with onset several days later than expected for a plausible causal association to vaccine; this child was discharged home after full resolution and further investigations are in progress to identify an infectious cause.

There have been 223 reports of myocarditis/pericarditis. Sixty-six individuals were diagnosed with myocarditis, 100 with pericarditis, and 57 with myopericarditis. Ages ranged from 10 to 95 with a median of 35 years, and 146 (65%) were male. Ninety-three had received Moderna Spikevax, 122 received Pfizer-BioNTech Comirnaty, one received Pfizer-BioNTech Comirnaty Pediatric, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. One hundred and three of these events occurred after a second dose (47 Moderna Spikevax, 54 Pfizer-BioNTech Comirnaty, 1 Pfizer-BioNTech Comirnaty Pediatric, and 1 AstraZeneca Vaxzevria/Verity COVISHIELD). Seventeen occurred after a third dose (14 Moderna Spikevax and 3 Pfizer-BioNTech Comirnaty), and one occurred after a fourth dose of Moderna. Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Fifty-eight (out of 66) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-four (out of 100) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 57) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14,24]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=216)**

Vaccine/Age Groups	*Dose 1*	*Dose 2*	*Done 3*	*Dose 4*	*All Doses*
Moderna Spikevax					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12-17	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.5%)
18-24	5 (2.3%)	14 (6.5%)	1 (0.5%)	0 (0%)	20 (9.3%)
25-29	10 (4.6%)	9 (4.2%)	2 (0.9%)	0 (0%)	21 (9.7%)
30-39	7 (3.2%)	10 (4.6%)	1 (0.5%)	0 (0%)	18 (8.3%)
40+	9 (4.2%)	14 (6.5%)	9 (4.2%)	1 (0.5%)	33 (15.3%)
All ages	31 (14.4%)	47 (21.8%)	14 (6.5%)	1 (0.5%)	93 (43.1%)
Pfizer-BioNTech Comirnaty					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.2%)	10 (4.6%)	1 (0.5%)	0 (0%)	18 (8.3%)
18-24	7 (3.2%)	15 (6.9%)	1 (0.5%)	0 (0%)	23 (10.6%)
25-29	4 (1.9%)	4 (1.9%)	0 (0%)	0 (0%)	8 (3.7%)
30-39	19 (8.8%)	6 (2.8%)	0 (0%)	0 (0%)	25 (11.6%)
40+	28 (13%)	19 (8.8%)	1 (0.5%)	0 (0%)	48 (22.2%)
All ages	65 (30.1%)	55 (25.5%)	3 (1.4%)	0 (0%)	123 (56.9%)
mRNA Vaccines					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.2%)	10 (4.6%)	2 (0.9%)	0 (0%)	19 (8.8%)
18-24	12 (5.6%)	29 (13.4%)	2 (0.9%)	0 (0%)	43 (19.9%)
25-29	14 (6.5%)	13 (6%)	2 (0.9%)	0 (0%)	29 (13.4%)
30-39	26 (12%)	16 (7.4%)	1 (0.5%)	0 (0%)	43 (19.9%)
40+	37 (17.1%)	33 (15.3%)	10 (4.6%)	1 (0.5%)	81 (37.5%)
All ages	96 (44.4%)	102 (47.2%)	17 (7.9%)	1 (0.5%)	216 (100%)

Total = 216 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including September 24, 2022.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022. Stratified by sex, age group, vaccine trade name, and dose **(N=216)**

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Moderna Spikevax	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	0 (0-0)	0 (0-0)	**907.4 (219.8-3347.4)**	0 (0-0)	211 (51.1-778.2)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	83 (33.7-181.8)	**270.2 (159.1-435.8)**	85.9 (20.8-316.8)	0 (0-0)	**166.3 (105.7-251.5)**	23.1 (5.6-85.2)	22.1 (5.3-81.4)	0 (0-0)	0 (0-0)	18.8 (5.8-52.4)
25-29	**160.7 (82.7-289.8)**	**156.9 (80.7-282.8)**	132.7 (41.1-369.7)	0 (0-0)	**155 (98.5-234.3)**	47.4 (14.7-132)	22 (5.3-81.3)	0 (0-0)	0 (0-0)	27.3 (9.9-65.6)
30-39	40.7 (16.5-89.2)	45.6 (20.1-93.3)	10.5 (2.5-38.6)	0 (0-0)	32.7 (18-55.9)	34.5 (12.5-83.1)	50.3 (22.2-103.1)	0 (0-0)	0 (0-0)	26.8 (13.8-48.3)
40+	21.5 (10.1-41.8)	17.9 (8.8-33.3)	7.1 (2.9-15.5)	6.9 (1.7-25.4)	13 (8.3-19.7)	10.7 (3.9-25.7)	17.8 (8.8-33.2)	7.9 (3.5-16.1)	0 (0-0)	10.1 (6.2-15.8)
All ages	45.1 (29.9-65.8)	**54.8 (39.1-75)**	13 (6.9-22.8)	6.8 (1.6-25)	**33.7 (26.5-42.4)**	19.3 (10.3-33.9)	23.9 (14.3-38)	6.4 (2.8-13)	0 (0-0)	13.9 (9.6-19.5)

Pfizer-BioNTech Comirnaty	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.5)	0 (0-0)	0 (0-0)	5.4 (1.3-20.1)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	45.4 (21.3-88.3)	55.4 (27.3-103.3)	**18.9 (4.6-69.7)**	0 (0-0)	44.9 (26.9-71.3)	7.9 (1.9-29)	24.6 (8.9-59.2)	0 (0-0)	0 (0-0)	13.2 (5.3-28.9)
18-24	34 (15-69.7)	**63.8 (34-111.8)**	16 (3.9-59)	0 (0-0)	**42.7 (26-66.8)**	13.4 (4.1-37.2)	41.8 (19.6-81.3)	0 (0-0)	0 (0-0)	21.5 (11.1-38.7)
25-29	**24.9 (9.1-60.1)**	**17.5 (5.4-48.8)**	0 (0-0)	0 (0-0)	**17.2 (7.6-35.2)**	8.1 (2-29.9)	17 (5.3-47.3)	0 (0-0)	0 (0-0)	9.7 (3.5-23.4)
30-39	68.5 (42.4-105.9)	18 (7.3-39.5)	0 (0-0)	0 (0-0)	37.3 (24.2-55.3)	12.1 (4.4-29.2)	8.4 (2.6-23.5)	0 (0-0)	0 (0-0)	8.6 (3.8-17.7)
40+	14.4 (8.3-23.6)	12.9 (7.1-22.1)	2.7 (0.7-10)	0 (0-0)	11 (7.4-15.9)	16.6 (10.3-25.6)	10 (5.3-17.5)	0 (0-0)	0 (0-0)	10.3 (7-14.7)
All ages	26.9 (19.9-35.6)	**22.7 (16.2-31.1)**	4.7 (1.7-11.4)	0 (0-0)	**20.7 (16.6-25.6)**	13.5 (9-19.5)	13.8 (9.2-20.2)	0 (0-0)	0 (0-0)	10.8 (8.1-14.2)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.5)	0 (0-0)	0 (0-0)	5.4 (1.3-20.1)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	44.8 (21-87.1)	54.6 (26.9-101.9)	37 (11.4-103.1)	0 (0-0)	47.4 (28.9-74.2)	7.8 (1.9-28.6)	24.2 (8.8-58.3)	0 (0-0)	0 (0-0)	13 (5.3-28.4)
18-24	46.1 (24.6-80.7)	116.3 (77.1-169.7)	26.9 (8.3-74.9)	0 (0-0)	71.6 (51.1-98.1)	15.5 (5.6-37.4)	37.1 (18.3-69.1)	0 (0-0)	0 (0-0)	20.8 (11.4-35.6)
25-29	64.7 (36.5-108.1)	60.5 (33.2-103.4)	28.2 (8.7-78.6)	0 (0-0)	56.3 (37.6-81.5)	18.1 (6.6-43.6)	18.4 (6.7-44.3)	0 (0-0)	0 (0-0)	14.2 (6.7-27.7)
30-39	60.3 (39.2-89.4)	27.1 (14.5-47.5)	5.7 (1.4-21.1)	0 (0-0)	35.5 (24.9-49.2)	17.9 (8.4-34.9)	20.8 (10.3-38.8)	0 (0-0)	0 (0-0)	14.7 (8.6-23.7)
40+	16.2 (10.3-24.5)	14.6 (9.2-22.3)	5.3 (2.3-10.9)	3.1 (0.7-11.3)	11.6 (8.5-15.4)	15.2 (9.8-22.8)	12.4 (7.7-19.1)	4.7 (2.1-9.6)	0 (0-0)	10 (7.4-13.3)
All ages	31.2 (24.5-39.3)	32.1 (25.3-40.3)	9 (5.2-14.8)	3 (0.7-10.9)	24.8 (21-29)	14.7 (10.5-20.3)	16.5 (12-22.4)	3.3 (1.4-6.7)	0 (0-0)	11.6 (9.2-14.4)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including September 24, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from the calculation of rates in this table). Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age group.

Table 3 interpretation:

The rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following sex, dose, and age groups:

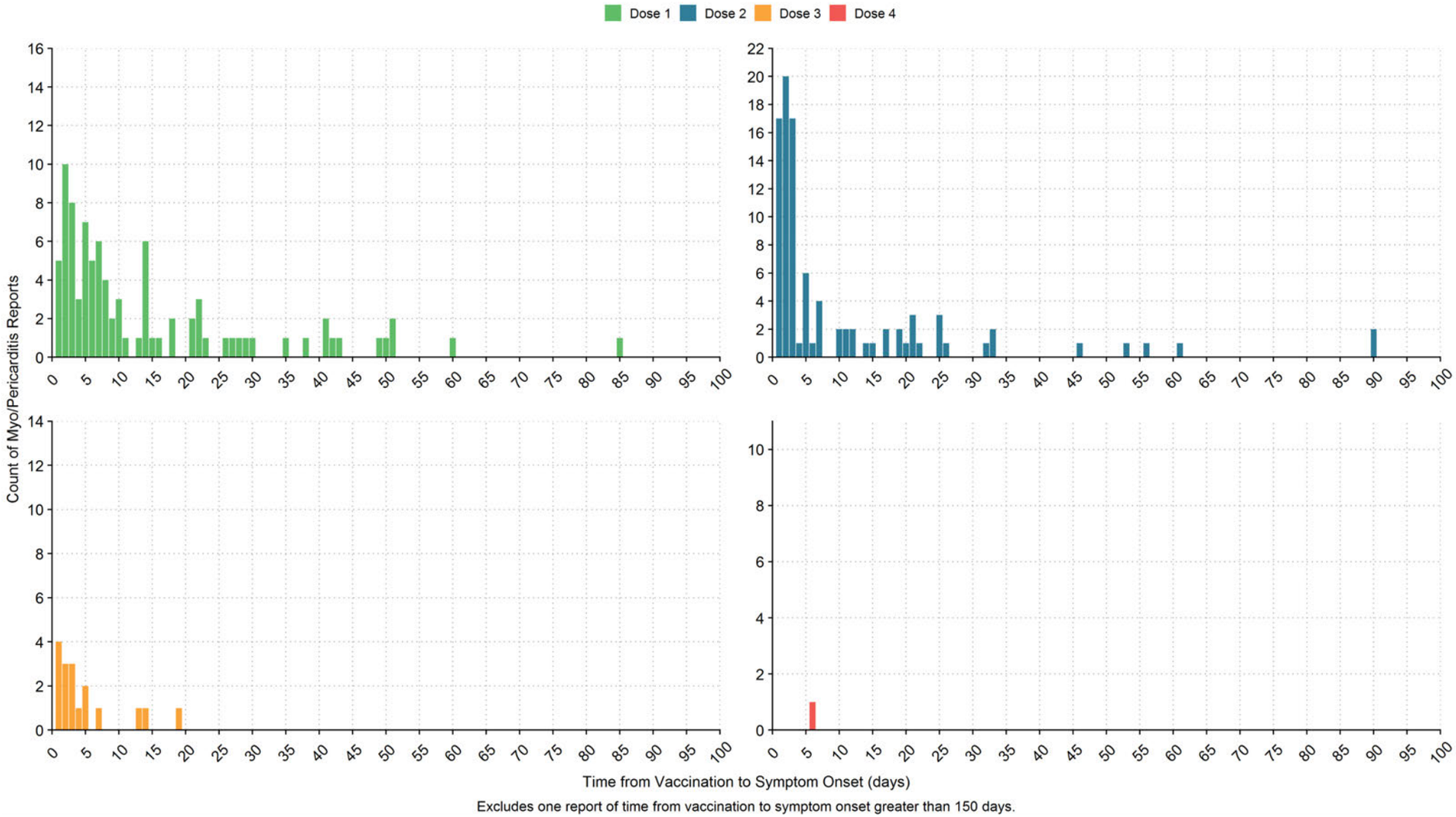
Males:

- 12-17 year olds: Dose 3 - However this is based on a single report in relation to only 1088 doses administered. This rate should be interpreted with caution.
- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 and all doses combined

Females:

- None showed a statistically significant difference between products.

Figure 3: Time from Vaccination to Symptom Onset of Myo/Pericarditis Reports, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=216)**



Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on September 28, 2022. Only AEFIs reported and doses administered up to September 24, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to September 24, 2022

This report summarizes COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including September 24, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Among reports in BC, anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, myocarditis and pericarditis were first recognized in Israel and the USA in young adults and adolescents, and have now also been seen in other countries including Canada and in BC reports.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is further reviewed and investigated, and then reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

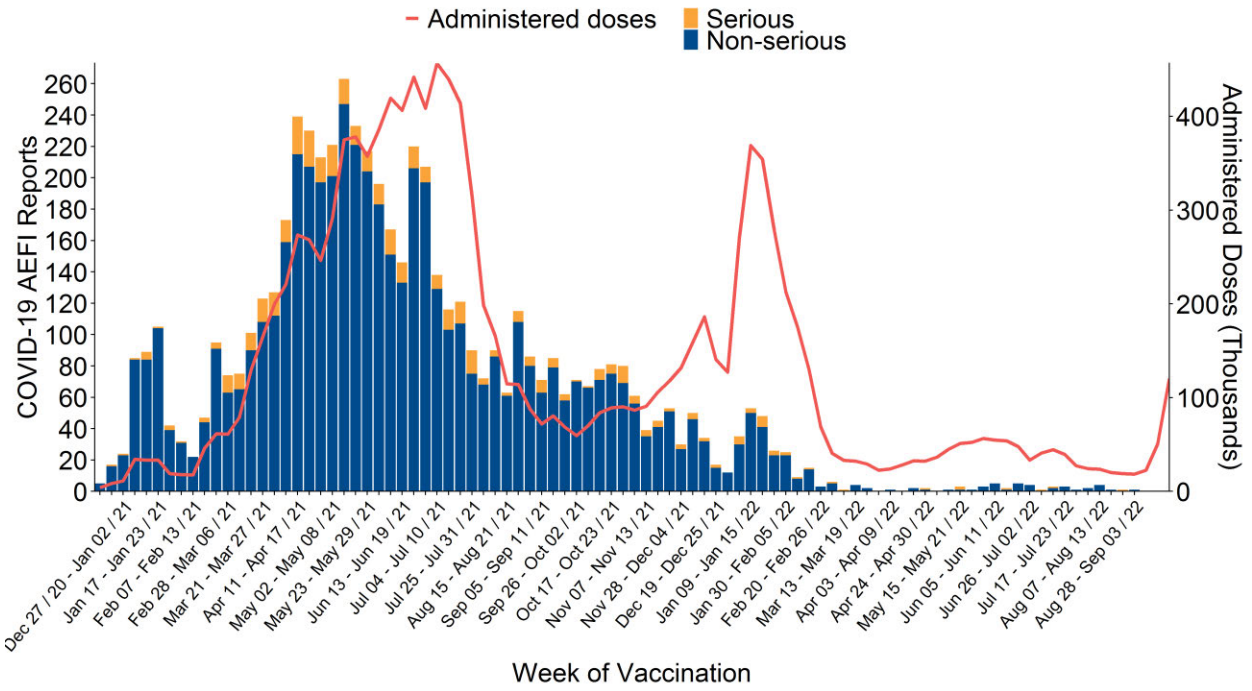
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of September 24, 2022, there have been 12,477,702 COVID-19 vaccine doses administered in BC and 5,888 COVID-19 AEFI reports (47.2 reports per 100,000 doses administered)
- 461 reports (7.8%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness
- Other events have been less frequently reported and are detailed below

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including September 24, 2022, a total of 12,477,702 doses have been administered. During this period, there have been 5,888 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.2 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second, third, and fourth doses of COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**

		COVID-19 Vaccine*				
	All COVID-19 Vaccines	**Moderna Spikevax**	**Moderna Spikevax Pediatric**	**Moderna Spikevax Bivalent**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5888**	**2104**	**6**	**0**	**3362**	**41**
Non-serious reports	5427	1952	5	0	3101	38
Serious reports	461	152	1	0	261	3
Proportion serious	7.8%	7.2%	16.7%	0.0%	7.8%	7.3%
Dose 1 reports	4076	1306	6	0	2394	31
Dose 2 reports	1440	552	0	0	845	9
Dose 3 reports	333	226	0	0	106	0
Dose 4 reports	25	16	0	0	9	0
Total doses administered	**12,477,702**	**3,924,397**	**21,263**	**143,476**	**7,539,697**	**398,189**
Dose 1 administered	4,537,878	932,612	21,189	1	3,056,949	209,887
Dose 2 administered	4,363,176	1,188,090	43	9	2,881,923	162,179
Dose 3 administered	2,848,835	1,476,493	23	4,178	1,340,307	26,119
Dose 4 administered	726,548	327,069	8	138,309	260,369	4
Total reporting rate	**47.2**	**53.6**	**28.2**	**0.0**	**44.6**	**10.3**
Serious rate	3.7	3.9	4.7	0.0	3.5	0.8
Dose 1 rate	89.8	140.0	28.3	0.0	78.3	14.8
Dose 2 rate	33.0	46.5	0.0	0.0	29.3	5.5
Dose 3 rate	11.7	15.3	0.0	0.0	7.9	0.0
Dose 4 rate	3.4	4.9	0.0	0.0	3.5	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Table 1 (continued): Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**

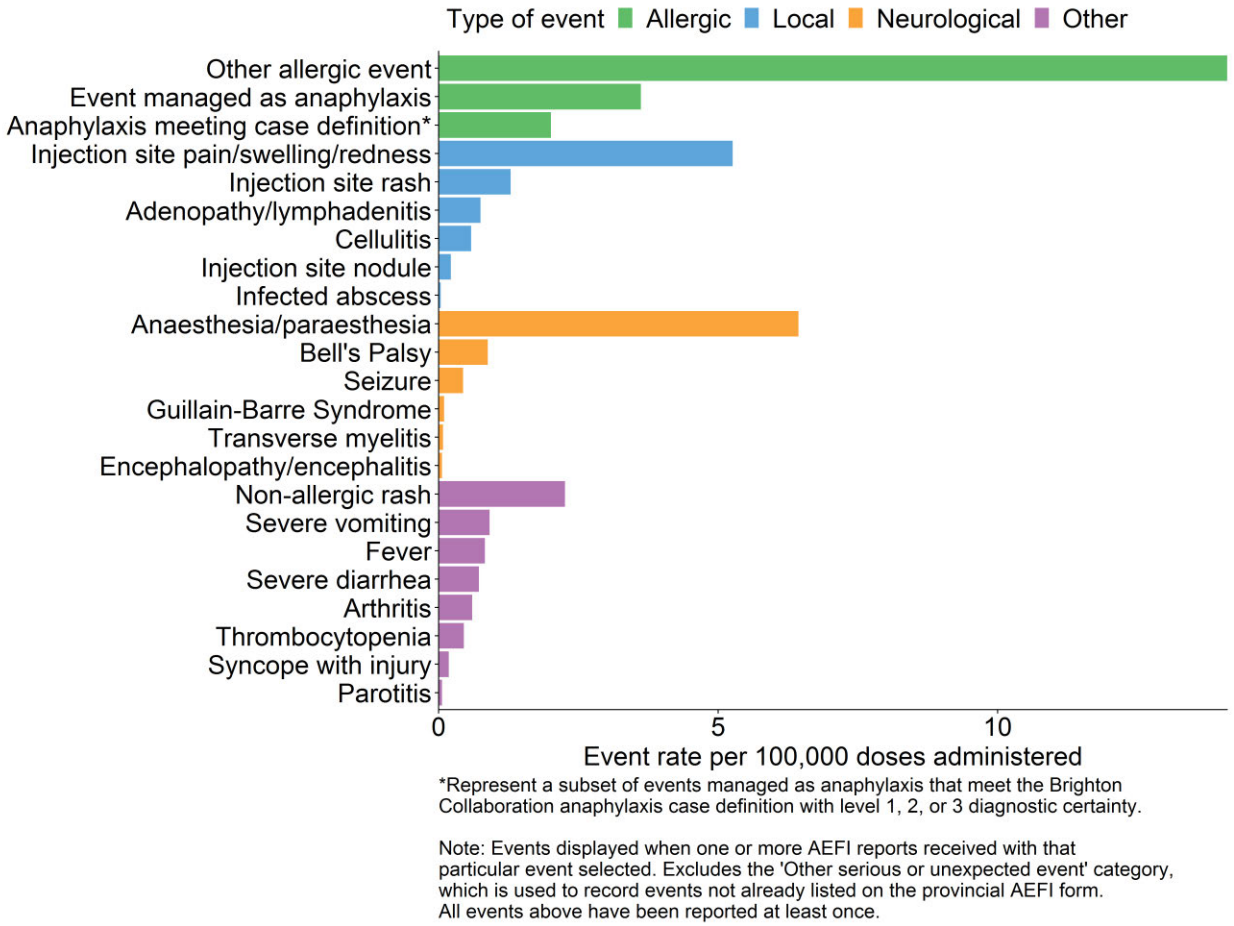
	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**Verity COVISHIELD**	**AstraZeneca Vaxzevria**	**J&J Janssen**	**Novavax NUVAXOVID**
Total reports	**5888**	**71**	**287**	**15**	**2**
Non-serious reports	5427	65	251	13	2
Serious reports	461	6	36	2	0
Proportion serious	7.8%	8.5%	12.5%	13.3%	0%
Dose 1 reports	4076	69	256	12	2
Dose 2 reports	1440	2	30	2	0
Dose 3 reports	333	0	0	1	0
Dose 4 reports	25	0	0	0	0
Total doses administered	**12,477,702**	**89,032**	**343,477**	**12,730**	**5,441**
Dose 1 administered	4,537,878	70,443	232,693	12,000	2,104
Dose 2 administered	4,363,176	18,443	109,975	534	1,980
Dose 3 administered	2,848,835	142	793	190	590
Dose 4 administered	726,548	4	16	6	763
Total reporting rate	**47.2**	**79.7**	**83.6**	**117.8**	**36.8**
Serious rate	3.7	6.7	10.5	15.7	0.0
Dose 1 rate	89.8	98.0	110.0	100.0	95.1
Dose 2 rate	33.0	10.8	27.3	374.5	0.0
Dose 3 rate	11.7	0.0	0.0	526.3	0.0
Dose 4 rate	3.4	0.0	0.0	0.0	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,888 AEFI reports received up to September 24, 2022 contained a total of 7,508 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=7,508)**



Event Descriptions

Four hundred fifty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 251 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Many events managed as anaphylaxis have features more compatible with anxiety or vasovagal syncope/pre-syncopal (fainting) events.

Seventy-two reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred sixty-one reports (7.8%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 432 individuals were admitted to hospital, including 2.9% of cases reported as anaphylaxis.

One hundred and ninety-eight reports contained a diagnosed neurological event. One hundred and ten individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional four individuals were reported as having transverse myelitis, however, one was unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and another was referred to a specialist for further investigation. Fifty-five individuals were reported with seizures (20% hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, including one with encephalopathy. Six additional individuals developed encephalitis or encephalopathy: one encephalitis was presumed to be viral in nature; one encephalopathy was attributed to a workplace toxin exposure; one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; two individuals with several comorbidities and encephalopathy made a spontaneous and full recovery within days, without a specific cause identified; one encephalitis was attributed to a new onset autoimmune condition diagnosed after receipt of vaccine. One individual was hospitalized for aseptic meningitis. There were twelve reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Five of these reports followed AstraZeneca vaccine, five followed Pfizer-BioNTech Comirnaty, and two followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but in two cases followed an illness compatible with recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19]

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Readers will note that some of the reported deaths described below appear to have a clear cause of death unrelated to the vaccine. Death may also be recorded as the outcome of a specific reportable event. Nineteen serious AEFI reports were received for individuals (median age: 76.5 years who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions; one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

- One death occurred in an elderly individual who suffered from multiple serious comorbidities. Investigation revealed the death was due to natural causes unrelated to the vaccine, but occurring in temporal association with vaccine receipt.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.
- One death occurred in an individual due to septic shock unrelated to the vaccine.
- Two deaths occurred in elderly individuals due to underlying cardiac compromise unrelated to the vaccine.

'Other serious or unexpected' events:
Some events may be reported as an "other serious or unexpected" event when these do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 188 were for various thrombotic/ thromboembolic conditions. These included 39 strokes (89.7% hospitalized) two cerebral venous sinus thromboses, 28 myocardial infarctions (92.9% hospitalized), 51 pulmonary emboli (58.9% hospitalized), 59 deep vein thromboses, and nine superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[20] Health Canada issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[21]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults aged 30-49 and two were aged 60-69 years. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia; this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Four serious AEFI reports in the 5-11 year age group have been reported. The first was for a new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[22] The second was for hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital. The third was for hospitalization following myo/pericarditis; this child was discharged with full resolution of symptoms. The fourth was for hospitalization following febrile seizures with onset several days later than expected for a plausible causal association to vaccine; this child was discharged home after full resolution and further investigations are in progress to identify an infectious cause.

There have been 223 reports of myocarditis/pericarditis. Sixty-six individuals were diagnosed with myocarditis, 100 with pericarditis, and 57 with myopericarditis. Ages ranged from 10 to 95 with a median of 35 years, and 146 (65%) were male. Ninety-three had received Moderna Spikevax, 122 received Pfizer-BioNTech Comirnaty, one received Pfizer-BioNTech Comirnaty Pediatric, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. One hundred and three of these events occurred after a second dose (47 Moderna Spikevax, 54 Pfizer-BioNTech Comirnaty, 1 Pfizer-BioNTech Comirnaty Pediatric, and 1 AstraZeneca Vaxzevria/Verity COVISHIELD). Seventeen occurred after a third dose (14 Moderna Spikevax and 3 Pfizer-BioNTech Comirnaty), and one occurred after a fourth dose of Moderna. Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Fifty-eight (out of 66) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-four (out of 100) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 57) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14,24]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=216)**

Vaccine/Age Groups	*Dose 1*	*Dose 2*	*Done 3*	*Dose 4*	*All Doses*
Moderna Spikevax					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12-17	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.5%)
18-24	5 (2.3%)	14 (6.5%)	1 (0.5%)	0 (0%)	20 (9.3%)
25-29	10 (4.6%)	9 (4.2%)	2 (0.9%)	0 (0%)	21 (9.7%)
30-39	7 (3.2%)	10 (4.6%)	1 (0.5%)	0 (0%)	18 (8.3%)
40+	9 (4.2%)	14 (6.5%)	9 (4.2%)	1 (0.5%)	33 (15.3%)
All ages	31 (14.4%)	47 (21.8%)	14 (6.5%)	1 (0.5%)	93 (43.1%)
Pfizer-BioNTech Comirnaty					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.2%)	10 (4.6%)	1 (0.5%)	0 (0%)	18 (8.3%)
18-24	7 (3.2%)	15 (6.9%)	1 (0.5%)	0 (0%)	23 (10.6%)
25-29	4 (1.9%)	4 (1.9%)	0 (0%)	0 (0%)	8 (3.7%)
30-39	19 (8.8%)	6 (2.8%)	0 (0%)	0 (0%)	25 (11.6%)
40+	28 (13%)	19 (8.8%)	1 (0.5%)	0 (0%)	48 (22.2%)
All ages	65 (30.1%)	55 (25.5%)	3 (1.4%)	0 (0%)	123 (56.9%)
mRNA Vaccines					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.2%)	10 (4.6%)	2 (0.9%)	0 (0%)	19 (8.8%)
18-24	12 (5.6%)	29 (13.4%)	2 (0.9%)	0 (0%)	43 (19.9%)
25-29	14 (6.5%)	13 (6%)	2 (0.9%)	0 (0%)	29 (13.4%)
30-39	26 (12%)	16 (7.4%)	1 (0.5%)	0 (0%)	43 (19.9%)
40+	37 (17.1%)	33 (15.3%)	10 (4.6%)	1 (0.5%)	81 (37.5%)
All ages	96 (44.4%)	102 (47.2%)	17 (7.9%)	1 (0.5%)	216 (100%)

Total = 216 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including September 24, 2022.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022. Stratified by sex, age group, vaccine trade name, and dose **(N=216)**

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Moderna Spikevax	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	0 (0-0)	0 (0-0)	**907.4 (219.8-3347.4)**	0 (0-0)	211 (51.1-778.2)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	83 (33.7-181.8)	**270.2 (159.1-435.8)**	85.9 (20.8-316.8)	0 (0-0)	**166.3 (105.7-251.5)**	23.1 (5.6-85.2)	22.1 (5.3-81.4)	0 (0-0)	0 (0-0)	18.8 (5.8-52.4)
25-29	**160.7 (82.7-289.8)**	**156.9 (80.7-282.8)**	132.7 (41.1-369.7)	0 (0-0)	**155 (98.5-234.3)**	47.4 (14.7-132)	22 (5.3-81.3)	0 (0-0)	0 (0-0)	27.3 (9.9-65.6)
30-39	40.7 (16.5-89.2)	45.6 (20.1-93.3)	10.5 (2.5-38.6)	0 (0-0)	32.7 (18-55.9)	34.5 (12.5-83.1)	50.3 (22.2-103.1)	0 (0-0)	0 (0-0)	26.8 (13.8-48.3)
40+	21.5 (10.1-41.8)	17.9 (8.8-33.3)	7.1 (2.9-15.5)	6.9 (1.7-25.4)	13 (8.3-19.7)	10.7 (3.9-25.7)	17.8 (8.8-33.2)	7.9 (3.5-16.1)	0 (0-0)	10.1 (6.2-15.8)
All ages	45.1 (29.9-65.8)	**54.8 (39.1-75)**	13 (6.9-22.8)	6.8 (1.6-25)	**33.7 (26.5-42.4)**	19.3 (10.3-33.9)	23.9 (14.3-38)	6.4 (2.8-13)	0 (0-0)	13.9 (9.6-19.5)

Pfizer-BioNTech Comirnaty	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.5)	0 (0-0)	0 (0-0)	5.4 (1.3-20.1)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	45.4 (21.3-88.3)	55.4 (27.3-103.3)	**18.9 (4.6-69.7)**	0 (0-0)	44.9 (26.9-71.3)	7.9 (1.9-29)	24.6 (8.9-59.2)	0 (0-0)	0 (0-0)	13.2 (5.3-28.9)
18-24	34 (15-69.7)	**63.8 (34-111.8)**	16 (3.9-59)	0 (0-0)	**42.7 (26-66.8)**	13.4 (4.1-37.2)	41.8 (19.6-81.3)	0 (0-0)	0 (0-0)	21.5 (11.1-38.7)
25-29	**24.9 (9.1-60.1)**	**17.5 (5.4-48.8)**	0 (0-0)	0 (0-0)	**17.2 (7.6-35.2)**	8.1 (2-29.9)	17 (5.3-47.3)	0 (0-0)	0 (0-0)	9.7 (3.5-23.4)
30-39	68.5 (42.4-105.9)	18 (7.3-39.5)	0 (0-0)	0 (0-0)	37.3 (24.2-55.3)	12.1 (4.4-29.2)	8.4 (2.6-23.5)	0 (0-0)	0 (0-0)	8.6 (3.8-17.7)
40+	14.4 (8.3-23.6)	12.9 (7.1-22.1)	2.7 (0.7-10)	0 (0-0)	11 (7.4-15.9)	16.6 (10.3-25.6)	10 (5.3-17.5)	0 (0-0)	0 (0-0)	10.3 (7-14.7)
All ages	26.9 (19.9-35.6)	**22.7 (16.2-31.1)**	4.7 (1.7-11.4)	0 (0-0)	**20.7 (16.6-25.6)**	13.5 (9-19.5)	13.8 (9.2-20.2)	0 (0-0)	0 (0-0)	10.8 (8.1-14.2)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.5)	0 (0-0)	0 (0-0)	5.4 (1.3-20.1)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	44.8 (21-87.1)	54.6 (26.9-101.9)	37 (11.4-103.1)	0 (0-0)	47.4 (28.9-74.2)	7.8 (1.9-28.6)	24.2 (8.8-58.3)	0 (0-0)	0 (0-0)	13 (5.3-28.4)
18-24	46.1 (24.6-80.7)	116.3 (77.1-169.7)	26.9 (8.3-74.9)	0 (0-0)	71.6 (51.1-98.1)	15.5 (5.6-37.4)	37.1 (18.3-69.1)	0 (0-0)	0 (0-0)	20.8 (11.4-35.6)
25-29	64.7 (36.5-108.1)	60.5 (33.2-103.4)	28.2 (8.7-78.6)	0 (0-0)	56.3 (37.6-81.5)	18.1 (6.6-43.6)	18.4 (6.7-44.3)	0 (0-0)	0 (0-0)	14.2 (6.7-27.7)
30-39	60.3 (39.2-89.4)	27.1 (14.5-47.5)	5.7 (1.4-21.1)	0 (0-0)	35.5 (24.9-49.2)	17.9 (8.4-34.9)	20.8 (10.3-38.8)	0 (0-0)	0 (0-0)	14.7 (8.6-23.7)
40+	16.2 (10.3-24.5)	14.6 (9.2-22.3)	5.3 (2.3-10.9)	3.1 (0.7-11.3)	11.6 (8.5-15.4)	15.2 (9.8-22.8)	12.4 (7.7-19.1)	4.7 (2.1-9.6)	0 (0-0)	10 (7.4-13.3)
All ages	31.2 (24.5-39.3)	32.1 (25.3-40.3)	9 (5.2-14.8)	3 (0.7-10.9)	24.8 (21-29)	14.7 (10.5-20.3)	16.5 (12-22.4)	3.3 (1.4-6.7)	0 (0-0)	11.6 (9.2-14.4)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including September 24, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from the calculation of rates in this table). Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age group.

Table 3 interpretation:

The rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following sex, dose, and age groups:

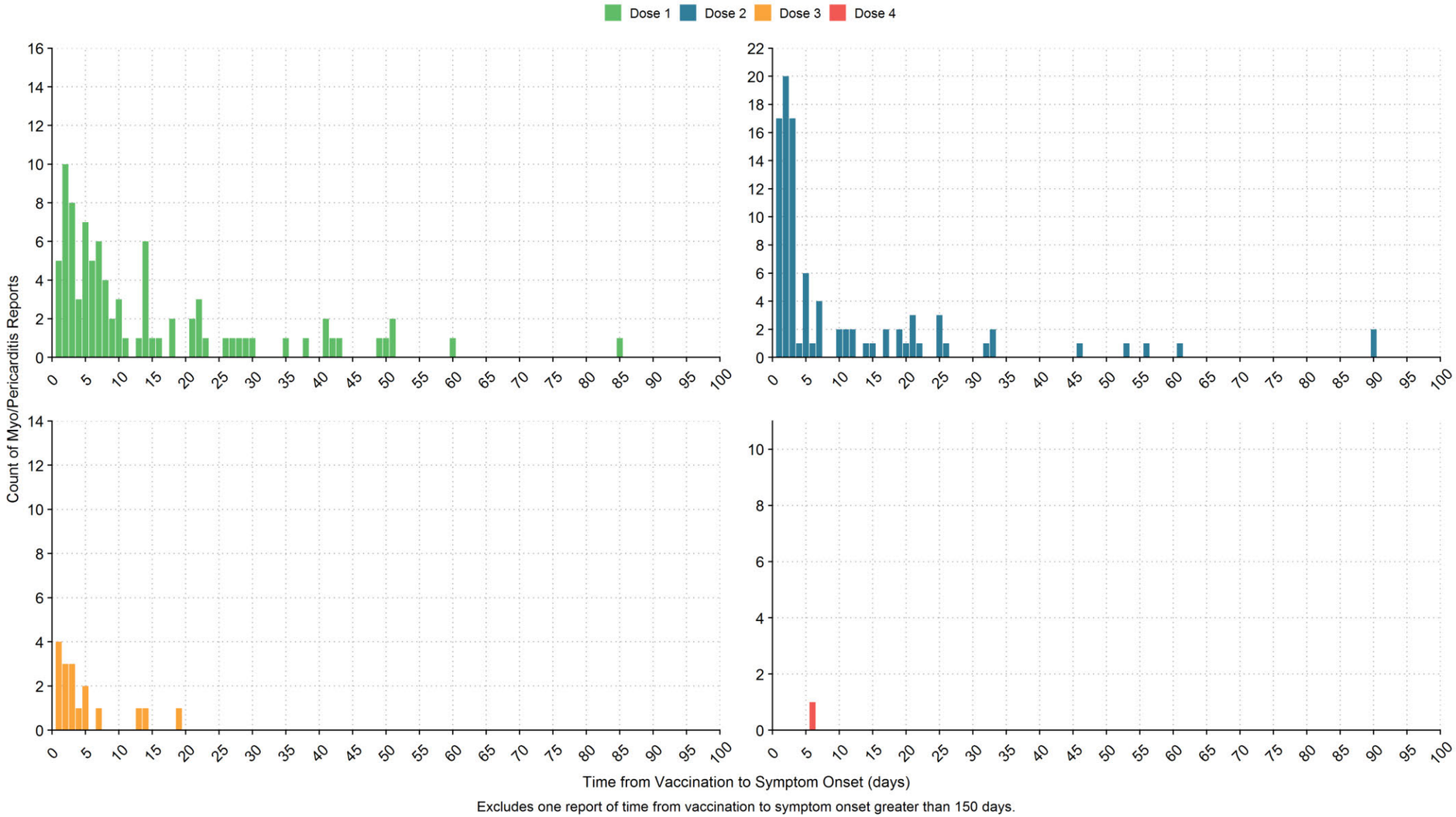
Males:

- 12-17 year olds: Dose 3 - However this is based on a single report in relation to only 1088 doses administered. This rate should be interpreted with caution.
- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 and all doses combined

Females:

- None showed a statistically significant difference between products.

Figure 3: Time from Vaccination to Symptom Onset of Myo/Pericarditis Reports, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=216)**



Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on September 28, 2022. Only AEFIs reported and doses administered up to September 24, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From: Dalati, Hadi [BCCDC]
To: Amos, Heather [BCCDC]; Minhas, Sableen
Cc: Naus, Monika [BCCDC]
Subject: FW: Monthly COVID-19 AEFI Report
Date: Wednesday, October 05, 2022 11:14:50 AM
Attachments: COVID19_AEFI_Monthly_Report_2022-09-29.docx
COVID19_AEFI_Monthly_Report_2022-09-29.pdf

Hello Sableen and Heather,
Monika informed me that the latest monthly COVID AEFi report (due September 29) is not up yet on our website.
Was there an issue with updating the page?
Apologies if I've missed anything and please let me know if you need more input from me.
Thank you,
Hadi

From: Dalati, Hadi [BCCDC]
Sent: Thursday, September 29, 2022 2:43 PM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Monthly COVID-19 AEFI Report
Hello all,
Please find attached the latest monthly COVID-19 AEFI report for posting.
As always, thank you for all your hard work.
Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to September 24, 2022

This report summarizes COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including September 24, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Among reports in BC, anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, myocarditis and pericarditis were first recognized in Israel and the USA in young adults and adolescents, and have now also been seen in other countries including Canada and in BC reports.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is further reviewed and investigated, and then reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

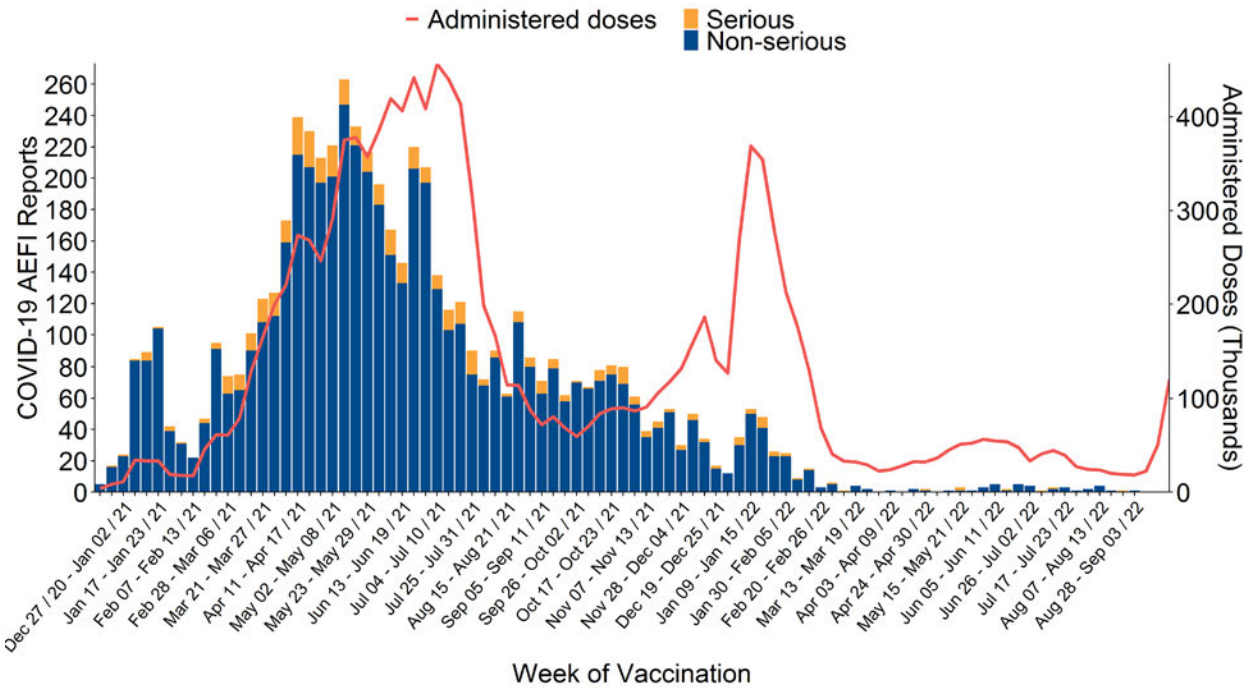
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of September 24, 2022, there have been 12,477,702 COVID-19 vaccine doses administered in BC and 5,888 COVID-19 AEFI reports (47.2 reports per 100,000 doses administered)
- 461 reports (7.8%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness
- Other events have been less frequently reported and are detailed below

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including September 24, 2022, a total of 12,477,702 doses have been administered. During this period, there have been 5,888 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.2 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second, third, and fourth doses of COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**

		COVID-19 Vaccine*				
	All COVID-19 Vaccines	**Moderna Spikevax**	**Moderna Spikevax Pediatric**	**Moderna Spikevax Bivalent**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5888**	**2104**	**6**	**0**	**3362**	**41**
Non-serious reports	5427	1952	5	0	3101	38
Serious reports	461	152	1	0	261	3
Proportion serious	7.8%	7.2%	16.7%	0.0%	7.8%	7.3%
Dose 1 reports	4076	1306	6	0	2394	31
Dose 2 reports	1440	552	0	0	845	9
Dose 3 reports	333	226	0	0	106	0
Dose 4 reports	25	16	0	0	9	0
Total doses administered	**12,477,702**	**3,924,397**	**21,263**	**143,476**	**7,539,697**	**398,189**
Dose 1 administered	4,537,878	932,612	21,189	1	3,056,949	209,887
Dose 2 administered	4,363,176	1,188,090	43	9	2,881,923	162,179
Dose 3 administered	2,848,835	1,476,493	23	4,178	1,340,307	26,119
Dose 4 administered	726,548	327,069	8	138,309	260,369	4
Total reporting rate	**47.2**	**53.6**	**28.2**	**0.0**	**44.6**	**10.3**
Serious rate	3.7	3.9	4.7	0.0	3.5	0.8
Dose 1 rate	89.8	140.0	28.3	0.0	78.3	14.8
Dose 2 rate	33.0	46.5	0.0	0.0	29.3	5.5
Dose 3 rate	11.7	15.3	0.0	0.0	7.9	0.0
Dose 4 rate	3.4	4.9	0.0	0.0	3.5	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Table 1 (continued): Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**

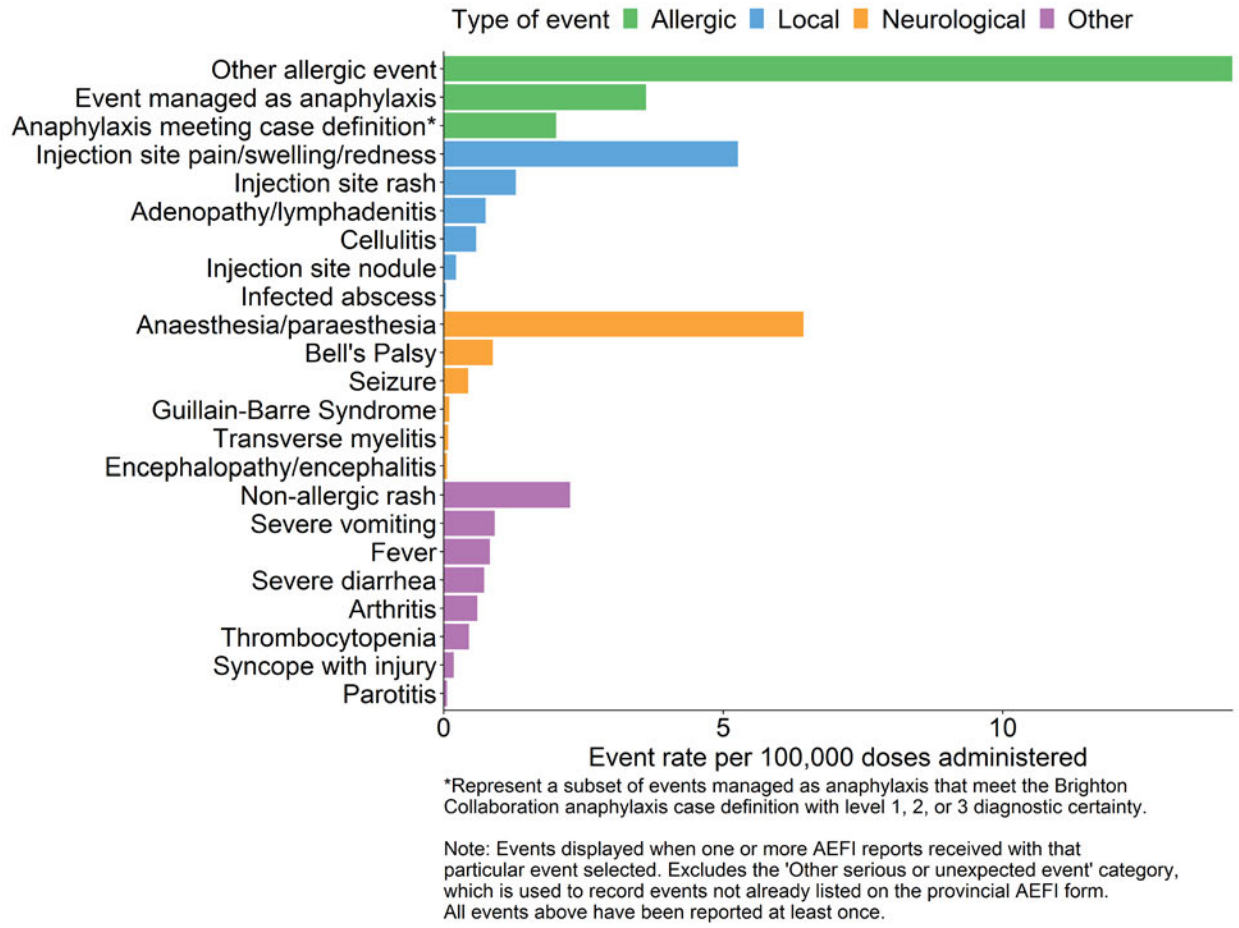
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**Verity COVISHIELD**	**AstraZeneca Vaxzevria**	**J&J Janssen**	**Novavax NUVAXOVID**
Total reports	**5888**	**71**	**287**	**15**	**2**
Non-serious reports	5427	65	251	13	2
Serious reports	461	6	36	2	0
Proportion serious	7.8%	8.5%	12.5%	13.3%	0%
Dose 1 reports	4076	69	256	12	2
Dose 2 reports	1440	2	30	2	0
Dose 3 reports	333	0	0	1	0
Dose 4 reports	25	0	0	0	0
Total doses administered	**12,477,702**	**89,032**	**343,477**	**12,730**	**5,441**
Dose 1 administered	4,537,878	70,443	232,693	12,000	2,104
Dose 2 administered	4,363,176	18,443	109,975	534	1,980
Dose 3 administered	2,848,835	142	793	190	590
Dose 4 administered	726,548	4	16	6	763
Total reporting rate	**47.2**	**79.7**	**83.6**	**117.8**	**36.8**
Serious rate	3.7	6.7	10.5	15.7	0.0
Dose 1 rate	89.8	98.0	110.0	100.0	95.1
Dose 2 rate	33.0	10.8	27.3	374.5	0.0
Dose 3 rate	11.7	0.0	0.0	526.3	0.0
Dose 4 rate	3.4	0.0	0.0	0.0	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,888 AEFI reports received up to September 24, 2022 contained a total of 7,508 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=7,508)**



Event Descriptions

Four hundred fifty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 251 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Many events managed as anaphylaxis have features more compatible with anxiety or vasovagal syncope/pre-syncopal (fainting) events.

Seventy-two reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred sixty-one reports (7.8%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 432 individuals were admitted to hospital, including 2.9% of cases reported as anaphylaxis.

One hundred and ninety-eight reports contained a diagnosed neurological event. One hundred and ten individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional four individuals were reported as having transverse myelitis, however, one was unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and another was referred to a specialist for further investigation. Fifty-five individuals were reported with seizures (20% hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, including one with encephalopathy. Six additional individuals developed encephalitis or encephalopathy: one encephalitis was presumed to be viral in nature; one encephalopathy was attributed to a workplace toxin exposure; one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; two individuals with several comorbidities and encephalopathy made a spontaneous and full recovery within days, without a specific cause identified; one encephalitis was attributed to a new onset autoimmune condition diagnosed after receipt of vaccine. One individual was hospitalized for aseptic meningitis. There were twelve reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Five of these reports followed AstraZeneca vaccine, five followed Pfizer-BioNTech Comirnaty, and two followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but in two cases followed an illness compatible with recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19]

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Readers will note that some of the reported deaths described below appear to have a clear cause of death unrelated to the vaccine. Death may also be recorded as the outcome of a specific reportable event. Nineteen serious AEFI reports were received for individuals (median age: 76.5 years who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions; one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

- One death occurred in an elderly individual who suffered from multiple serious comorbidities. Investigation revealed the death was due to natural causes unrelated to the vaccine, but occurring in temporal association with vaccine receipt.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.
- One death occurred in an individual due to septic shock unrelated to the vaccine.
- Two deaths occurred in elderly individuals due to underlying cardiac compromise unrelated to the vaccine.

'Other serious or unexpected' events:
Some events may be reported as an "other serious or unexpected" event when these do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 188 were for various thrombotic/ thromboembolic conditions. These included 39 strokes (89.7% hospitalized) two cerebral venous sinus thromboses, 28 myocardial infarctions (92.9% hospitalized), 51 pulmonary emboli (58.9% hospitalized), 59 deep vein thromboses, and nine superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[20] Health Canada issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[21]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults aged 30-49 and two were aged 60-69 years. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia; this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Four serious AEFI reports in the 5-11 year age group have been reported. The first was for a new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[22] The second was for hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital. The third was for hospitalization following myo/pericarditis; this child was discharged with full resolution of symptoms. The fourth was for hospitalization following febrile seizures with onset several days later than expected for a plausible causal association to vaccine; this child was discharged home after full resolution and further investigations are in progress to identify an infectious cause.

There have been 223 reports of myocarditis/pericarditis. Sixty-six individuals were diagnosed with myocarditis, 100 with pericarditis, and 57 with myopericarditis. Ages ranged from 10 to 95 with a median of 35 years, and 146 (65%) were male. Ninety-three had received Moderna Spikevax, 122 received Pfizer-BioNTech Comirnaty, one received Pfizer-BioNTech Comirnaty Pediatric, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. One hundred and three of these events occurred after a second dose (47 Moderna Spikevax, 54 Pfizer-BioNTech Comirnaty, 1 Pfizer-BioNTech Comirnaty Pediatric, and 1 AstraZeneca Vaxzevria/Verity COVISHIELD). Seventeen occurred after a third dose (14 Moderna Spikevax and 3 Pfizer-BioNTech Comirnaty), and one occurred after a fourth dose of Moderna. Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Fifty-eight (out of 66) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-four (out of 100) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 57) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14,24]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=216)**

Vaccine/Age Groups	*Dose 1*	*Dose 2*	*Done 3*	*Dose 4*	*All Doses*
Moderna Spikevax					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12-17	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.5%)
18-24	5 (2.3%)	14 (6.5%)	1 (0.5%)	0 (0%)	20 (9.3%)
25-29	10 (4.6%)	9 (4.2%)	2 (0.9%)	0 (0%)	21 (9.7%)
30-39	7 (3.2%)	10 (4.6%)	1 (0.5%)	0 (0%)	18 (8.3%)
40+	9 (4.2%)	14 (6.5%)	9 (4.2%)	1 (0.5%)	33 (15.3%)
All ages	31 (14.4%)	47 (21.8%)	14 (6.5%)	1 (0.5%)	93 (43.1%)
Pfizer-BioNTech Comirnaty					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.2%)	10 (4.6%)	1 (0.5%)	0 (0%)	18 (8.3%)
18-24	7 (3.2%)	15 (6.9%)	1 (0.5%)	0 (0%)	23 (10.6%)
25-29	4 (1.9%)	4 (1.9%)	0 (0%)	0 (0%)	8 (3.7%)
30-39	19 (8.8%)	6 (2.8%)	0 (0%)	0 (0%)	25 (11.6%)
40+	28 (13%)	19 (8.8%)	1 (0.5%)	0 (0%)	48 (22.2%)
All ages	65 (30.1%)	55 (25.5%)	3 (1.4%)	0 (0%)	123 (56.9%)
mRNA Vaccines					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.2%)	10 (4.6%)	2 (0.9%)	0 (0%)	19 (8.8%)
18-24	12 (5.6%)	29 (13.4%)	2 (0.9%)	0 (0%)	43 (19.9%)
25-29	14 (6.5%)	13 (6%)	2 (0.9%)	0 (0%)	29 (13.4%)
30-39	26 (12%)	16 (7.4%)	1 (0.5%)	0 (0%)	43 (19.9%)
40+	37 (17.1%)	33 (15.3%)	10 (4.6%)	1 (0.5%)	81 (37.5%)
All ages	96 (44.4%)	102 (47.2%)	17 (7.9%)	1 (0.5%)	216 (100%)

Total = 216 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including September 24, 2022.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022. Stratified by sex, age group, vaccine trade name, and dose **(N=216)**

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Moderna Spikevax	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	0 (0-0)	0 (0-0)	**907.4 (219.8-3347.4)**	0 (0-0)	211 (51.1-778.2)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	83 (33.7-181.8)	**270.2 (159.1-435.8)**	85.9 (20.8-316.8)	0 (0-0)	**166.3 (105.7-251.5)**	23.1 (5.6-85.2)	22.1 (5.3-81.4)	0 (0-0)	0 (0-0)	18.8 (5.8-52.4)
25-29	**160.7 (82.7-289.8)**	**156.9 (80.7-282.8)**	132.7 (41.1-369.7)	0 (0-0)	**155 (98.5-234.3)**	47.4 (14.7-132)	22 (5.3-81.3)	0 (0-0)	0 (0-0)	27.3 (9.9-65.6)
30-39	40.7 (16.5-89.2)	45.6 (20.1-93.3)	10.5 (2.5-38.6)	0 (0-0)	32.7 (18-55.9)	34.5 (12.5-83.1)	50.3 (22.2-103.1)	0 (0-0)	0 (0-0)	26.8 (13.8-48.3)
40+	21.5 (10.1-41.8)	17.9 (8.8-33.3)	7.1 (2.9-15.5)	6.9 (1.7-25.4)	13 (8.3-19.7)	10.7 (3.9-25.7)	17.8 (8.8-33.2)	7.9 (3.5-16.1)	0 (0-0)	10.1 (6.2-15.8)
All ages	45.1 (29.9-65.8)	**54.8 (39.1-75)**	13 (6.9-22.8)	6.8 (1.6-25)	**33.7 (26.5-42.4)**	19.3 (10.3-33.9)	23.9 (14.3-38)	6.4 (2.8-13)	0 (0-0)	13.9 (9.6-19.5)

Pfizer-BioNTech Comirnaty	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.5)	0 (0-0)	0 (0-0)	5.4 (1.3-20.1)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	45.4 (21.3-88.3)	55.4 (27.3-103.3)	**18.9 (4.6-69.7)**	0 (0-0)	44.9 (26.9-71.3)	7.9 (1.9-29)	24.6 (8.9-59.2)	0 (0-0)	0 (0-0)	13.2 (5.3-28.9)
18-24	34 (15-69.7)	**63.8 (34-111.8)**	16 (3.9-59)	0 (0-0)	**42.7 (26-66.8)**	13.4 (4.1-37.2)	41.8 (19.6-81.3)	0 (0-0)	0 (0-0)	21.5 (11.1-38.7)
25-29	**24.9 (9.1-60.1)**	**17.5 (5.4-48.8)**	0 (0-0)	0 (0-0)	**17.2 (7.6-35.2)**	8.1 (2-29.9)	17 (5.3-47.3)	0 (0-0)	0 (0-0)	9.7 (3.5-23.4)
30-39	68.5 (42.4-105.9)	18 (7.3-39.5)	0 (0-0)	0 (0-0)	37.3 (24.2-55.3)	12.1 (4.4-29.2)	8.4 (2.6-23.5)	0 (0-0)	0 (0-0)	8.6 (3.8-17.7)
40+	14.4 (8.3-23.6)	12.9 (7.1-22.1)	2.7 (0.7-10)	0 (0-0)	11 (7.4-15.9)	16.6 (10.3-25.6)	10 (5.3-17.5)	0 (0-0)	0 (0-0)	10.3 (7-14.7)
All ages	26.9 (19.9-35.6)	**22.7 (16.2-31.1)**	4.7 (1.7-11.4)	0 (0-0)	**20.7 (16.6-25.6)**	13.5 (9-19.5)	13.8 (9.2-20.2)	0 (0-0)	0 (0-0)	10.8 (8.1-14.2)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.5)	0 (0-0)	0 (0-0)	5.4 (1.3-20.1)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	44.8 (21-87.1)	54.6 (26.9-101.9)	37 (11.4-103.1)	0 (0-0)	47.4 (28.9-74.2)	7.8 (1.9-28.6)	24.2 (8.8-58.3)	0 (0-0)	0 (0-0)	13 (5.3-28.4)
18-24	46.1 (24.6-80.7)	116.3 (77.1-169.7)	26.9 (8.3-74.9)	0 (0-0)	71.6 (51.1-98.1)	15.5 (5.6-37.4)	37.1 (18.3-69.1)	0 (0-0)	0 (0-0)	20.8 (11.4-35.6)
25-29	64.7 (36.5-108.1)	60.5 (33.2-103.4)	28.2 (8.7-78.6)	0 (0-0)	56.3 (37.6-81.5)	18.1 (6.6-43.6)	18.4 (6.7-44.3)	0 (0-0)	0 (0-0)	14.2 (6.7-27.7)
30-39	60.3 (39.2-89.4)	27.1 (14.5-47.5)	5.7 (1.4-21.1)	0 (0-0)	35.5 (24.9-49.2)	17.9 (8.4-34.9)	20.8 (10.3-38.8)	0 (0-0)	0 (0-0)	14.7 (8.6-23.7)
40+	16.2 (10.3-24.5)	14.6 (9.2-22.3)	5.3 (2.3-10.9)	3.1 (0.7-11.3)	11.6 (8.5-15.4)	15.2 (9.8-22.8)	12.4 (7.7-19.1)	4.7 (2.1-9.6)	0 (0-0)	10 (7.4-13.3)
All ages	31.2 (24.5-39.3)	32.1 (25.3-40.3)	9 (5.2-14.8)	3 (0.7-10.9)	24.8 (21-29)	14.7 (10.5-20.3)	16.5 (12-22.4)	3.3 (1.4-6.7)	0 (0-0)	11.6 (9.2-14.4)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including September 24, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from the calculation of rates in this table). Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age group.

Table 3 interpretation:

The rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following sex, dose, and age groups:

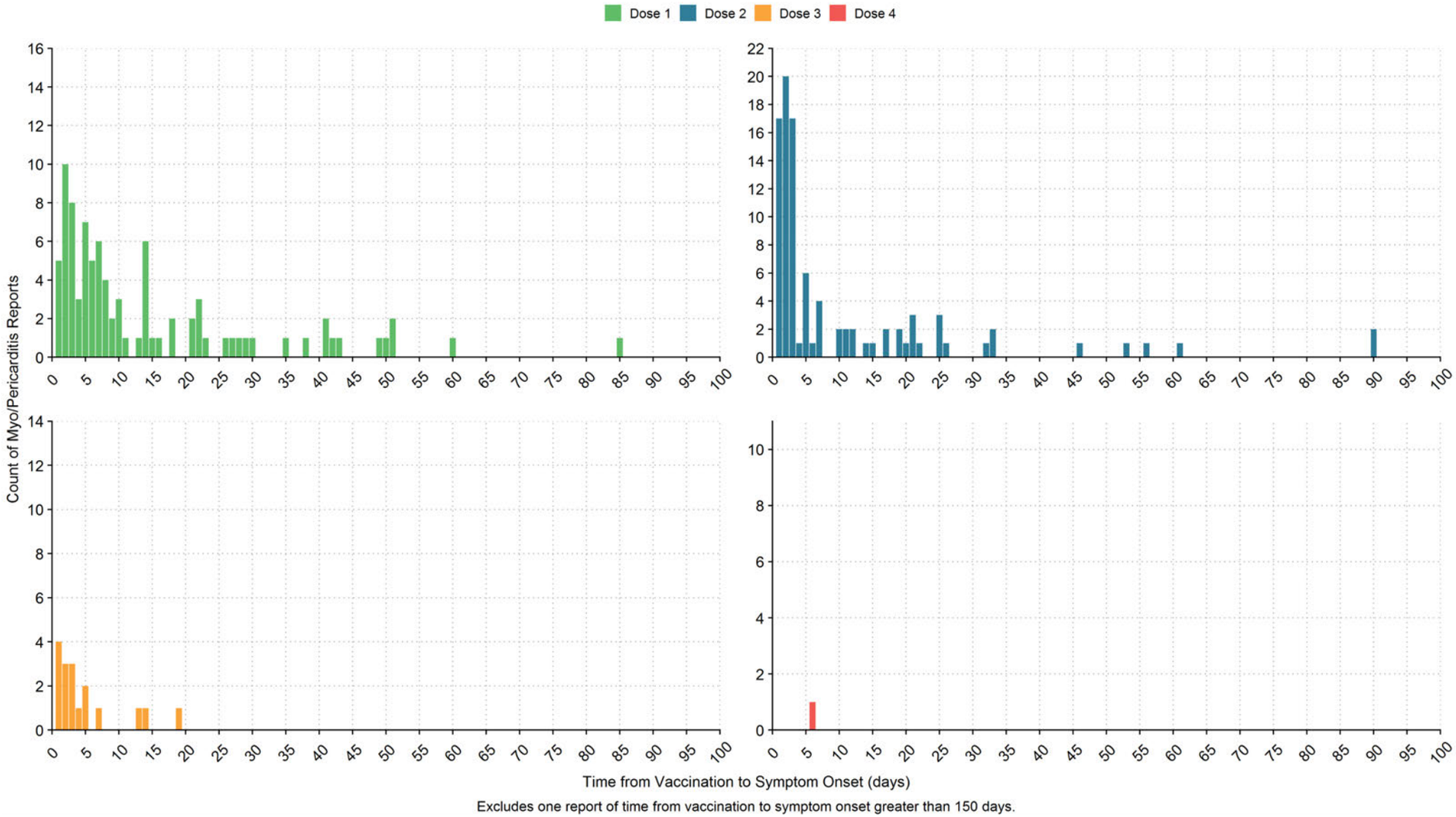
Males:

- 12-17 year olds: Dose 3 - However this is based on a single report in relation to only 1088 doses administered. This rate should be interpreted with caution.
- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 and all doses combined

Females:

- None showed a statistically significant difference between products.

Figure 3: Time from Vaccination to Symptom Onset of Myo/Pericarditis Reports, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=216)**



Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on September 28, 2022. Only AEFIs reported and doses administered up to September 24, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to September 24, 2022

This report summarizes COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including September 24, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Among reports in BC, anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, myocarditis and pericarditis were first recognized in Israel and the USA in young adults and adolescents, and have now also been seen in other countries including Canada and in BC reports.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is further reviewed and investigated, and then reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

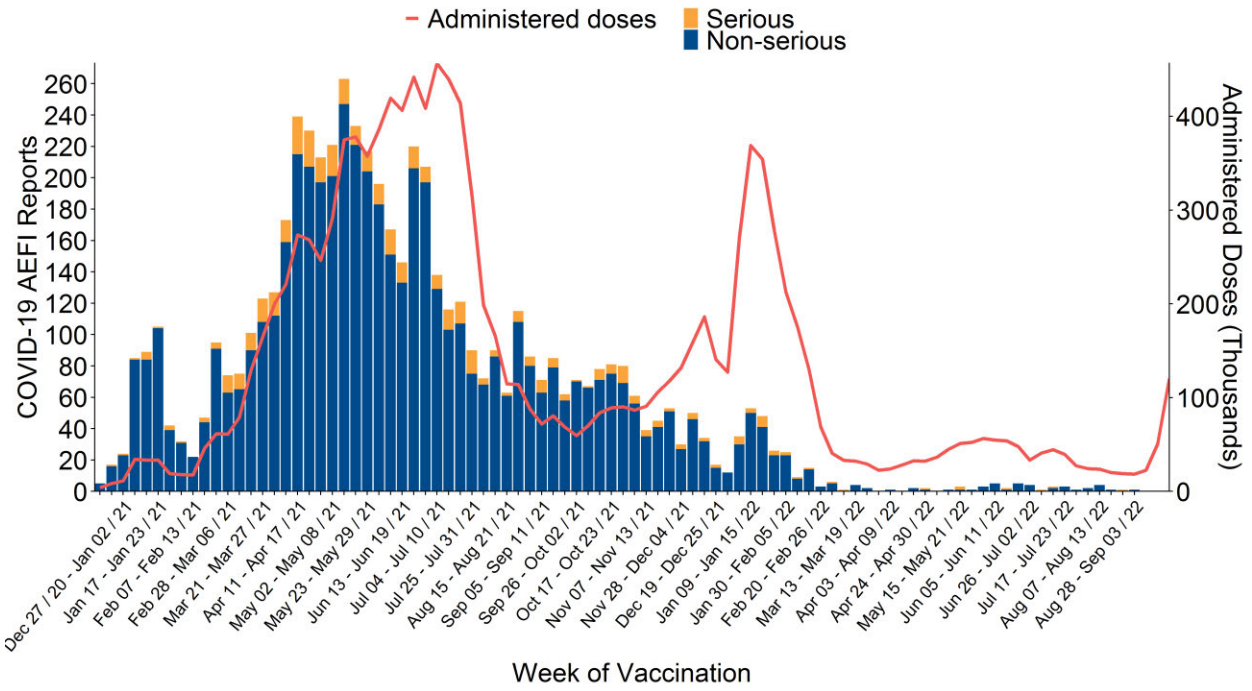
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of September 24, 2022, there have been 12,477,702 COVID-19 vaccine doses administered in BC and 5,888 COVID-19 AEFI reports (47.2 reports per 100,000 doses administered)
- 461 reports (7.8%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness
- Other events have been less frequently reported and are detailed below

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including September 24, 2022, a total of 12,477,702 doses have been administered. During this period, there have been 5,888 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.2 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second, third, and fourth doses of COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**

		COVID-19 Vaccine*				
	All COVID-19 Vaccines	**Moderna Spikevax**	**Moderna Spikevax Pediatric**	**Moderna Spikevax Bivalent**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5888**	**2104**	**6**	**0**	**3362**	**41**
Non-serious reports	5427	1952	5	0	3101	38
Serious reports	461	152	1	0	261	3
Proportion serious	7.8%	7.2%	16.7%	0.0%	7.8%	7.3%
Dose 1 reports	4076	1306	6	0	2394	31
Dose 2 reports	1440	552	0	0	845	9
Dose 3 reports	333	226	0	0	106	0
Dose 4 reports	25	16	0	0	9	0
Total doses administered	**12,477,702**	**3,924,397**	**21,263**	**143,476**	**7,539,697**	**398,189**
Dose 1 administered	4,537,878	932,612	21,189	1	3,056,949	209,887
Dose 2 administered	4,363,176	1,188,090	43	9	2,881,923	162,179
Dose 3 administered	2,848,835	1,476,493	23	4,178	1,340,307	26,119
Dose 4 administered	726,548	327,069	8	138,309	260,369	4
Total reporting rate	**47.2**	**53.6**	**28.2**	**0.0**	**44.6**	**10.3**
Serious rate	3.7	3.9	4.7	0.0	3.5	0.8
Dose 1 rate	89.8	140.0	28.3	0.0	78.3	14.8
Dose 2 rate	33.0	46.5	0.0	0.0	29.3	5.5
Dose 3 rate	11.7	15.3	0.0	0.0	7.9	0.0
Dose 4 rate	3.4	4.9	0.0	0.0	3.5	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Table 1 (continued): Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**

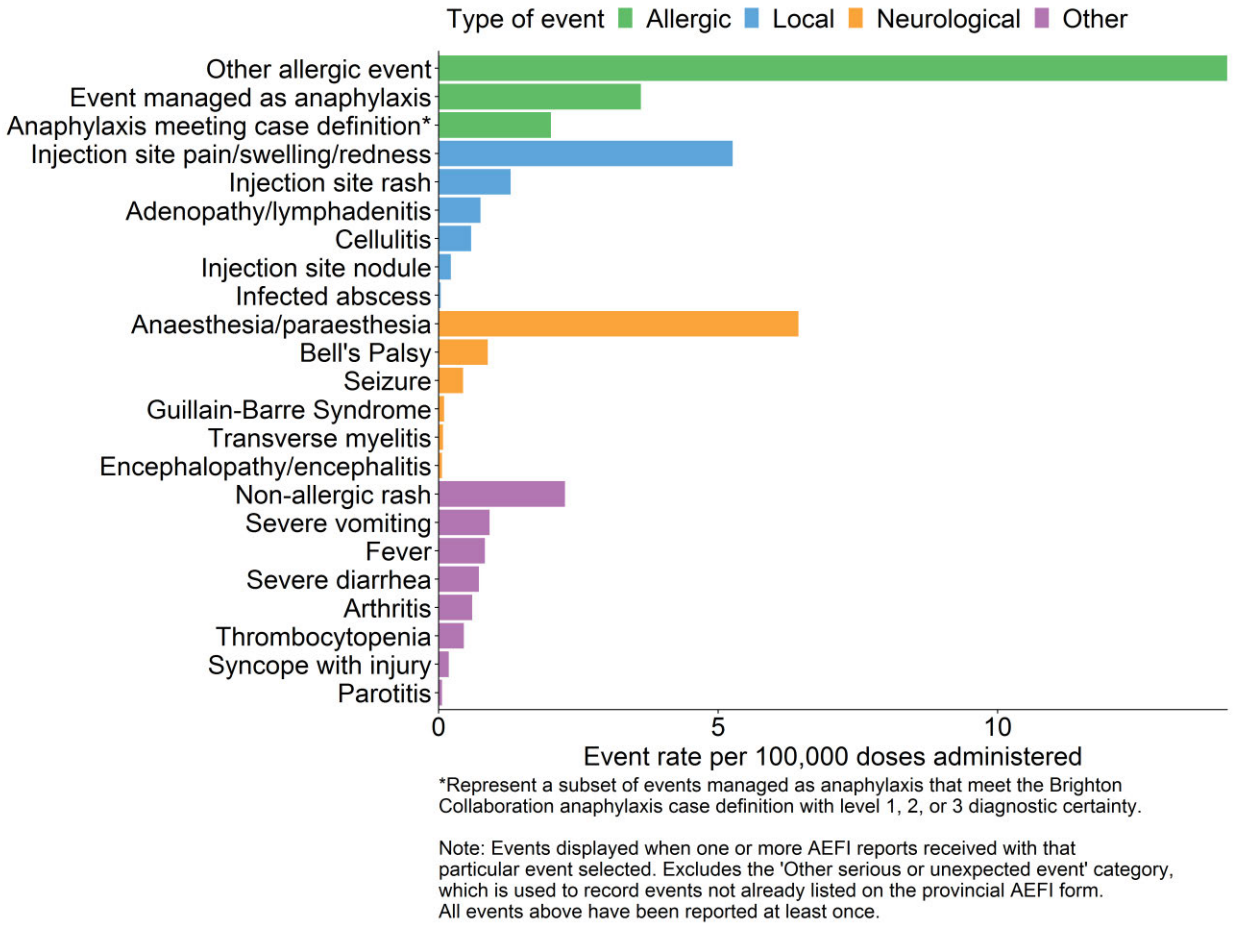
	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**Verity COVISHIELD**	**AstraZeneca Vaxzevria**	**J&J Janssen**	**Novavax NUVAXOVID**
Total reports	**5888**	**71**	**287**	**15**	**2**
Non-serious reports	5427	65	251	13	2
Serious reports	461	6	36	2	0
Proportion serious	7.8%	8.5%	12.5%	13.3%	0%
Dose 1 reports	4076	69	256	12	2
Dose 2 reports	1440	2	30	2	0
Dose 3 reports	333	0	0	1	0
Dose 4 reports	25	0	0	0	0
Total doses administered	**12,477,702**	**89,032**	**343,477**	**12,730**	**5,441**
Dose 1 administered	4,537,878	70,443	232,693	12,000	2,104
Dose 2 administered	4,363,176	18,443	109,975	534	1,980
Dose 3 administered	2,848,835	142	793	190	590
Dose 4 administered	726,548	4	16	6	763
Total reporting rate	**47.2**	**79.7**	**83.6**	**117.8**	**36.8**
Serious rate	3.7	6.7	10.5	15.7	0.0
Dose 1 rate	89.8	98.0	110.0	100.0	95.1
Dose 2 rate	33.0	10.8	27.3	374.5	0.0
Dose 3 rate	11.7	0.0	0.0	526.3	0.0
Dose 4 rate	3.4	0.0	0.0	0.0	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,888 AEFI reports received up to September 24, 2022 contained a total of 7,508 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=7,508)**



Event Descriptions

Four hundred fifty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 251 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Many events managed as anaphylaxis have features more compatible with anxiety or vasovagal syncope/pre-syncopal (fainting) events.

Seventy-two reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred sixty-one reports (7.8%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 432 individuals were admitted to hospital, including 2.9% of cases reported as anaphylaxis.

One hundred and ninety-eight reports contained a diagnosed neurological event. One hundred and ten individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional four individuals were reported as having transverse myelitis, however, one was unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and another was referred to a specialist for further investigation. Fifty-five individuals were reported with seizures (20% hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, including one with encephalopathy. Six additional individuals developed encephalitis or encephalopathy: one encephalitis was presumed to be viral in nature; one encephalopathy was attributed to a workplace toxin exposure; one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; two individuals with several comorbidities and encephalopathy made a spontaneous and full recovery within days, without a specific cause identified; one encephalitis was attributed to a new onset autoimmune condition diagnosed after receipt of vaccine. One individual was hospitalized for aseptic meningitis. There were twelve reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Five of these reports followed AstraZeneca vaccine, five followed Pfizer-BioNTech Comirnaty, and two followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but in two cases followed an illness compatible with recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19]

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Readers will note that some of the reported deaths described below appear to have a clear cause of death unrelated to the vaccine. Death may also be recorded as the outcome of a specific reportable event. Nineteen serious AEFI reports were received for individuals (median age: 76.5 years who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions; one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

- One death occurred in an elderly individual who suffered from multiple serious comorbidities. Investigation revealed the death was due to natural causes unrelated to the vaccine, but occurring in temporal association with vaccine receipt.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.
- One death occurred in an individual due to septic shock unrelated to the vaccine.
- Two deaths occurred in elderly individuals due to underlying cardiac compromise unrelated to the vaccine.

'Other serious or unexpected' events:
Some events may be reported as an "other serious or unexpected" event when these do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 188 were for various thrombotic/ thromboembolic conditions. These included 39 strokes (89.7% hospitalized) two cerebral venous sinus thromboses, 28 myocardial infarctions (92.9% hospitalized), 51 pulmonary emboli (58.9% hospitalized), 59 deep vein thromboses, and nine superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[20] Health Canada issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[21]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults aged 30-49 and two were aged 60-69 years. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia; this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Four serious AEFI reports in the 5-11 year age group have been reported. The first was for a new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[22] The second was for hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital. The third was for hospitalization following myo/pericarditis; this child was discharged with full resolution of symptoms. The fourth was for hospitalization following febrile seizures with onset several days later than expected for a plausible causal association to vaccine; this child was discharged home after full resolution and further investigations are in progress to identify an infectious cause.

There have been 223 reports of myocarditis/pericarditis. Sixty-six individuals were diagnosed with myocarditis, 100 with pericarditis, and 57 with myopericarditis. Ages ranged from 10 to 95 with a median of 35 years, and 146 (65%) were male. Ninety-three had received Moderna Spikevax, 122 received Pfizer-BioNTech Comirnaty, one received Pfizer-BioNTech Comirnaty Pediatric, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. One hundred and three of these events occurred after a second dose (47 Moderna Spikevax, 54 Pfizer-BioNTech Comirnaty, 1 Pfizer-BioNTech Comirnaty Pediatric, and 1 AstraZeneca Vaxzevria/Verity COVISHIELD). Seventeen occurred after a third dose (14 Moderna Spikevax and 3 Pfizer-BioNTech Comirnaty), and one occurred after a fourth dose of Moderna. Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Fifty-eight (out of 66) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-four (out of 100) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 57) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14,24]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=216)**

Vaccine/Age Groups	*Dose 1*	*Dose 2*	*Done 3*	*Dose 4*	*All Doses*
Moderna Spikevax					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12-17	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.5%)
18-24	5 (2.3%)	14 (6.5%)	1 (0.5%)	0 (0%)	20 (9.3%)
25-29	10 (4.6%)	9 (4.2%)	2 (0.9%)	0 (0%)	21 (9.7%)
30-39	7 (3.2%)	10 (4.6%)	1 (0.5%)	0 (0%)	18 (8.3%)
40+	9 (4.2%)	14 (6.5%)	9 (4.2%)	1 (0.5%)	33 (15.3%)
All ages	31 (14.4%)	47 (21.8%)	14 (6.5%)	1 (0.5%)	93 (43.1%)
Pfizer-BioNTech Comirnaty					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.2%)	10 (4.6%)	1 (0.5%)	0 (0%)	18 (8.3%)
18-24	7 (3.2%)	15 (6.9%)	1 (0.5%)	0 (0%)	23 (10.6%)
25-29	4 (1.9%)	4 (1.9%)	0 (0%)	0 (0%)	8 (3.7%)
30-39	19 (8.8%)	6 (2.8%)	0 (0%)	0 (0%)	25 (11.6%)
40+	28 (13%)	19 (8.8%)	1 (0.5%)	0 (0%)	48 (22.2%)
All ages	65 (30.1%)	55 (25.5%)	3 (1.4%)	0 (0%)	123 (56.9%)
mRNA Vaccines					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.2%)	10 (4.6%)	2 (0.9%)	0 (0%)	19 (8.8%)
18-24	12 (5.6%)	29 (13.4%)	2 (0.9%)	0 (0%)	43 (19.9%)
25-29	14 (6.5%)	13 (6%)	2 (0.9%)	0 (0%)	29 (13.4%)
30-39	26 (12%)	16 (7.4%)	1 (0.5%)	0 (0%)	43 (19.9%)
40+	37 (17.1%)	33 (15.3%)	10 (4.6%)	1 (0.5%)	81 (37.5%)
All ages	96 (44.4%)	102 (47.2%)	17 (7.9%)	1 (0.5%)	216 (100%)

Total = 216 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including September 24, 2022.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022. Stratified by sex, age group, vaccine trade name, and dose **(N=216)**

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Moderna Spikevax	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	0 (0-0)	0 (0-0)	**907.4 (219.8-3347.4)**	0 (0-0)	211 (51.1-778.2)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	83 (33.7-181.8)	**270.2 (159.1-435.8)**	85.9 (20.8-316.8)	0 (0-0)	**166.3 (105.7-251.5)**	23.1 (5.6-85.2)	22.1 (5.3-81.4)	0 (0-0)	0 (0-0)	18.8 (5.8-52.4)
25-29	**160.7 (82.7-289.8)**	**156.9 (80.7-282.8)**	132.7 (41.1-369.7)	0 (0-0)	**155 (98.5-234.3)**	47.4 (14.7-132)	22 (5.3-81.3)	0 (0-0)	0 (0-0)	27.3 (9.9-65.6)
30-39	40.7 (16.5-89.2)	45.6 (20.1-93.3)	10.5 (2.5-38.6)	0 (0-0)	32.7 (18-55.9)	34.5 (12.5-83.1)	50.3 (22.2-103.1)	0 (0-0)	0 (0-0)	26.8 (13.8-48.3)
40+	21.5 (10.1-41.8)	17.9 (8.8-33.3)	7.1 (2.9-15.5)	6.9 (1.7-25.4)	13 (8.3-19.7)	10.7 (3.9-25.7)	17.8 (8.8-33.2)	7.9 (3.5-16.1)	0 (0-0)	10.1 (6.2-15.8)
All ages	45.1 (29.9-65.8)	**54.8 (39.1-75)**	13 (6.9-22.8)	6.8 (1.6-25)	**33.7 (26.5-42.4)**	19.3 (10.3-33.9)	23.9 (14.3-38)	6.4 (2.8-13)	0 (0-0)	13.9 (9.6-19.5)

Pfizer-BioNTech Comirnaty	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.5)	0 (0-0)	0 (0-0)	5.4 (1.3-20.1)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	45.4 (21.3-88.3)	55.4 (27.3-103.3)	**18.9 (4.6-69.7)**	0 (0-0)	44.9 (26.9-71.3)	7.9 (1.9-29)	24.6 (8.9-59.2)	0 (0-0)	0 (0-0)	13.2 (5.3-28.9)
18-24	34 (15-69.7)	**63.8 (34-111.8)**	16 (3.9-59)	0 (0-0)	**42.7 (26-66.8)**	13.4 (4.1-37.2)	41.8 (19.6-81.3)	0 (0-0)	0 (0-0)	21.5 (11.1-38.7)
25-29	**24.9 (9.1-60.1)**	**17.5 (5.4-48.8)**	0 (0-0)	0 (0-0)	**17.2 (7.6-35.2)**	8.1 (2-29.9)	17 (5.3-47.3)	0 (0-0)	0 (0-0)	9.7 (3.5-23.4)
30-39	68.5 (42.4-105.9)	18 (7.3-39.5)	0 (0-0)	0 (0-0)	37.3 (24.2-55.3)	12.1 (4.4-29.2)	8.4 (2.6-23.5)	0 (0-0)	0 (0-0)	8.6 (3.8-17.7)
40+	14.4 (8.3-23.6)	12.9 (7.1-22.1)	2.7 (0.7-10)	0 (0-0)	11 (7.4-15.9)	16.6 (10.3-25.6)	10 (5.3-17.5)	0 (0-0)	0 (0-0)	10.3 (7-14.7)
All ages	26.9 (19.9-35.6)	**22.7 (16.2-31.1)**	4.7 (1.7-11.4)	0 (0-0)	**20.7 (16.6-25.6)**	13.5 (9-19.5)	13.8 (9.2-20.2)	0 (0-0)	0 (0-0)	10.8 (8.1-14.2)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.5)	0 (0-0)	0 (0-0)	5.4 (1.3-20.1)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	44.8 (21-87.1)	54.6 (26.9-101.9)	37 (11.4-103.1)	0 (0-0)	47.4 (28.9-74.2)	7.8 (1.9-28.6)	24.2 (8.8-58.3)	0 (0-0)	0 (0-0)	13 (5.3-28.4)
18-24	46.1 (24.6-80.7)	116.3 (77.1-169.7)	26.9 (8.3-74.9)	0 (0-0)	71.6 (51.1-98.1)	15.5 (5.6-37.4)	37.1 (18.3-69.1)	0 (0-0)	0 (0-0)	20.8 (11.4-35.6)
25-29	64.7 (36.5-108.1)	60.5 (33.2-103.4)	28.2 (8.7-78.6)	0 (0-0)	56.3 (37.6-81.5)	18.1 (6.6-43.6)	18.4 (6.7-44.3)	0 (0-0)	0 (0-0)	14.2 (6.7-27.7)
30-39	60.3 (39.2-89.4)	27.1 (14.5-47.5)	5.7 (1.4-21.1)	0 (0-0)	35.5 (24.9-49.2)	17.9 (8.4-34.9)	20.8 (10.3-38.8)	0 (0-0)	0 (0-0)	14.7 (8.6-23.7)
40+	16.2 (10.3-24.5)	14.6 (9.2-22.3)	5.3 (2.3-10.9)	3.1 (0.7-11.3)	11.6 (8.5-15.4)	15.2 (9.8-22.8)	12.4 (7.7-19.1)	4.7 (2.1-9.6)	0 (0-0)	10 (7.4-13.3)
All ages	31.2 (24.5-39.3)	32.1 (25.3-40.3)	9 (5.2-14.8)	3 (0.7-10.9)	24.8 (21-29)	14.7 (10.5-20.3)	16.5 (12-22.4)	3.3 (1.4-6.7)	0 (0-0)	11.6 (9.2-14.4)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including September 24, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from the calculation of rates in this table). Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age group.

Table 3 interpretation:

The rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following sex, dose, and age groups:

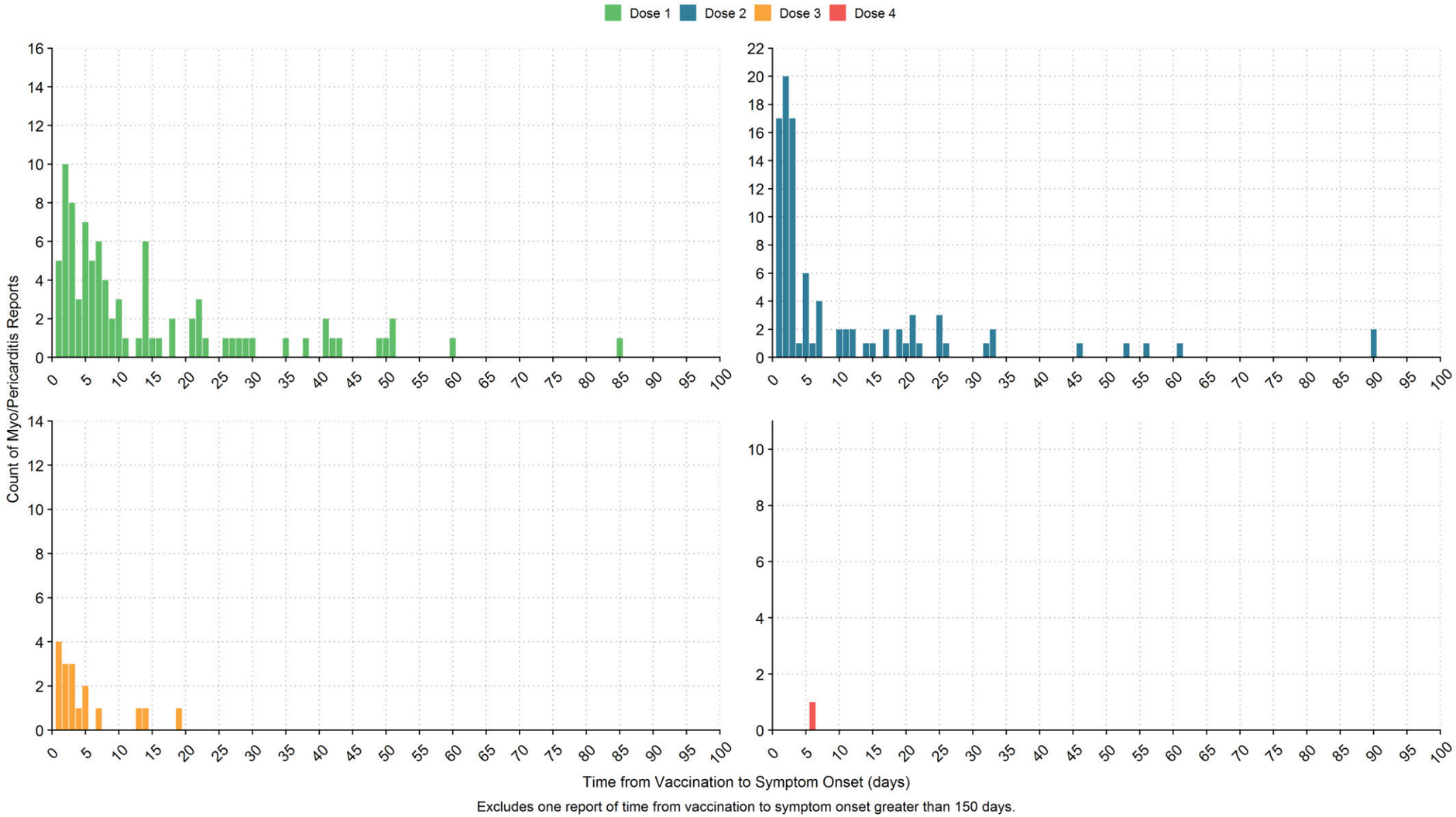
Males:

- 12-17 year olds: Dose 3 - However this is based on a single report in relation to only 1088 doses administered. This rate should be interpreted with caution.
- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 and all doses combined

Females:

- None showed a statistically significant difference between products.

Figure 3: Time from Vaccination to Symptom Onset of Myo/Pericarditis Reports, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=216)**



Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on September 28, 2022. Only AEFIs reported and doses administered up to September 24, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From:	Naus, Monika [BCCDC]
To:	Gabel, Brent [BCCDC]; MNDS.Assist [BCCDC]
Cc:	Dalati, Hadi [BCCDC]; Amos, Heather [BCCDC]; Minhas, Sableen
Subject:	FW: Monthly COVID-19 AEFI Report
Date:	Wednesday, October 05, 2022 2:41:00 PM
Attachments:	COVID19_AEFI_Monthly_Report_2022-09-29.pdf
Importance:	High

Hi Brent or Jess
Our weekly report was supposed to have been posted last Thursday but was not. It may be that Heather and Sableen are on an extended long weekend.
Can you please post in the BC weekly report section please?
http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccine-safety
Thank you,
Monika

Monika Naus MD FRCPC
Medical Director, Immunization Programs and Vaccine Preventable Diseases Service
BC Centre for Disease Control
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Tel 604.707.2540
Cell 604.219.4524
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday)
mnds.assist@bccdc.ca Tel 604 707 2519
I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Wednesday, October 05, 2022 11:15 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: FW: Monthly COVID-19 AEFI Report

Hello Sableen and Heather,
Monika informed me that the latest monthly COVID AEFi report (due September 29) is not up yet on our website.
Was there an issue with updating the page?
Apologies if I've missed anything and please let me know if you need more input from me.
Thank you,
Hadi

> **From:** Dalati, Hadi [BCCDC]
> **Sent:** Thursday, September 29, 2022 2:43 PM
> **To:** Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
> **Cc:** Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
> **Subject:** Monthly COVID-19 AEFI Report
> Hello all,
> Please find attached the latest monthly COVID-19 AEFI report for posting.
> As always, thank you for all your hard work.
> Best,
> **Hadi Dalati, MPH**
> **Communicable Disease Epidemiologist**
> **Communicable Diseases and Immunization Service (CDIS)**

BC Centre for Disease Control

Provincial Health Services Authority

Tel (604)707-2537

Fax (604)707-2515

I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to September 24, 2022

This report summarizes COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including September 24, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Among reports in BC, anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, myocarditis and pericarditis were first recognized in Israel and the USA in young adults and adolescents, and have now also been seen in other countries including Canada and in BC reports.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is further reviewed and investigated, and then reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

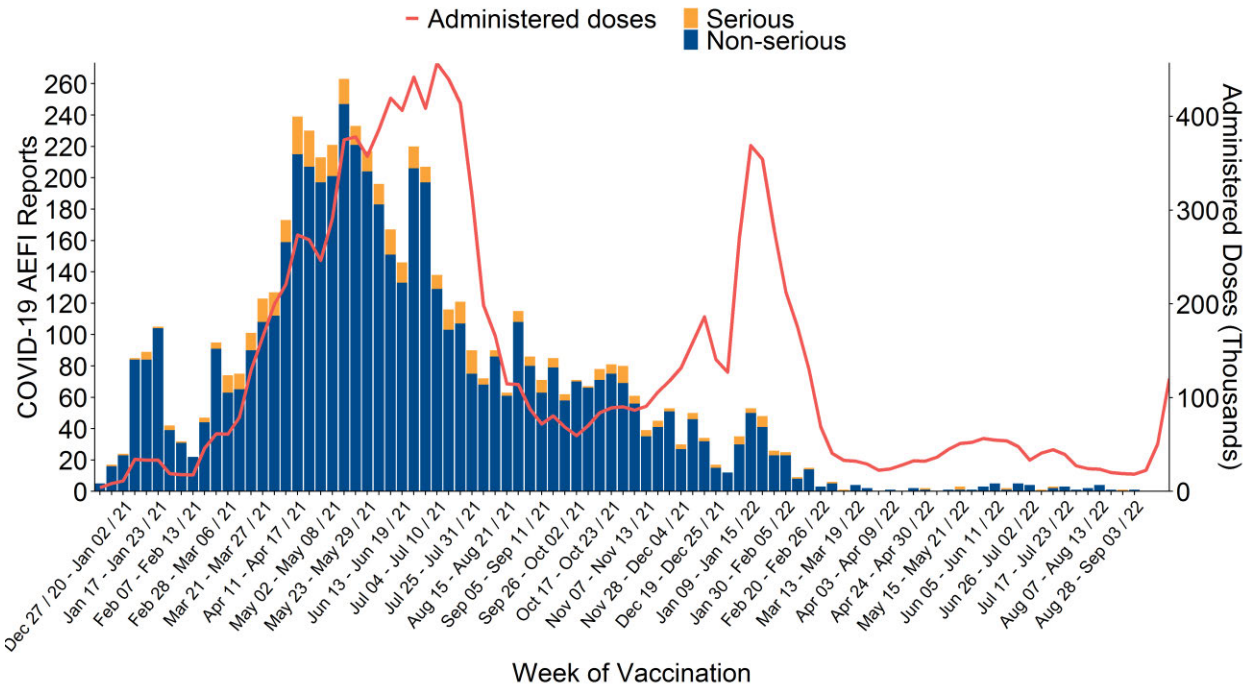
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of September 24, 2022, there have been 12,477,702 COVID-19 vaccine doses administered in BC and 5,888 COVID-19 AEFI reports (47.2 reports per 100,000 doses administered)
- 461 reports (7.8%) met the serious definition, for a rate of 3.7 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness
- Other events have been less frequently reported and are detailed below

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including September 24, 2022, a total of 12,477,702 doses have been administered. During this period, there have been 5,888 AEFI reports following a COVID-19 vaccine, for a reporting rate of 47.2 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second, third, and fourth doses of COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**

		COVID-19 Vaccine*				
	All COVID-19 Vaccines	**Moderna Spikevax**	**Moderna Spikevax Pediatric**	**Moderna Spikevax Bivalent**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5888**	**2104**	**6**	**0**	**3362**	**41**
Non-serious reports	5427	1952	5	0	3101	38
Serious reports	461	152	1	0	261	3
Proportion serious	7.8%	7.2%	16.7%	0.0%	7.8%	7.3%
Dose 1 reports	4076	1306	6	0	2394	31
Dose 2 reports	1440	552	0	0	845	9
Dose 3 reports	333	226	0	0	106	0
Dose 4 reports	25	16	0	0	9	0
Total doses administered	**12,477,702**	**3,924,397**	**21,263**	**143,476**	**7,539,697**	**398,189**
Dose 1 administered	4,537,878	932,612	21,189	1	3,056,949	209,887
Dose 2 administered	4,363,176	1,188,090	43	9	2,881,923	162,179
Dose 3 administered	2,848,835	1,476,493	23	4,178	1,340,307	26,119
Dose 4 administered	726,548	327,069	8	138,309	260,369	4
Total reporting rate	**47.2**	**53.6**	**28.2**	**0.0**	**44.6**	**10.3**
Serious rate	3.7	3.9	4.7	0.0	3.5	0.8
Dose 1 rate	89.8	140.0	28.3	0.0	78.3	14.8
Dose 2 rate	33.0	46.5	0.0	0.0	29.3	5.5
Dose 3 rate	11.7	15.3	0.0	0.0	7.9	0.0
Dose 4 rate	3.4	4.9	0.0	0.0	3.5	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Table 1 (continued): Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Sep. 24, 2022 **(N=5,888)**

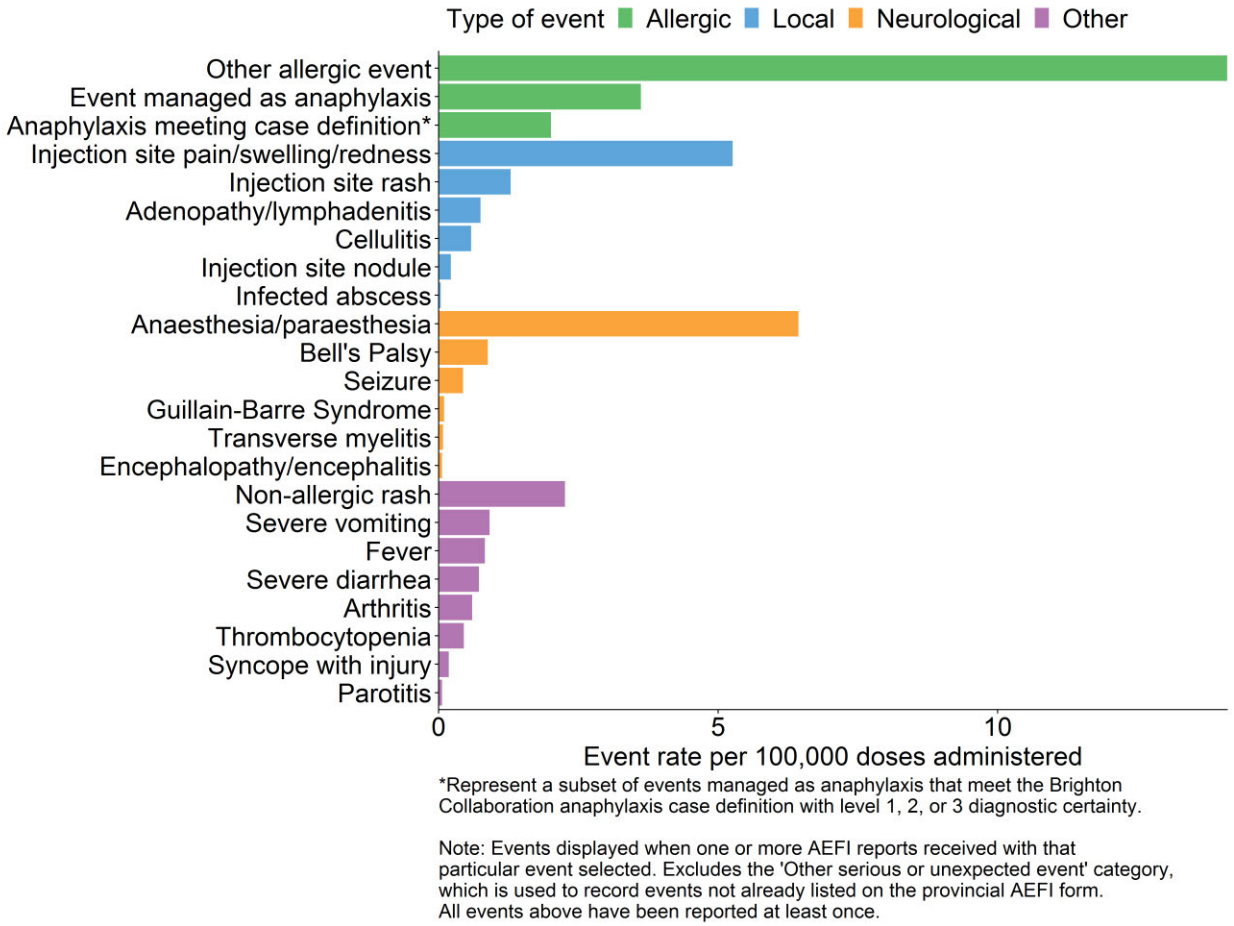
	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**Verity COVISHIELD**	**AstraZeneca Vaxzevria**	**J&J Janssen**	**Novavax NUVAXOVID**
Total reports	**5888**	**71**	**287**	**15**	**2**
Non-serious reports	5427	65	251	13	2
Serious reports	461	6	36	2	0
Proportion serious	7.8%	8.5%	12.5%	13.3%	0%
Dose 1 reports	4076	69	256	12	2
Dose 2 reports	1440	2	30	2	0
Dose 3 reports	333	0	0	1	0
Dose 4 reports	25	0	0	0	0
Total doses administered	**12,477,702**	**89,032**	**343,477**	**12,730**	**5,441**
Dose 1 administered	4,537,878	70,443	232,693	12,000	2,104
Dose 2 administered	4,363,176	18,443	109,975	534	1,980
Dose 3 administered	2,848,835	142	793	190	590
Dose 4 administered	726,548	4	16	6	763
Total reporting rate	**47.2**	**79.7**	**83.6**	**117.8**	**36.8**
Serious rate	3.7	6.7	10.5	15.7	0.0
Dose 1 rate	89.8	98.0	110.0	100.0	95.1
Dose 2 rate	33.0	10.8	27.3	374.5	0.0
Dose 3 rate	11.7	0.0	0.0	526.3	0.0
Dose 4 rate	3.4	0.0	0.0	0.0	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 5,888 AEFI reports received up to September 24, 2022 contained a total of 7,508 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=7,508)**



Event Descriptions

Four hundred fifty-two reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 251 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Many events managed as anaphylaxis have features more compatible with anxiety or vasovagal syncope/pre-syncopal (fainting) events.

Seventy-two reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing.

Four hundred sixty-one reports (7.8%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 432 individuals were admitted to hospital, including 2.9% of cases reported as anaphylaxis.

One hundred and ninety-eight reports contained a diagnosed neurological event. One hundred and ten individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional four individuals were reported as having transverse myelitis, however, one was unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and another was referred to a specialist for further investigation. Fifty-five individuals were reported with seizures (20% hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, including one with encephalopathy. Six additional individuals developed encephalitis or encephalopathy: one encephalitis was presumed to be viral in nature; one encephalopathy was attributed to a workplace toxin exposure; one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; two individuals with several comorbidities and encephalopathy made a spontaneous and full recovery within days, without a specific cause identified; one encephalitis was attributed to a new onset autoimmune condition diagnosed after receipt of vaccine. One individual was hospitalized for aseptic meningitis. There were twelve reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Five of these reports followed AstraZeneca vaccine, five followed Pfizer-BioNTech Comirnaty, and two followed Moderna Spikevax. A possible infectious cause of GBS was not identified in five of the cases but in two cases followed an illness compatible with recent infection. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19]

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Readers will note that some of the reported deaths described below appear to have a clear cause of death unrelated to the vaccine. Death may also be recorded as the outcome of a specific reportable event. Nineteen serious AEFI reports were received for individuals (median age: 76.5 years who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In five individuals, death was the outcome of cardiac arrest. Three of these were elderly individuals, many with multiple underlying medical conditions; one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

- One death occurred in an elderly individual who suffered from multiple serious comorbidities. Investigation revealed the death was due to natural causes unrelated to the vaccine, but occurring in temporal association with vaccine receipt.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.
- One death occurred in an individual due to septic shock unrelated to the vaccine.
- Two deaths occurred in elderly individuals due to underlying cardiac compromise unrelated to the vaccine.

'Other serious or unexpected' events:
Some events may be reported as an "other serious or unexpected" event when these do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 188 were for various thrombotic/ thromboembolic conditions. These included 39 strokes (89.7% hospitalized) two cerebral venous sinus thromboses, 28 myocardial infarctions (92.9% hospitalized), 51 pulmonary emboli (58.9% hospitalized), 59 deep vein thromboses, and nine superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[20] Health Canada issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[21]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults aged 30-49 and two were aged 60-69 years. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin which likely lead to the thrombocytopenia; this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Four serious AEFI reports in the 5-11 year age group have been reported. The first was for a new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[22] The second was for hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital. The third was for hospitalization following myo/pericarditis; this child was discharged with full resolution of symptoms. The fourth was for hospitalization following febrile seizures with onset several days later than expected for a plausible causal association to vaccine; this child was discharged home after full resolution and further investigations are in progress to identify an infectious cause.

There have been 223 reports of myocarditis/pericarditis. Sixty-six individuals were diagnosed with myocarditis, 100 with pericarditis, and 57 with myopericarditis. Ages ranged from 10 to 95 with a median of 35 years, and 146 (65%) were male. Ninety-three had received Moderna Spikevax, 122 received Pfizer-BioNTech Comirnaty, one received Pfizer-BioNTech Comirnaty Pediatric, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. One hundred and three of these events occurred after a second dose (47 Moderna Spikevax, 54 Pfizer-BioNTech Comirnaty, 1 Pfizer-BioNTech Comirnaty Pediatric, and 1 AstraZeneca Vaxzevria/Verity COVISHIELD). Seventeen occurred after a third dose (14 Moderna Spikevax and 3 Pfizer-BioNTech Comirnaty), and one occurred after a fourth dose of Moderna. Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Fifty-eight (out of 66) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-four (out of 100) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 57) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14,24]

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=216)**

Vaccine/Age Groups	*Dose 1*	*Dose 2*	*Done 3*	*Dose 4*	*All Doses*
Moderna Spikevax					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12-17	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	1 (0.5%)
18-24	5 (2.3%)	14 (6.5%)	1 (0.5%)	0 (0%)	20 (9.3%)
25-29	10 (4.6%)	9 (4.2%)	2 (0.9%)	0 (0%)	21 (9.7%)
30-39	7 (3.2%)	10 (4.6%)	1 (0.5%)	0 (0%)	18 (8.3%)
40+	9 (4.2%)	14 (6.5%)	9 (4.2%)	1 (0.5%)	33 (15.3%)
All ages	31 (14.4%)	47 (21.8%)	14 (6.5%)	1 (0.5%)	93 (43.1%)
Pfizer-BioNTech Comirnaty					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.2%)	10 (4.6%)	1 (0.5%)	0 (0%)	18 (8.3%)
18-24	7 (3.2%)	15 (6.9%)	1 (0.5%)	0 (0%)	23 (10.6%)
25-29	4 (1.9%)	4 (1.9%)	0 (0%)	0 (0%)	8 (3.7%)
30-39	19 (8.8%)	6 (2.8%)	0 (0%)	0 (0%)	25 (11.6%)
40+	28 (13%)	19 (8.8%)	1 (0.5%)	0 (0%)	48 (22.2%)
All ages	65 (30.1%)	55 (25.5%)	3 (1.4%)	0 (0%)	123 (56.9%)
mRNA Vaccines					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)	1 (0.5%)
12-17	7 (3.2%)	10 (4.6%)	2 (0.9%)	0 (0%)	19 (8.8%)
18-24	12 (5.6%)	29 (13.4%)	2 (0.9%)	0 (0%)	43 (19.9%)
25-29	14 (6.5%)	13 (6%)	2 (0.9%)	0 (0%)	29 (13.4%)
30-39	26 (12%)	16 (7.4%)	1 (0.5%)	0 (0%)	43 (19.9%)
40+	37 (17.1%)	33 (15.3%)	10 (4.6%)	1 (0.5%)	81 (37.5%)
All ages	96 (44.4%)	102 (47.2%)	17 (7.9%)	1 (0.5%)	216 (100%)

Total = 216 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including September 24, 2022.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Sep. 24, 2022. Stratified by sex, age group, vaccine trade name, and dose **(N=216)**

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Moderna Spikevax	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	0 (0-0)	0 (0-0)	**907.4 (219.8-3347.4)**	0 (0-0)	211 (51.1-778.2)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	83 (33.7-181.8)	**270.2 (159.1-435.8)**	85.9 (20.8-316.8)	0 (0-0)	**166.3 (105.7-251.5)**	23.1 (5.6-85.2)	22.1 (5.3-81.4)	0 (0-0)	0 (0-0)	18.8 (5.8-52.4)
25-29	**160.7 (82.7-289.8)**	**156.9 (80.7-282.8)**	132.7 (41.1-369.7)	0 (0-0)	**155 (98.5-234.3)**	47.4 (14.7-132)	22 (5.3-81.3)	0 (0-0)	0 (0-0)	27.3 (9.9-65.6)
30-39	40.7 (16.5-89.2)	45.6 (20.1-93.3)	10.5 (2.5-38.6)	0 (0-0)	32.7 (18-55.9)	34.5 (12.5-83.1)	50.3 (22.2-103.1)	0 (0-0)	0 (0-0)	26.8 (13.8-48.3)
40+	21.5 (10.1-41.8)	17.9 (8.8-33.3)	7.1 (2.9-15.5)	6.9 (1.7-25.4)	13 (8.3-19.7)	10.7 (3.9-25.7)	17.8 (8.8-33.2)	7.9 (3.5-16.1)	0 (0-0)	10.1 (6.2-15.8)
All ages	45.1 (29.9-65.8)	**54.8 (39.1-75)**	13 (6.9-22.8)	6.8 (1.6-25)	**33.7 (26.5-42.4)**	19.3 (10.3-33.9)	23.9 (14.3-38)	6.4 (2.8-13)	0 (0-0)	13.9 (9.6-19.5)

Pfizer-BioNTech Comirnaty	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.5)	0 (0-0)	0 (0-0)	5.4 (1.3-20.1)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	45.4 (21.3-88.3)	55.4 (27.3-103.3)	**18.9 (4.6-69.7)**	0 (0-0)	44.9 (26.9-71.3)	7.9 (1.9-29)	24.6 (8.9-59.2)	0 (0-0)	0 (0-0)	13.2 (5.3-28.9)
18-24	34 (15-69.7)	**63.8 (34-111.8)**	16 (3.9-59)	0 (0-0)	**42.7 (26-66.8)**	13.4 (4.1-37.2)	41.8 (19.6-81.3)	0 (0-0)	0 (0-0)	21.5 (11.1-38.7)
25-29	**24.9 (9.1-60.1)**	**17.5 (5.4-48.8)**	0 (0-0)	0 (0-0)	**17.2 (7.6-35.2)**	8.1 (2-29.9)	17 (5.3-47.3)	0 (0-0)	0 (0-0)	9.7 (3.5-23.4)
30-39	68.5 (42.4-105.9)	18 (7.3-39.5)	0 (0-0)	0 (0-0)	37.3 (24.2-55.3)	12.1 (4.4-29.2)	8.4 (2.6-23.5)	0 (0-0)	0 (0-0)	8.6 (3.8-17.7)
40+	14.4 (8.3-23.6)	12.9 (7.1-22.1)	2.7 (0.7-10)	0 (0-0)	11 (7.4-15.9)	16.6 (10.3-25.6)	10 (5.3-17.5)	0 (0-0)	0 (0-0)	10.3 (7-14.7)
All ages	26.9 (19.9-35.6)	**22.7 (16.2-31.1)**	4.7 (1.7-11.4)	0 (0-0)	**20.7 (16.6-25.6)**	13.5 (9-19.5)	13.8 (9.2-20.2)	0 (0-0)	0 (0-0)	10.8 (8.1-14.2)

mRNA Vaccines	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.2-49.5)	0 (0-0)	0 (0-0)	5.4 (1.3-20.1)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	44.8 (21-87.1)	54.6 (26.9-101.9)	37 (11.4-103.1)	0 (0-0)	47.4 (28.9-74.2)	7.8 (1.9-28.6)	24.2 (8.8-58.3)	0 (0-0)	0 (0-0)	13 (5.3-28.4)
18-24	46.1 (24.6-80.7)	116.3 (77.1-169.7)	26.9 (8.3-74.9)	0 (0-0)	71.6 (51.1-98.1)	15.5 (5.6-37.4)	37.1 (18.3-69.1)	0 (0-0)	0 (0-0)	20.8 (11.4-35.6)
25-29	64.7 (36.5-108.1)	60.5 (33.2-103.4)	28.2 (8.7-78.6)	0 (0-0)	56.3 (37.6-81.5)	18.1 (6.6-43.6)	18.4 (6.7-44.3)	0 (0-0)	0 (0-0)	14.2 (6.7-27.7)
30-39	60.3 (39.2-89.4)	27.1 (14.5-47.5)	5.7 (1.4-21.1)	0 (0-0)	35.5 (24.9-49.2)	17.9 (8.4-34.9)	20.8 (10.3-38.8)	0 (0-0)	0 (0-0)	14.7 (8.6-23.7)
40+	16.2 (10.3-24.5)	14.6 (9.2-22.3)	5.3 (2.3-10.9)	3.1 (0.7-11.3)	11.6 (8.5-15.4)	15.2 (9.8-22.8)	12.4 (7.7-19.1)	4.7 (2.1-9.6)	0 (0-0)	10 (7.4-13.3)
All ages	31.2 (24.5-39.3)	32.1 (25.3-40.3)	9 (5.2-14.8)	3 (0.7-10.9)	24.8 (21-29)	14.7 (10.5-20.3)	16.5 (12-22.4)	3.3 (1.4-6.7)	0 (0-0)	11.6 (9.2-14.4)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including September 24, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from the calculation of rates in this table). Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age group.

Table 3 interpretation:

The rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following sex, dose, and age groups:

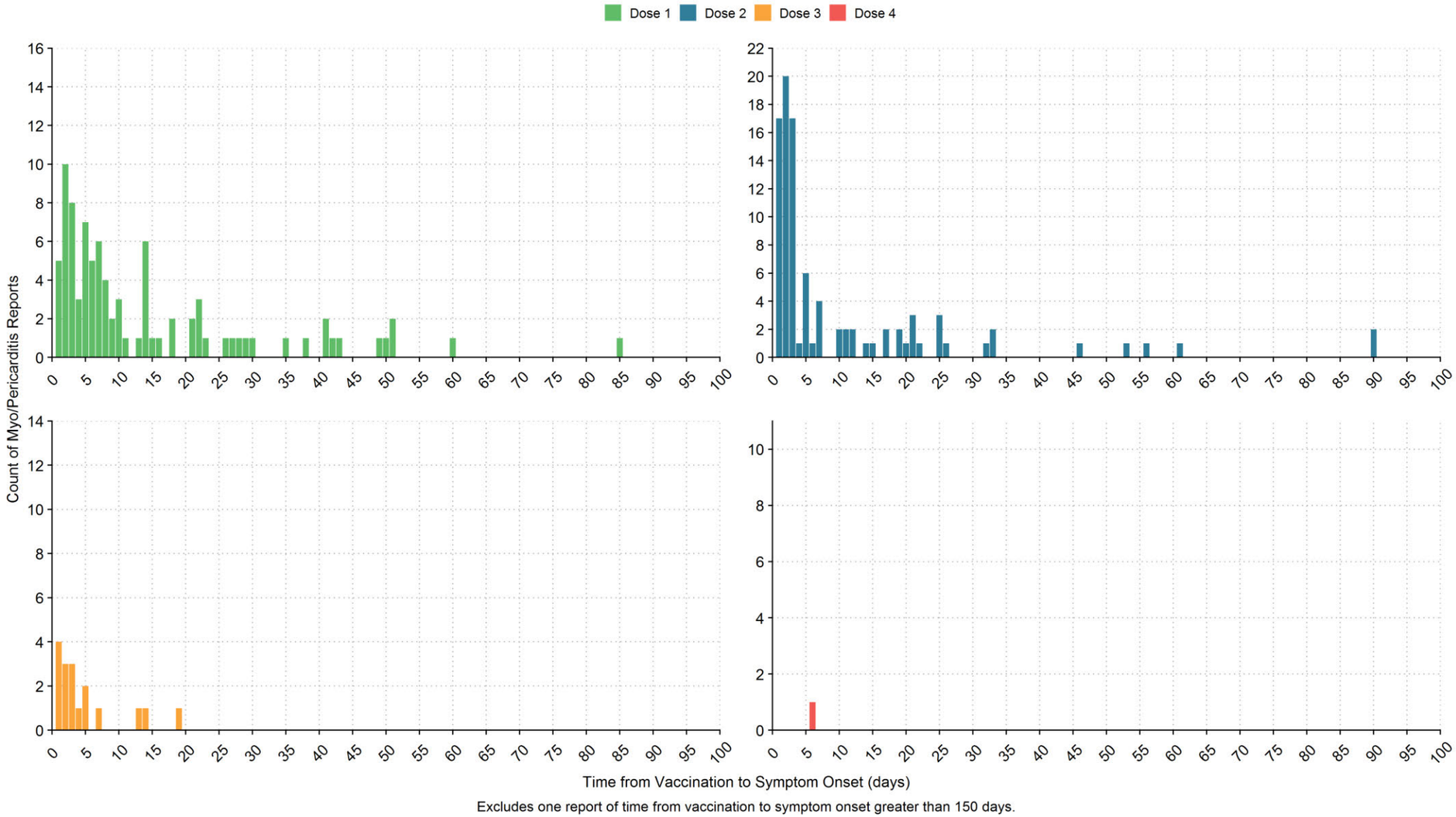
Males:

- 12-17 year olds: Dose 3 - However this is based on a single report in relation to only 1088 doses administered. This rate should be interpreted with caution.
- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 and all doses combined

Females:

- None showed a statistically significant difference between products.

Figure 3: Time from Vaccination to Symptom Onset of Myo/Pericarditis Reports, British Columbia, Dec. 13, 2020 - Sep. 24, 2022 **(N=216)**



Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on September 28, 2022. Only AEFIs reported and doses administered up to September 24, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From:	Taylor, Jessica [BCCDC] on behalf of MNDS.Assist [BCCDC]
To:	Naus, Monika [BCCDC]
Cc:	Dalati, Hadi [BCCDC]; Amos, Heather [BCCDC]; Minhas, Sableen; Gabel, Brent [BCCDC]; Cummings, Esther [BCCDC]; MNDS.Assist [BCCDC]
Subject:	RE: Monthly COVID-19 AEFI Report
Date:	Wednesday, October 05, 2022 3:14:03 PM

Hi all,

Between Brent, myself and those with web editing permissions within the team we will work to ensure these are posted in house.

Thanks

Jess

Jessica Taylor

(Mon-Wed) Admin Assistant Dr. Monika Naus, Medical Director, Immunization Program and Vaccine Preventable Diseases & Dr. David Patrick, Director of Research and Medical Epidemiology Lead for AMR

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From: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>

Sent: Wednesday, October 05, 2022 2:59 PM

To: MNDS.Assist [BCCDC] <mnds.assist@bccdc.ca>

Cc: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>; Gabel, Brent [BCCDC] <Brent.Gabel@bccdc.ca>

Subject: RE: Monthly COVID-19 AEFI Report

In the future, can we do it in-house here Jess? Can Esther or the surveillance analyst do this on Thursdays? There is no reason why it has to be done by Comms.
Thank you,
Monika

Monika Naus MD FRCPC
Medical Director, Immunization Programs and Vaccine Preventable Diseases Service
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mnds.assist@bccdc.ca Tel 604 707 2519
I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

From: Taylor, Jessica [BCCDC] <Jessica.Taylor@bccdc.ca> **On Behalf Of** MNDS.Assist [BCCDC]

Sent: Wednesday, October 05, 2022 2:56 PM

To: Minhas, Sableen <sableen.minhas@phsa.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Gabel, Brent [BCCDC] <Brent.Gabel@bccdc.ca>; MNDS.Assist [BCCDC] <mnds.assist@bccdc.ca>

Cc: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>

Subject: RE: Monthly COVID-19 AEFI Report

I have done it Sableen. Not to worry.

Thanks

Jess

Jessica Taylor
(Mon-Wed) Admin Assistant Dr. Monika Naus, Medical Director, Immunization Program and Vaccine Preventable Diseases & Dr. David Patrick, Director of Research and Medical Epidemiology Lead for AMR
BC Centre for Disease Control 655 West 12th Ave, Vancouver BC V5Z 4R4
T: (604) 707-2519/F: (604) 707-2515
jessica.taylor@bccdc.ca and/or MNDS.Assist@bccdc.ca

From: Minhas, Sableen <sableen.minhas@phsa.ca>
Sent: Wednesday, October 05, 2022 2:53 PM
To: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>; Gabel, Brent [BCCDC] <Brent.Gabel@bccdc.ca>; MNDS.Assist [BCCDC] <mnds.assist@bccdc.ca>
Cc: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Subject: RE: Monthly COVID-19 AEFI Report

Hi Monika,

I think I may have missed this! I can post it to the website right now.

Sableen Minhas
Communications Specialist
BC Centre for Disease Control
Provincial Health Services Authority

From: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Sent: Wednesday, October 05, 2022 2:41 PM
To: Gabel, Brent [BCCDC] <Brent.Gabel@bccdc.ca>; MNDS.Assist [BCCDC] <mnds.assist@bccdc.ca>
Cc: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>; Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Subject: FW: Monthly COVID-19 AEFI Report
Importance: High

Hi Brent or Jess
Our weekly report was supposed to have been posted last Thursday but was not. It may be that Heather and Sableen are on an extended long weekend.
Can you please post in the BC weekly report section please?
http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccine-safety
Thank you,
Monika

Monika Naus MD FRCPC
Medical Director, Immunization Programs and Vaccine Preventable Diseases Service
BC Centre for Disease Control
monika.naus@bccdc.ca
Tel 604.707.2540
Cell 604.219.4524
Assistant: Jessica Taylor (Monday - Wednesday) and Esther Cummings (Thursday/Friday)
mnds.assist@bccdc.ca Tel 604 707 2519
I gratefully acknowledge that I live on the territory of the Coast Salish Peoples.

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Wednesday, October 05, 2022 11:15 AM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: FW: Monthly COVID-19 AEFI Report

Hello Sableen and Heather,
Monika informed me that the latest monthly COVID AEFi report (due September 29) is not up yet on our website.
Was there an issue with updating the page?
Apologies if I've missed anything and please let me know if you need more input from me.
Thank you,
Hadi

From: Dalati, Hadi [BCCDC]
Sent: Thursday, September 29, 2022 2:43 PM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>; Minhas, Sableen <sableen.minhas@phsa.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Monthly COVID-19 AEFI Report

Hello all,
Please find attached the latest monthly COVID-19 AEFI report for posting.
As always, thank you for all your hard work.
Best,

Hadi Dalati, MPH
Communicable Disease Epidemiologist
Communicable Diseases and Immunization Service (CDIS)
BC Centre for Disease Control
Provincial Health Services Authority
Tel (604)707-2537
Fax (604)707-2515
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ilwətaʔ/Selilwitulh (TsleilWaututh) Nations.

From: Taylor, Jessica [BCCDC] on behalf of MNDS.Assist [BCCDC]
To: Amos, Heather [BCCDC]
Cc: Dalati, Hadi [BCCDC]; MNDS.Assist [BCCDC]; Naus, Monika [BCCDC]
Subject: FW: Monthly COVID-19 AEFI Report
Date: Thursday, January 05, 2023 3:09:55 PM
Attachments: COVID19_AEFI_Monthly_Report_2023-01-05.docx
COVID19_AEFI_Monthly_Report_2023-01-05.pdf

Hi Heather,
Permission to post the following below to the website?
This is a reoccurring report that we update every 4 weeks, since it's merely an updated report that we post, do you think it would be possible to get a blanket reoccurring permission for us to simply post this monthly report? If there were any other changes we wanted to make we would of course ask for permission first?
Thanks
Jess

Jessica Taylor
(Mon-Thurs) Admin Assistant Dr. Monika Naus, Medical Director, Immunization Program Vaccine Preventable Diseases
BC Centre for Disease Control / Provincial Health Services Authority

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, January 05, 2023 2:04 PM
To: MNDS.Assist [BCCDC] <mnds.assist@bccdc.ca>; Taylor, Jessica [BCCDC] <Jessica.Taylor@bccdc.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Monthly COVID-19 AEFI Report

Hi Jess,
Please find attached the newest Monthly COVID AEFI report to be posted here:
http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccine-safety
Under "B.C.'s Reports on Adverse Events".
Also, you wanted me to remind you to remove the note that says: "The next report will be available the first week of January 2023." from
http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccine-safety#aefi
Thank you very much,

Hadi Dalati, MPH (he/his)
Communicable Disease Epidemiologist
Immunization Programs and Vaccine Preventable Diseases Service
BC Centre for Disease Control
Provincial Health Services Authority
Office: 655 W 12th Ave, Vancouver, BC, V5Z 4R4
Tel: (604)707-2537
Fax: (604)707-2515
Email: hadi.dalati@bccdc.ca
I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓ əm (Musqueam), Skwxwú7mesh (Squamish), and Səl̓ílwətaʔ/Selilwitulh (TsleilWaututh) Nations.
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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to December 31, 2022

This report summarizes COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including December 31, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Among reports in BC, anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, myocarditis and pericarditis were first recognized in Israel and the USA in young adults and adolescents, and have now also been seen in other countries including Canada and in BC reports.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is further reviewed and investigated, and then reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

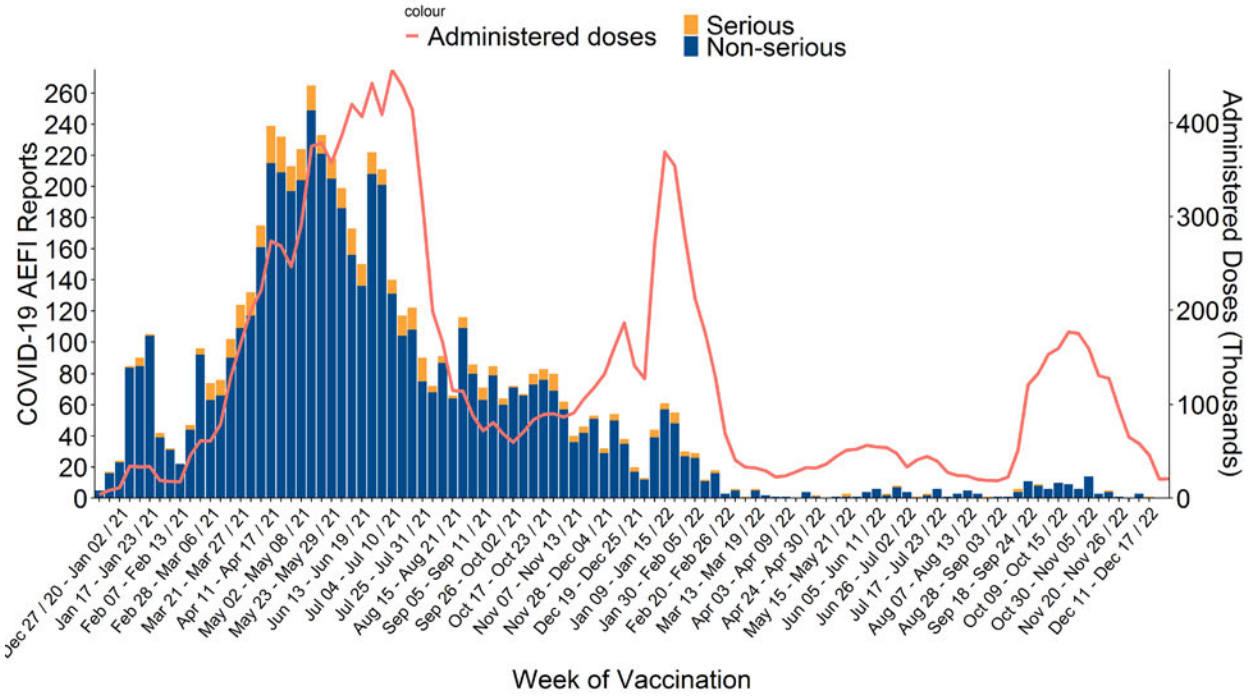
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of December 31, 2022, there have been 14,013,312 COVID-19 vaccine doses administered in BC and 6,101 COVID-19 AEFI reports (43.5 reports per 100,000 doses administered)
- 478 reports (7.8%) met the serious definition, for a rate of 3.4 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness
- Other events have been less frequently reported and are detailed below

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Dec. 31, 2022 **(N=6,101)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including December 31, 2022, a total of 14,013,312 doses have been administered. During this period, there have been 6,101 AEFI reports following a COVID-19 vaccine, for a reporting rate of 43.5 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second, third, and fourth doses of COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Dec. 31, 2022 **(N=6,101)**

	COVID-19 Vaccine*								
	All COVID-19 Vaccines	**Moderna Spikevax**	**Moderna Spikevax Bivalent**	**Moderna Spikevax Pediatric**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Bivalent**	**Pfizer-BioNTech Comirnaty Pediatric (6mo - 4yrs)**	**Pfizer-BioNTech Comirnaty Pediatric (5 - 11yrs)**	**Pfizer-BioNTech Comirnaty Pediatric Bivalent (5 - 11yrs)**
Total reports	**6101**	**2158**	**48**	**22**	**3423**	**16**	**0**	**56**	**0**
Non-serious reports	5623	2001	46	21	3157	14	0	51	0
Serious reports	478	157	2	1	266	2	0	5	0
Proportion serious	7.8%	7.3%	4.2%	4.5%	7.8%	12.5%	0.0%	8.9%	0.0%
Dose 1 reports	4124	1315	0	14	2416	0	0	37	0
Dose 2 reports	1477	561	0	2	865	0	0	15	0
Dose 3 reports	382	252	4	0	122	1	0	2	0
Dose 4 reports	77	24	34	0	12	7	0	0	0
Total doses administered	**14,013,312**	**3,928,555**	**939,143**	**59,430**	**7,570,466**	**610,802**	**102**	**447,645**	**1,134**
Recorded as Dose 1	4,578,990	933,298	3,560	39,850	3,059,911	8,531	86	214,415	62
Recorded as Dose 2	4,399,029	1,189,181	1,374	19,317	2,885,688	1,678	12	169,232	11
Recorded as Dose 3	2,961,163	1,477,298	30,876	142	1,346,431	39,144	4	63,754	1,051
Recorded as Dose 4	1,673,626	328,405	700,120	73	275,749	367,511	0	244	10
Total reporting rate	**43.5**	**54.9**	**5.1**	**37.0**	**45.2**	**2.6**	**0.0**	**12.5**	**0.0**
Serious rate	3.4	4.0	0.2	1.7	3.5	0.3	0.0	1.1	0.0
Dose 1 rate	90.1	140.9	0.0	35.1	79.0	0.0	0.0	17.3	0.0
Dose 2 rate	33.6	47.2	0.0	10.4	30.0	0.0	0.0	8.9	0.0
Dose 3 rate	12.9	17.1	13.0	0.0	9.1	2.6	0.0	3.1	0.0
Dose 4 rate	4.6	7.3	4.9	0.0	4.4	1.9	--	0.0	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Table 1 (continued): Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Dec. 31, 2022 **(N=6,101)**

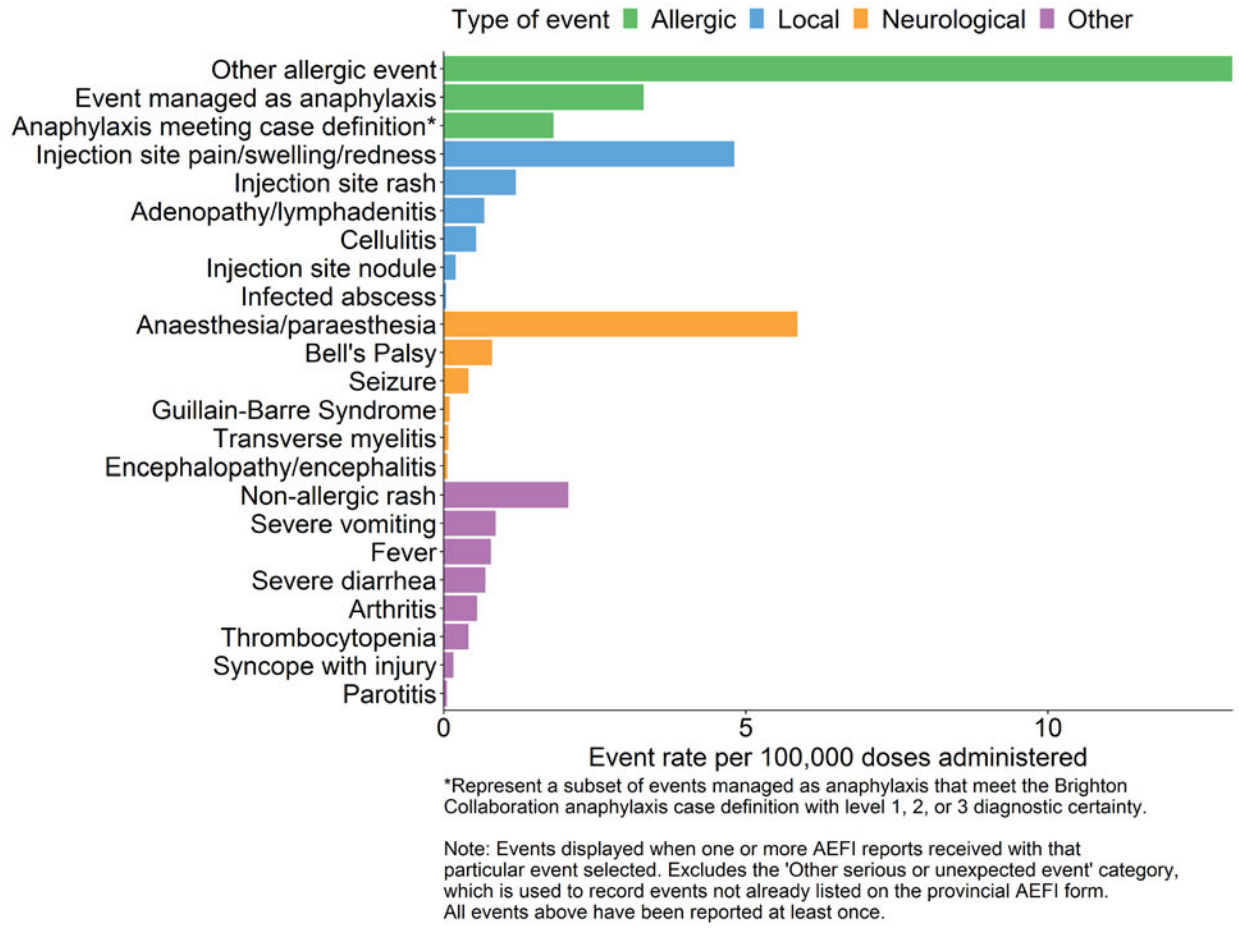
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**Verity COVISHIELD**	**AstraZeneca Vaxzevria**	**J&J Janssen**	**Novavax NUVAXOVID**
Total reports	**6101**	**74**	**287**	**15**	**2**
Non-serious reports	5623	68	251	13	2
Serious reports	478	6	36	2	0
Proportion serious	7.8%	8.1%	12.5%	13.3%	0%
Dose 1 reports	4124	72	256	12	2
Dose 2 reports	1477	2	30	2	0
Dose 3 reports	382	0	0	1	0
Dose 4 reports	77	0	0	0	0
Total doses administered	**14,013,312**	**90,669**	**345,294**	**13,057**	**7,012**
Recorded as Dose 1	4,578,990	71,190	233,558	12,258	2,270
Recorded as Dose 2	4,399,029	19,129	110,627	559	2,221
Recorded as Dose 3	2,961,163	343	1,066	205	849
Recorded as Dose 4	1,673,626	6	42	35	1,430
Total reporting rate	**43.5**	**81.6**	**83.1**	**114.9**	**28.5**
Serious rate	3.4	6.6	10.4	15.3	0.0
Dose 1 rate	90.1	101.1	109.6	97.9	88.1
Dose 2 rate	33.6	10.5	27.1	357.8	0.0
Dose 3 rate	12.9	0.0	0.0	487.8	0.0
Dose 4 rate	4.6	0.0	0.0	0.0	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 6,101 AEFI reports received up to December 31, 2022 contained a total of 7,769 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Dec. 31, 2022 **(N=7,769)**



Event Descriptions

Four hundred sixty-four reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 255 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Many events managed as anaphylaxis have features more compatible with anxiety or vasovagal syncope/pre-syncopal (fainting) events.

Seventy-five reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing, therefore none meet criteria for level 1 of the Brighton case definition.

Four hundred seventy-eight reports (7.8%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 448 individuals were admitted to hospital, including 2.8% of cases reported as anaphylaxis.

Two hundred and six reports contained a diagnosed neurological event. One hundred and twelve individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional five individuals were reported as having transverse myelitis, however, one was unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and another was referred to a specialist for further investigation. Fifty-eight individuals were reported with seizures (19% of whom were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, including one with encephalopathy. Six additional individuals developed encephalitis or encephalopathy: one encephalitis was presumed to be viral in nature; one encephalopathy was attributed to a workplace toxin exposure; one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; two individuals with several comorbidities and encephalopathy made a spontaneous and full recovery within days, without a specific cause identified; one encephalitis was attributed to a new onset autoimmune condition diagnosed after receipt of vaccine. One individual was hospitalized for aseptic meningitis. There were fourteen reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Five of these reports followed AstraZeneca vaccine, six followed Pfizer-BioNTech Comirnaty, and three followed Moderna Spikevax. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19]

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Readers will note that some of the reported deaths described below appear to have a clear cause of death unrelated to the vaccine. Death may also be recorded as the outcome of a specific reportable event. Twenty serious AEFI reports were received for individuals (median age: 78 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In six individuals, death was the outcome of cardiac arrest. Four of these were elderly individuals with underlying medical conditions; one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

- One death occurred in an elderly individual who suffered from multiple serious comorbidities. Investigation revealed the death was due to natural causes unrelated to the vaccine, but occurring in temporal association with vaccine receipt.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.
- One death occurred in an individual due to septic shock unrelated to the vaccine.
- Two deaths occurred in elderly individuals due to underlying cardiac compromise unrelated to the vaccine.

'Other serious or unexpected' events:
Some events may be reported as an "other serious or unexpected" event when these do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 190 were for various thrombotic/ thromboembolic conditions. These included 40 strokes (90% hospitalized) two cerebral venous sinus thromboses, 28 myocardial infarctions (92.9% hospitalized), 51 pulmonary emboli (58.9% hospitalized), 60 deep vein thromboses, and nine superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[20] Health Canada issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[21]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults aged 30-49 and two were aged 60-69 years. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin; this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Five serious AEFI reports in the 5-11 year age group have been reported. The first was for a new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[22] The second was for hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital. The third was for hospitalization following myo/pericarditis; this child was discharged with full resolution of symptoms. The fourth was for hospitalization following prolonged fever that coincided with a diagnosis of pneumonia; this child was treated and discharged. The fifth was a hospitalization for bloody stools that were attributed to a diagnosis of ulcerative colitis.

One serious AEFI report in the 6 months to 5 years age group has been reported. This was for hospitalization following febrile seizures. The temporal relationship of the seizure was more in keeping with a viral illness that onset after vaccine receipt, rather than with vaccine receipt. This child was discharged home after full resolution.[†]

There have been 231 reports of myocarditis/pericarditis. Sixty-eight individuals were diagnosed with myocarditis, 106 with pericarditis, and 57 with myopericarditis. Ages ranged from 10 to 95 with a median of 35 years, and 153 (66%) were male. Ninety-seven had received Moderna Spikevax, 126 received Pfizer-BioNTech Comirnaty, one received Pfizer-BioNTech Comirnaty Pediatric, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. One hundred and five of these events occurred after a second dose (47 Moderna Spikevax, 56 Pfizer-BioNTech Comirnaty, 1 Pfizer-BioNTech Comirnaty Pediatric, and 1 AstraZeneca Vaxzevria/Verity COVISHIELD). Twenty-one occurred after a third dose (16 Moderna Spikevax and 5 Pfizer-BioNTech Comirnaty), and one occurred after a fourth dose of Moderna. Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Sixty (out of 68) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-eight (out of 106) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 57) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14,24]

[†] In previous reports (September 29, 2022 through November 24, 2022), this child was erroneously described in the 5-11 year old age group instead of the 6 months to 5 years age group.

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Dec. 31, 2022 **(N=224)**

Vaccine/Age Groups	*Dose 1*	*Dose 2*	*Dose 3*	*Dose 4*	*All Doses*
Moderna Spikevax					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12-17	0 (0%)	0 (0%)	1 (0.4%)	0 (0%)	1 (0.4%)
18-24	5 (2.2%)	14 (6.2%)	2 (0.9%)	0 (0%)	21 (9.4%)
25-29	10 (4.5%)	9 (4%)	3 (1.3%)	0 (0%)	22 (9.8%)
30-39	7 (3.1%)	10 (4.5%)	1 (0.4%)	0 (0%)	18 (8%)
40+	11 (4.9%)	14 (6.2%)	9 (4%)	1 (0.4%)	35 (15.6%)
All ages	33 (14.7%)	47 (21%)	16 (7.1%)	1 (0.4%)	97 (43.3%)
Pfizer-BioNTech Comirnaty					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.4%)
12-17	7 (3.1%)	10 (4.5%)	1 (0.4%)	0 (0%)	18 (8%)
18-24	7 (3.1%)	15 (6.7%)	2 (0.9%)	0 (0%)	24 (10.7%)
25-29	4 (1.8%)	4 (1.8%)	0 (0%)	0 (0%)	8 (3.6%)
30-39	19 (8.5%)	6 (2.7%)	0 (0%)	0 (0%)	25 (11.2%)
40+	28 (12.5%)	21 (9.4%)	2 (0.9%)	0 (0%)	51 (22.8%)
All ages	65 (29%)	57 (25.4%)	5 (2.2%)	0 (0%)	127 (56.7%)
mRNA Vaccines					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.4%)
12-17	7 (3.1%)	10 (4.5%)	2 (0.9%)	0 (0%)	19 (8.5%)
18-24	12 (5.4%)	29 (12.9%)	4 (1.8%)	0 (0%)	45 (20.1%)
25-29	14 (6.2%)	13 (5.8%)	3 (1.3%)	0 (0%)	30 (13.4%)
30-39	26 (11.6%)	16 (7.1%)	1 (0.4%)	0 (0%)	43 (19.2%)
40+	39 (17.4%)	35 (15.6%)	11 (4.9%)	1 (0.4%)	86 (38.4%)
All ages	98 (43.8%)	104 (46.4%)	21 (9.4%)	1 (0.4%)	224 (100%)

Total = 224 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including December 31, 2022.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Dec. 31, 2022. Stratified by sex, age group, vaccine trade name, and dose **(N=224)**

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Moderna Spikevax	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	0 (0-0)	0 (0-0)	**958.8 (232.2-3536.8)**	0 (0-0)	221.6 (53.7-817.4)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	87.4 (35.5-191.5)	**284.9 (167.7-459.3)**	180.3 (55.8-502.3)	0 (0-0)	**184.9 (118.9-276.9)**	24.3 (5.9-89.5)	23.2 (5.6-85.7)	0 (0-0)	0 (0-0)	19.8 (6.1-55.1)
25-29	**161.2 (82.9-290.7)**	**157.3 (80.9-283.6)**	203.6 (74-490.4)	0 (0-0)	**164.4 (105.7-246.2)**	47.4 (14.7-132.2)	22 (5.3-81.3)	0 (0-0)	0 (0-0)	27.4 (9.9-65.9)
30-39	40.5 (16.5-88.8)	45.5 (20-93.1)	10.7 (2.6-39.3)	0 (0-0)	32.8 (18-56.1)	34.4 (12.5-82.8)	50.2 (22.1-102.9)	0 (0-0)	0 (0-0)	26.9 (13.8-48.5)
40+	28.4 (14.6-51.2)	17.7 (8.7-33.1)	7 (2.8-15.4)	6.9 (1.7-25.3)	14.4 (9.3-21.3)	10.6 (3.9-25.5)	17.7 (8.7-32.9)	7.8 (3.4-16)	0 (0-0)	10 (6.1-15.7)
All ages	48.2 (32.5-69.3)	**53.9 (38.4-73.7)**	15.9 (9-26.6)	6.7 (1.6-24.9)	**35.4 (28-44.2)**	19 (10.1-33.2)	23.5 (14.1-37.3)	6.4 (2.8-13)	0 (0-0)	13.7 (9.5-19.3)

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Pfizer-BioNTech Comirnaty	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.3-49.5)	0 (0-0)	0 (0-0)	5 (1.2-18.6)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	46 (21.6-89.4)	56.3 (27.8-105)	**19.1 (4.6-70.4)**	0 (0-0)	45.3 (27.2-72)	8 (1.9-29.5)	25 (9.1-60.3)	0 (0-0)	0 (0-0)	13.3 (5.4-29.2)
18-24	34 (15-69.6)	**63.7 (33.9-111.6)**	32 (9.9-89.1)	0 (0-0)	**45.4 (28.1-70.3)**	13.3 (4.1-37.2)	41.7 (19.6-81.1)	0 (0-0)	0 (0-0)	21.5 (11-38.7)
25-29	**25 (9.1-60.2)**	**17.5 (5.4-48.8)**	0 (0-0)	0 (0-0)	**17.2 (7.6-35.2)**	8.1 (2-29.9)	17 (5.3-47.4)	0 (0-0)	0 (0-0)	9.7 (3.5-23.4)
30-39	68.2 (42.2-105.5)	17.9 (7.3-39.3)	0 (0-0)	0 (0-0)	37 (24.1-54.9)	12.1 (4.4-29.1)	8.4 (2.6-23.4)	0 (0-0)	0 (0-0)	8.6 (3.8-17.5)
40+	14.3 (8.2-23.4)	15.4 (8.9-25.2)	2.7 (0.6-9.9)	0 (0-0)	11.8 (8-16.9)	16.4 (10.2-25.4)	9.9 (5.3-17.4)	2.3 (0.6-8.5)	0 (0-0)	10.6 (7.2-15)
All ages	26.8 (19.9-35.5)	**24 (17.3-32.6)**	6.1 (2.5-13.4)	0 (0-0)	**21.3 (17.2-26.2)**	13.5 (9-19.5)	13.8 (9.1-20.1)	1.3 (0.3-4.9)	0 (0-0)	10.9 (8.2-14.3)

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
mRNA Vaccines	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.3 (3.2-49)	0 (0-0)	0 (0-0)	5 (1.2-18.3)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	45.3 (21.2-88)	55.5 (27.4-103.5)	34.4 (10.6-95.8)	0 (0-0)	44.5 (27.1-69.7)	7.9 (1.9-29)	24.7 (9-59.4)	0 (0-0)	0 (0-0)	12.2 (4.9-26.7)
18-24	46.5 (24.8-81.5)	117.6 (78-171.6)	52.1 (21.1-114.1)	0 (0-0)	73.3 (52.8-99.5)	15.6 (5.7-37.7)	37.4 (18.5-69.8)	0 (0-0)	0 (0-0)	19.8 (10.9-33.8)
25-29	64.6 (36.4-108)	60.6 (33.3-103.5)	41 (14.9-98.8)	0 (0-0)	55.5 (37.4-79.9)	18.1 (6.6-43.5)	18.4 (6.7-44.3)	0 (0-0)	0 (0-0)	13.2 (6.2-25.7)
30-39	59.8 (38.9-88.7)	27 (14.4-47.3)	5.5 (1.3-20.4)	0 (0-0)	32.6 (22.9-45.2)	17.8 (8.3-34.6)	20.7 (10.2-38.7)	0 (0-0)	0 (0-0)	13.3 (7.8-21.5)
40+	17.8 (11.6-26.4)	16.2 (10.4-24.2)	5.2 (2.3-10.7)	1.6 (0.4-5.8)	11 (8.3-14.5)	15.1 (9.7-22.6)	12.3 (7.6-19)	5.5 (2.6-10.7)	0 (0-0)	8.9 (6.6-11.8)
All ages	31.9 (25.1-40)	32.8 (25.9-41.1)	10.9 (6.6-17)	1.3 (0.3-4.8)	23.2 (19.8-27)	14.6 (10.4-20.1)	16.4 (11.9-22.2)	3.8 (1.8-7.4)	0 (0-0)	10.4 (8.3-12.9)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including December 31, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from the calculation of rates in this table).

Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age group.

Table 3 interpretation:
The rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following sex, dose, and age groups:

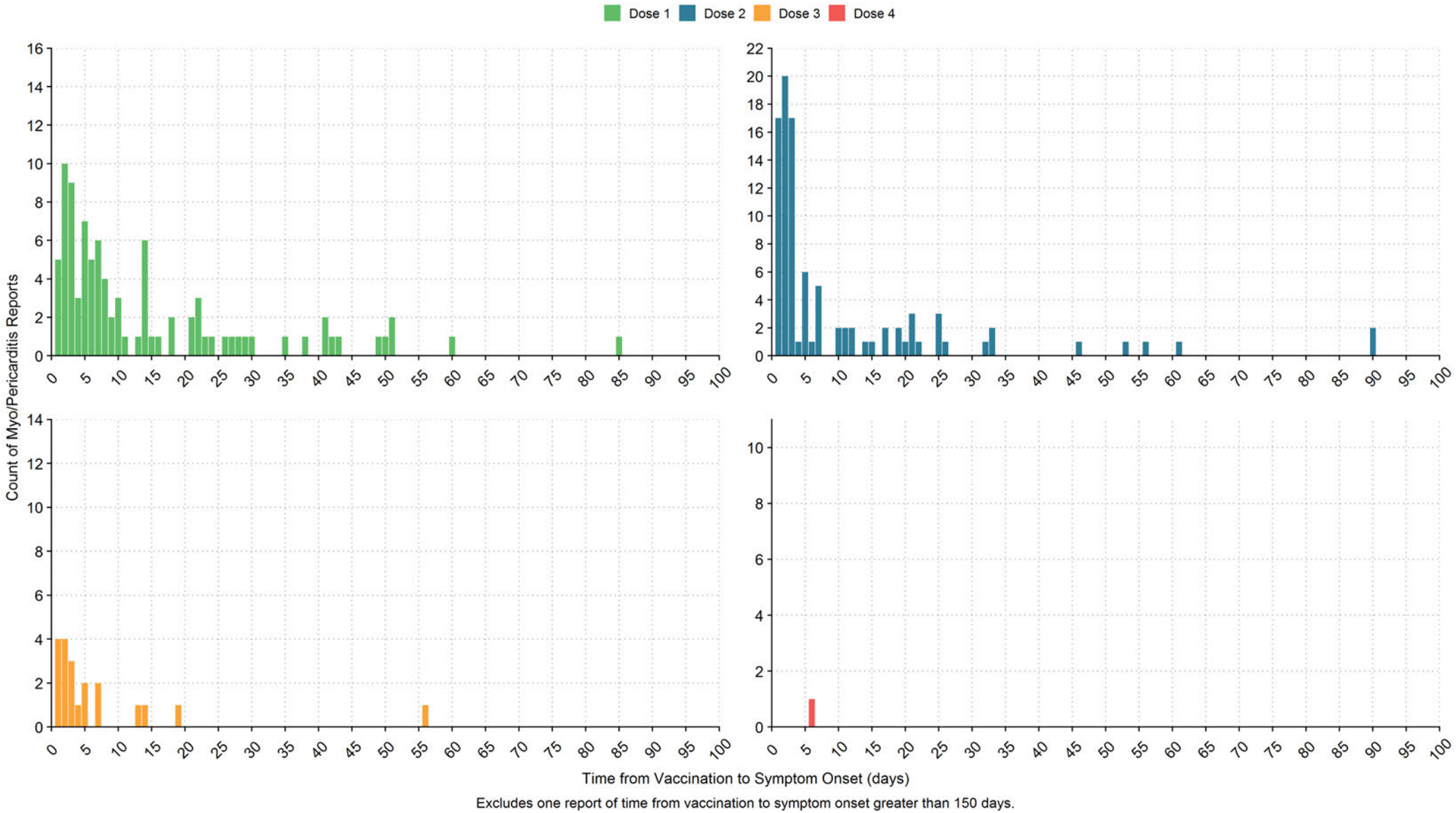
Males:

- 12-17 year olds: Dose 3 - However this is based on a single report in relation to only 1088 doses administered. This rate should be interpreted with caution.
- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 and all doses combined

Females:

- None showed a statistically significant difference between products.

Figure 3: Time from Vaccination to Symptom Onset of Myo/Pericarditis Reports, British Columbia, Dec. 13, 2020 - Dec. 31, 2022 **(N=224)**



Excludes one report of time from vaccination to symptom onset greater than 150 days.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on January 4, 2023. Only AEFIs reported and doses administered up to December 31, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to December 31, 2022

This report summarizes COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including December 31, 2022. Refer to the BCCDC website for reporting guidelines.[1] Events can be reported even when there is no certainty of a causal association. Refer to the Data Notes section at the end of this report for additional information on the source data.

Summary

The COVID-19 vaccines demonstrated safety in clinical trials prior to authorization for worldwide use.[2-4] During post-marketing surveillance, larger numbers of individuals are vaccinated, and this allows for detection of rare events undetected in clinical trials.

Among reports in BC, anaphylaxis and allergic events are the most frequently reported events following all of the COVID-19 vaccines. About half of the cases managed as anaphylaxis had lower level of diagnostic certainty and may reflect events such as anxiety or pre-syncopal (fainting) events managed as anaphylaxis out of an abundance of caution.

In association with the mRNA vaccines, myocarditis and pericarditis were first recognized in Israel and the USA in young adults and adolescents, and have now also been seen in other countries including Canada and in BC reports.[5-9]

There have been six reports of thrombosis with thrombocytopenia syndrome (TTS) reported in BC to date, of which 5 were associated with the adenovirus vector vaccines. This syndrome was identified in March 2021 in Europe in association with the AstraZeneca vaccine and also in the US with the Janssen vaccine, with a small number of cases accumulating in Canada associated with use of the adenovirus vector vaccines. The rate of occurrence has been estimated at about 1 in 67,000 recipients following the first dose and 1 in 500,000 following the second dose.[8,10,11]

Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the BC Immunization Manual.[12] When an AEFI report is received at a local public health unit, it is further reviewed and investigated, and then reported in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the Canadian Adverse Event Following Immunization Surveillance System where additional review and analysis for potential safety signals is performed at the national level.[13] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[14]

Definitions

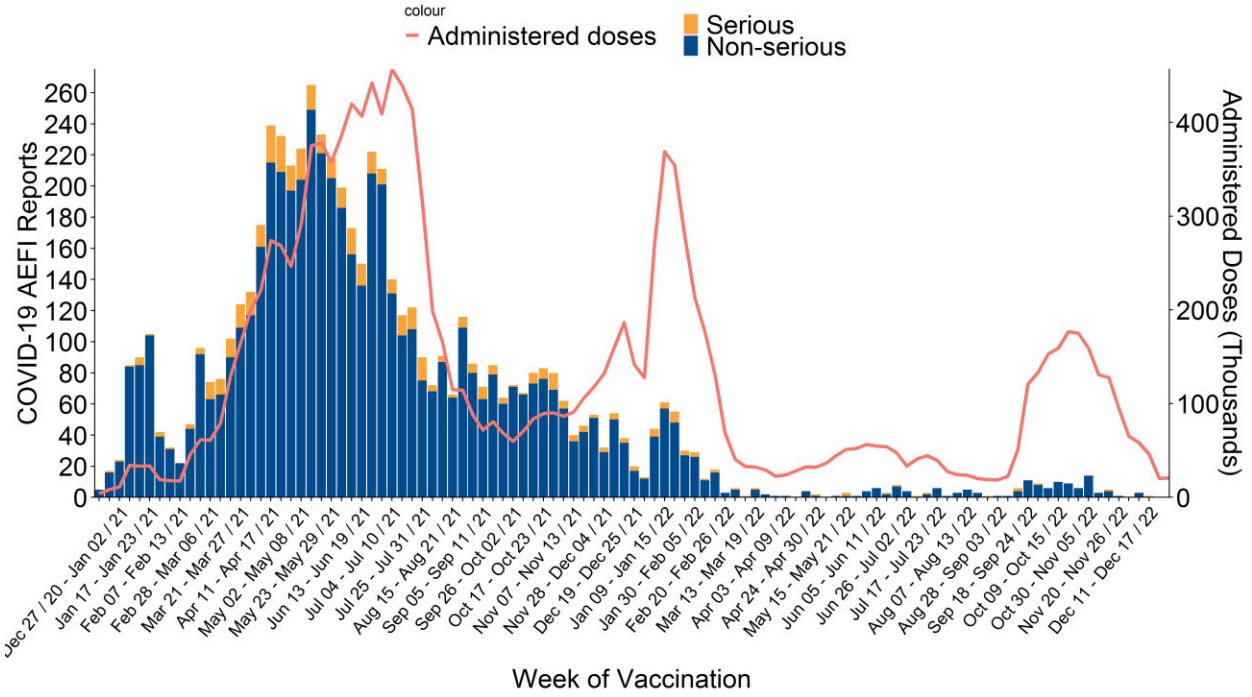
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of December 31, 2022, there have been 14,013,312 COVID-19 vaccine doses administered in BC and 6,101 COVID-19 AEFI reports (43.5 reports per 100,000 doses administered)
- 478 reports (7.8%) met the serious definition, for a rate of 3.4 per 100,000 doses administered
- The most frequently reported events were other allergic event, anaesthesia/paraesthesia, and injection site pain/swelling/redness
- Other events have been less frequently reported and are detailed below

Summary of AEFI Reports

Figure 1: Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Dec. 31, 2022 **(N=6,101)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including December 31, 2022, a total of 14,013,312 doses have been administered. During this period, there have been 6,101 AEFI reports following a COVID-19 vaccine, for a reporting rate of 43.5 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted, but Figure 1 shows that reports have declined as the immunization campaign has progressed, even as the doses administered have continued to increase. This is because the AEFI reporting rates associated with second, third, and fourth doses of COVID-19 vaccines administered have been substantially lower than the rate associated with the first dose.

Table 1: Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Dec. 31, 2022 **(N=6,101)**

	COVID-19 Vaccine*								
	All COVID-19 Vaccines	**Moderna Spikevax**	**Moderna Spikevax Bivalent**	**Moderna Spikevax Pediatric**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Bivalent**	**Pfizer-BioNTech Comirnaty Pediatric (6mo - 4yrs)**	**Pfizer-BioNTech Comirnaty Pediatric (5 - 11yrs)**	**Pfizer-BioNTech Comirnaty Pediatric Bivalent (5 - 11yrs)**
Total reports	**6101**	**2158**	**48**	**22**	**3423**	**16**	**0**	**56**	**0**
Non-serious reports	5623	2001	46	21	3157	14	0	51	0
Serious reports	478	157	2	1	266	2	0	5	0
Proportion serious	7.8%	7.3%	4.2%	4.5%	7.8%	12.5%	0.0%	8.9%	0.0%
Dose 1 reports	4124	1315	0	14	2416	0	0	37	0
Dose 2 reports	1477	561	0	2	865	0	0	15	0
Dose 3 reports	382	252	4	0	122	1	0	2	0
Dose 4 reports	77	24	34	0	12	7	0	0	0
Total doses administered	**14,013,312**	**3,928,555**	**939,143**	**59,430**	**7,570,466**	**610,802**	**102**	**447,645**	**1,134**
Recorded as Dose 1	4,578,990	933,298	3,560	39,850	3,059,911	8,531	86	214,415	62
Recorded as Dose 2	4,399,029	1,189,181	1,374	19,317	2,885,688	1,678	12	169,232	11
Recorded as Dose 3	2,961,163	1,477,298	30,876	142	1,346,431	39,144	4	63,754	1,051
Recorded as Dose 4	1,673,626	328,405	700,120	73	275,749	367,511	0	244	10
Total reporting rate	**43.5**	**54.9**	**5.1**	**37.0**	**45.2**	**2.6**	**0.0**	**12.5**	**0.0**
Serious rate	3.4	4.0	0.2	1.7	3.5	0.3	0.0	1.1	0.0
Dose 1 rate	90.1	140.9	0.0	35.1	79.0	0.0	0.0	17.3	0.0
Dose 2 rate	33.6	47.2	0.0	10.4	30.0	0.0	0.0	8.9	0.0
Dose 3 rate	12.9	17.1	13.0	0.0	9.1	2.6	0.0	3.1	0.0
Dose 4 rate	4.6	7.3	4.9	0.0	4.4	1.9	--	0.0	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Table 1 (continued): Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Dec. 31, 2022 **(N=6,101)**

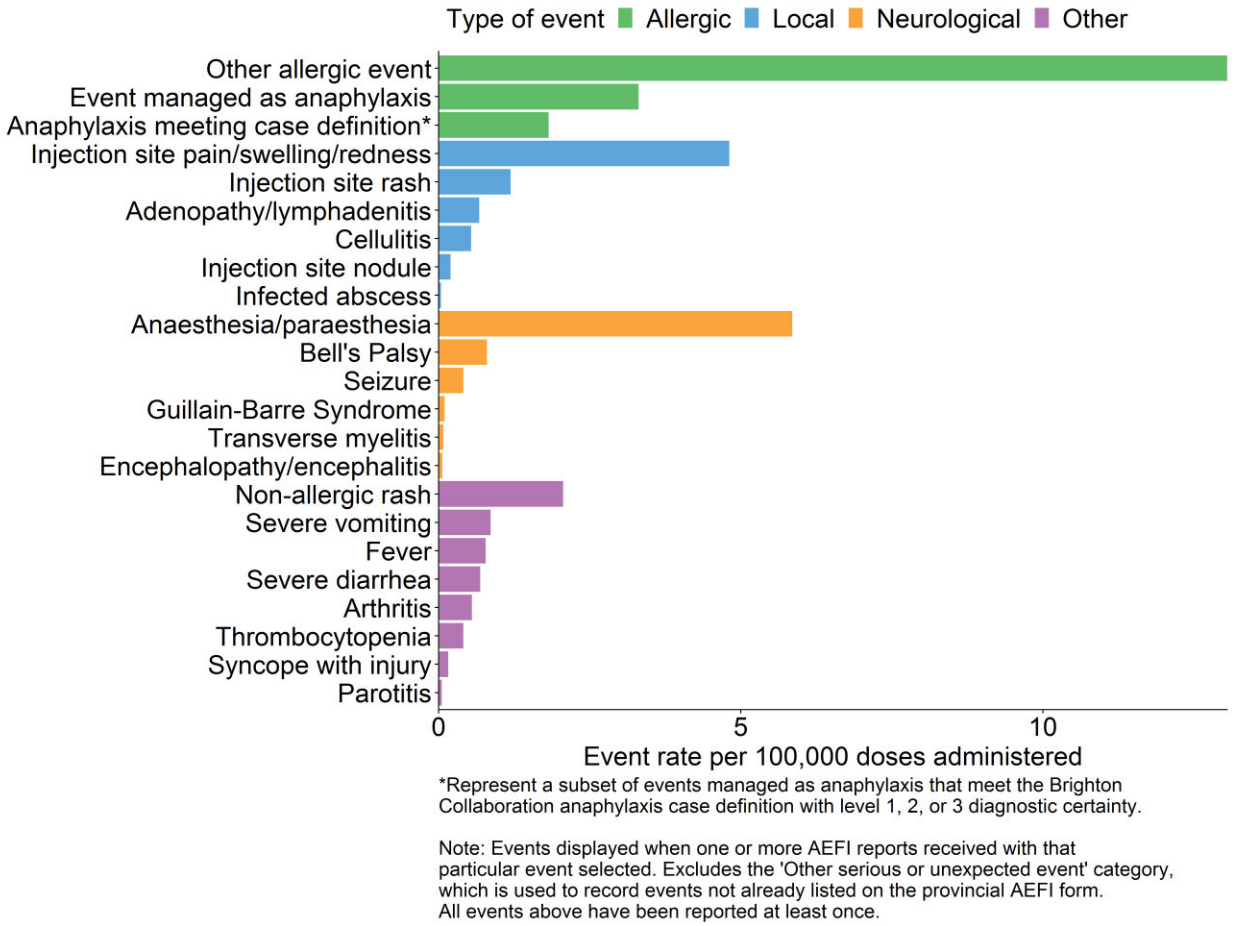
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**Verity COVISHIELD**	**AstraZeneca Vaxzevria**	**J&J Janssen**	**Novavax NUVAXOVID**
Total reports	**6101**	**74**	**287**	**15**	**2**
Non-serious reports	5623	68	251	13	2
Serious reports	478	6	36	2	0
Proportion serious	7.8%	8.1%	12.5%	13.3%	0%
Dose 1 reports	4124	72	256	12	2
Dose 2 reports	1477	2	30	2	0
Dose 3 reports	382	0	0	1	0
Dose 4 reports	77	0	0	0	0
Total doses administered	**14,013,312**	**90,669**	**345,294**	**13,057**	**7,012**
Recorded as Dose 1	4,578,990	71,190	233,558	12,258	2,270
Recorded as Dose 2	4,399,029	19,129	110,627	559	2,221
Recorded as Dose 3	2,961,163	343	1,066	205	849
Recorded as Dose 4	1,673,626	6	42	35	1,430
Total reporting rate	**43.5**	**81.6**	**83.1**	**114.9**	**28.5**
Serious rate	3.4	6.6	10.4	15.3	0.0
Dose 1 rate	90.1	101.1	109.6	97.9	88.1
Dose 2 rate	33.6	10.5	27.1	357.8	0.0
Dose 3 rate	12.9	0.0	0.0	487.8	0.0
Dose 4 rate	4.6	0.0	0.0	0.0	0.0

Note: Rates calculated per 100,000 doses administered. Doses administered are those recorded in the immunization registry and include vaccine receipt out of province. Doses recorded as 2 and higher may have been administered with a product different from that received for earlier doses.

Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 6,101 AEFI reports received up to December 31, 2022 contained a total of 7,769 adverse events for a ratio of 1.3 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), anaesthesia/paraesthesia, and events managed as anaphylaxis (Figure 2).

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Dec. 31, 2022 **(N=7,769)**



Event Descriptions

Four hundred sixty-four reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 255 (55%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[16] Many events managed as anaphylaxis have features more compatible with anxiety or vasovagal syncope/pre-syncopal (fainting) events.

Seventy-five reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis.[17] None of these reports were confirmed by microbial testing, therefore none meet criteria for level 1 of the Brighton case definition.

Four hundred seventy-eight reports (7.8%), including some of the events described above, were considered **serious** (refer to serious AEFI definition above). Of these, 448 individuals were admitted to hospital, including 2.8% of cases reported as anaphylaxis.

Two hundred and six reports contained a diagnosed neurological event. One hundred and twelve individuals experienced Bell's palsy within 30 days following COVID-19 vaccination. Six individuals were admitted to hospital and diagnosed with transverse myelitis, including one with a history of multiple sclerosis. An additional five individuals were reported as having transverse myelitis, however, one was unconfirmed by diagnostic imaging, one had a workup inconsistent with transverse myelitis, and another was referred to a specialist for further investigation. Fifty-eight individuals were reported with seizures (19% of whom were hospitalized). Four individuals were admitted to hospital for an intracerebral hemorrhage, including one with encephalopathy. Six additional individuals developed encephalitis or encephalopathy: one encephalitis was presumed to be viral in nature; one encephalopathy was attributed to a workplace toxin exposure; one individual with multiple chronic neurologic conditions developed encephalopathy presumed to be unrelated to the vaccine; two individuals with several comorbidities and encephalopathy made a spontaneous and full recovery within days, without a specific cause identified; one encephalitis was attributed to a new onset autoimmune condition diagnosed after receipt of vaccine. One individual was hospitalized for aseptic meningitis. There were fourteen reports for individuals hospitalized with Guillain-Barre Syndrome (GBS), now all discharged. Five of these reports followed AstraZeneca vaccine, six followed Pfizer-BioNTech Comirnaty, and three followed Moderna Spikevax. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.[14,18,19]

Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.[12] Readers will note that some of the reported deaths described below appear to have a clear cause of death unrelated to the vaccine. Death may also be recorded as the outcome of a specific reportable event. Twenty serious AEFI reports were received for individuals (median age: 78 years) who died within 30 days of receiving a COVID-19 vaccine.

- For five of the deaths, vaccination was not considered to be a contributing factor by the health care provider who attended and investigated the death and considered the individuals' medical history.
- One death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified.
- In six individuals, death was the outcome of cardiac arrest. Four of these were elderly individuals with underlying medical conditions; one had cardiac risk factors and was hospitalized for a myocardial infarction, and one had severe coronary artery disease that predated vaccine administration.
- Two deaths occurred in elderly individuals following a stroke and hospital admission. Both had previous history of stroke along with other medical conditions.
- One death occurred in an individual with metastatic cancer who had been hospitalized for complications of thrombocytopenia and hemolytic anemia.

- One death occurred in an elderly individual who suffered from multiple serious comorbidities. Investigation revealed the death was due to natural causes unrelated to the vaccine, but occurring in temporal association with vaccine receipt.
- One death occurred in an elderly individual with multiple comorbidities, whose health was declining before vaccine administration.
- One death occurred in an individual due to septic shock unrelated to the vaccine.
- Two deaths occurred in elderly individuals due to underlying cardiac compromise unrelated to the vaccine.

'Other serious or unexpected' events:
Some events may be reported as an "other serious or unexpected" event when these do not have their own discrete event on the provincial AEFI report form. These are outlined in this section; some of these events have been described above in the **serious events** section. Amongst these events, 190 were for various thrombotic/ thromboembolic conditions. These included 40 strokes (90% hospitalized) two cerebral venous sinus thromboses, 28 myocardial infarctions (92.9% hospitalized), 51 pulmonary emboli (58.9% hospitalized), 60 deep vein thromboses, and nine superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[10,11]

One "other serious" report was received for an individual with capillary leak syndrome with onset five weeks after AstraZeneca vaccine. Capillary leak syndrome is a very rare condition now recognized as potentially associated with the AstraZeneca vaccine. By June 2021 only six cases had been identified in Europe following over 78 million doses of AstraZeneca vaccine administered.[20] Health Canada issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.[21]

There have been six non-fatal confirmed cases of TTS reported in BC to date, four of whom were adults aged 30-49 and two were aged 60-69 years. The first had onset four days after receipt of the AstraZeneca vaccine with a low platelet count found upon presentation for care, and a diagnosis of pulmonary embolism. The second case had abdominal symptoms that progressed the week after receiving the AstraZeneca vaccine, with a diagnosis of abdominal venous thrombus and thrombocytopenia. The third case also had symptoms develop in the week after AstraZeneca vaccine. Upon presentation to care, thrombocytopenia was detected. The individual was assessed for possible TTS, and identification of an abdominal venous thrombus was made in hospital. All three of these individuals followed the first dose of AstraZeneca and had a positive anti-platelet factor 4 antibody test. The fourth individual suffered a stroke a week after the second dose of the AstraZeneca vaccine. Thrombocytopenia was identified in hospital; the anti-platelet factor 4 antibody test was negative. The fifth individual met the Brighton Collaboration criteria for TTS level 1-H because they had received heparin; this case also tested negative for the anti-platelet factor 4 antibody test. The sixth individual had onset 10 days after receipt of Janssen vaccine with a diagnosis of portal vein thrombosis; TTS was confirmed with anti-platelet factor 4 antibody testing.

Five serious AEFI reports in the 5-11 year age group have been reported. The first was for a new onset type 1 diabetes mellitus in a child with a strong familial history of this condition. Diabetes mellitus has not been shown to be associated with COVID-19 vaccines. People with diabetes are encouraged to get vaccinated because they are at higher risk of developing more severe COVID-19.[22] The second was for hospitalization due to immune thrombocytopenia purpura in a child recovering from an illness compatible with a viral respiratory infection before vaccination. Their platelet counts recovered and they were discharged from hospital. The third was for hospitalization following myo/pericarditis; this child was discharged with full resolution of symptoms. The fourth was for hospitalization following prolonged fever that coincided with a diagnosis of pneumonia; this child was treated and discharged. The fifth was a hospitalization for bloody stools that were attributed to a diagnosis of ulcerative colitis.

One serious AEFI report in the 6 months to 5 years age group has been reported. This was for hospitalization following febrile seizures. The temporal relationship of the seizure was more in keeping with a viral illness that onset after vaccine receipt, rather than with vaccine receipt. This child was discharged home after full resolution.[†]

There have been 231 reports of myocarditis/pericarditis. Sixty-eight individuals were diagnosed with myocarditis, 106 with pericarditis, and 57 with myopericarditis. Ages ranged from 10 to 95 with a median of 35 years, and 153 (66%) were male. Ninety-seven had received Moderna Spikevax, 126 received Pfizer-BioNTech Comirnaty, one received Pfizer-BioNTech Comirnaty Pediatric, and seven received AstraZeneca Vaxzevria/Verity COVISHIELD. One hundred and five of these events occurred after a second dose (47 Moderna Spikevax, 56 Pfizer-BioNTech Comirnaty, 1 Pfizer-BioNTech Comirnaty Pediatric, and 1 AstraZeneca Vaxzevria/Verity COVISHIELD). Twenty-one occurred after a third dose (16 Moderna Spikevax and 5 Pfizer-BioNTech Comirnaty), and one occurred after a fourth dose of Moderna. Some had alternate explanations including rheumatic diseases, a genetic syndrome associated with cardiac disorders, or viral infection. Sixty (out of 68) of the myocarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Forty-eight (out of 106) pericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition. Twenty-five (out of 57) myopericarditis cases met the diagnostic criteria for level 1, 2, or 3 of the Brighton Collaboration case definition for both myocarditis and pericarditis.[23] These conditions have been seen in association with the mRNA vaccines in several countries including the US and UK as well as in Canada, especially in adolescent and young adult males and with the 2nd dose.[5-7,14,24]

[†] In previous reports (September 29, 2022 through November 24, 2022), this child was erroneously described in the 5-11 year old age group instead of the 6 months to 5 years age group.

Table 2: Number of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Dec. 31, 2022 **(N=224)**

Vaccine/Age Groups	*Dose 1*	*Dose 2*	*Dose 3*	*Dose 4*	*All Doses*
Moderna Spikevax					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
12-17	0 (0%)	0 (0%)	1 (0.4%)	0 (0%)	1 (0.4%)
18-24	5 (2.2%)	14 (6.2%)	2 (0.9%)	0 (0%)	21 (9.4%)
25-29	10 (4.5%)	9 (4%)	3 (1.3%)	0 (0%)	22 (9.8%)
30-39	7 (3.1%)	10 (4.5%)	1 (0.4%)	0 (0%)	18 (8%)
40+	11 (4.9%)	14 (6.2%)	9 (4%)	1 (0.4%)	35 (15.6%)
All ages	33 (14.7%)	47 (21%)	16 (7.1%)	1 (0.4%)	97 (43.3%)
Pfizer-BioNTech Comirnaty					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.4%)
12-17	7 (3.1%)	10 (4.5%)	1 (0.4%)	0 (0%)	18 (8%)
18-24	7 (3.1%)	15 (6.7%)	2 (0.9%)	0 (0%)	24 (10.7%)
25-29	4 (1.8%)	4 (1.8%)	0 (0%)	0 (0%)	8 (3.6%)
30-39	19 (8.5%)	6 (2.7%)	0 (0%)	0 (0%)	25 (11.2%)
40+	28 (12.5%)	21 (9.4%)	2 (0.9%)	0 (0%)	51 (22.8%)
All ages	65 (29%)	57 (25.4%)	5 (2.2%)	0 (0%)	127 (56.7%)
mRNA Vaccines					
Under 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5-11	0 (0%)	1 (0.4%)	0 (0%)	0 (0%)	1 (0.4%)
12-17	7 (3.1%)	10 (4.5%)	2 (0.9%)	0 (0%)	19 (8.5%)
18-24	12 (5.4%)	29 (12.9%)	4 (1.8%)	0 (0%)	45 (20.1%)
25-29	14 (6.2%)	13 (5.8%)	3 (1.3%)	0 (0%)	30 (13.4%)
30-39	26 (11.6%)	16 (7.1%)	1 (0.4%)	0 (0%)	43 (19.2%)
40+	39 (17.4%)	35 (15.6%)	11 (4.9%)	1 (0.4%)	86 (38.4%)
All ages	98 (43.8%)	104 (46.4%)	21 (9.4%)	1 (0.4%)	224 (100%)

Total = 224 reports of myocarditis/pericarditis following an mRNA COVID-19 Vaccine (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from this table). Based on data reported to BCCDC (Panorama) up to and including December 31, 2022.

Table 3: Rates of Myo/Pericarditis reports following receipt of an mRNA COVID-19 vaccine, British Columbia, Dec. 13, 2020 - Dec. 31, 2022. Stratified by sex, age group, vaccine trade name, and dose **(N=224)**

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Moderna Spikevax	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	0 (0-0)	0 (0-0)	**958.8 (232.2-3536.8)**	0 (0-0)	221.6 (53.7-817.4)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
18-24	87.4 (35.5-191.5)	**284.9 (167.7-459.3)**	180.3 (55.8-502.3)	0 (0-0)	**184.9 (118.9-276.9)**	24.3 (5.9-89.5)	23.2 (5.6-85.7)	0 (0-0)	0 (0-0)	19.8 (6.1-55.1)
25-29	**161.2 (82.9-290.7)**	**157.3 (80.9-283.6)**	203.6 (74-490.4)	0 (0-0)	**164.4 (105.7-246.2)**	47.4 (14.7-132.2)	22 (5.3-81.3)	0 (0-0)	0 (0-0)	27.4 (9.9-65.9)
30-39	40.5 (16.5-88.8)	45.5 (20-93.1)	10.7 (2.6-39.3)	0 (0-0)	32.8 (18-56.1)	34.4 (12.5-82.8)	50.2 (22.1-102.9)	0 (0-0)	0 (0-0)	26.9 (13.8-48.5)
40+	28.4 (14.6-51.2)	17.7 (8.7-33.1)	7 (2.8-15.4)	6.9 (1.7-25.3)	14.4 (9.3-21.3)	10.6 (3.9-25.5)	17.7 (8.7-32.9)	7.8 (3.4-16)	0 (0-0)	10 (6.1-15.7)
All ages	48.2 (32.5-69.3)	**53.9 (38.4-73.7)**	15.9 (9-26.6)	6.7 (1.6-24.9)	**35.4 (28-44.2)**	19 (10.1-33.2)	23.5 (14.1-37.3)	6.4 (2.8-13)	0 (0-0)	13.7 (9.5-19.3)

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
Pfizer-BioNTech Comirnaty	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.4 (3.3-49.5)	0 (0-0)	0 (0-0)	5 (1.2-18.6)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	46 (21.6-89.4)	56.3 (27.8-105)	**19.1 (4.6-70.4)**	0 (0-0)	45.3 (27.2-72)	8 (1.9-29.5)	25 (9.1-60.3)	0 (0-0)	0 (0-0)	13.3 (5.4-29.2)
18-24	34 (15-69.6)	**63.7 (33.9-111.6)**	32 (9.9-89.1)	0 (0-0)	**45.4 (28.1-70.3)**	13.3 (4.1-37.2)	41.7 (19.6-81.1)	0 (0-0)	0 (0-0)	21.5 (11-38.7)
25-29	**25 (9.1-60.2)**	**17.5 (5.4-48.8)**	0 (0-0)	0 (0-0)	**17.2 (7.6-35.2)**	8.1 (2-29.9)	17 (5.3-47.4)	0 (0-0)	0 (0-0)	9.7 (3.5-23.4)
30-39	68.2 (42.2-105.5)	17.9 (7.3-39.3)	0 (0-0)	0 (0-0)	37 (24.1-54.9)	12.1 (4.4-29.1)	8.4 (2.6-23.4)	0 (0-0)	0 (0-0)	8.6 (3.8-17.5)
40+	14.3 (8.2-23.4)	15.4 (8.9-25.2)	2.7 (0.6-9.9)	0 (0-0)	11.8 (8-16.9)	16.4 (10.2-25.4)	9.9 (5.3-17.4)	2.3 (0.6-8.5)	0 (0-0)	10.6 (7.2-15)
All ages	26.8 (19.9-35.5)	**24 (17.3-32.6)**	6.1 (2.5-13.4)	0 (0-0)	**21.3 (17.2-26.2)**	13.5 (9-19.5)	13.8 (9.1-20.1)	1.3 (0.3-4.9)	0 (0-0)	10.9 (8.2-14.3)

Vaccine / Age Group	Reporting Rate* (95% CI)									
	Males					Females				
mRNA Vaccines	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Under 5	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
5-11	0 (0-0)	13.3 (3.2-49)	0 (0-0)	0 (0-0)	5 (1.2-18.3)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)
12-17	45.3 (21.2-88)	55.5 (27.4-103.5)	34.4 (10.6-95.8)	0 (0-0)	44.5 (27.1-69.7)	7.9 (1.9-29)	24.7 (9-59.4)	0 (0-0)	0 (0-0)	12.2 (4.9-26.7)
18-24	46.5 (24.8-81.5)	117.6 (78-171.6)	52.1 (21.1-114.1)	0 (0-0)	73.3 (52.8-99.5)	15.6 (5.7-37.7)	37.4 (18.5-69.8)	0 (0-0)	0 (0-0)	19.8 (10.9-33.8)
25-29	64.6 (36.4-108)	60.6 (33.3-103.5)	41 (14.9-98.8)	0 (0-0)	55.5 (37.4-79.9)	18.1 (6.6-43.5)	18.4 (6.7-44.3)	0 (0-0)	0 (0-0)	13.2 (6.2-25.7)
30-39	59.8 (38.9-88.7)	27 (14.4-47.3)	5.5 (1.3-20.4)	0 (0-0)	32.6 (22.9-45.2)	17.8 (8.3-34.6)	20.7 (10.2-38.7)	0 (0-0)	0 (0-0)	13.3 (7.8-21.5)
40+	17.8 (11.6-26.4)	16.2 (10.4-24.2)	5.2 (2.3-10.7)	1.6 (0.4-5.8)	11 (8.3-14.5)	15.1 (9.7-22.6)	12.3 (7.6-19)	5.5 (2.6-10.7)	0 (0-0)	8.9 (6.6-11.8)
All ages	31.9 (25.1-40)	32.8 (25.9-41.1)	10.9 (6.6-17)	1.3 (0.3-4.8)	23.2 (19.8-27)	14.6 (10.4-20.1)	16.4 (11.9-22.2)	3.8 (1.8-7.4)	0 (0-0)	10.4 (8.3-12.9)

* Rates calculated per 1 million doses administered. Based on data reported to BCCDC (Panorama) up to and including December 31, 2022. These rates were calculated from all reports of myocarditis/pericarditis submitted the BCCDC, without assessment against the Brighton Collaboration case definition (7 reports following AstraZeneca Vaxzevria/Verity COVISHIELD vaccine were omitted from the calculation of rates in this table).
Rates shown in bold represent a significant difference between products (Moderna Spikevax vs Pfizer-BioNTech Comirnaty) within the same sex and age group.

Table 3 interpretation:
The rates for myo/pericarditis following Moderna Spikevax in BC are higher than rates following Pfizer-BioNTech Comirnaty vaccine for the following sex, dose, and age groups:

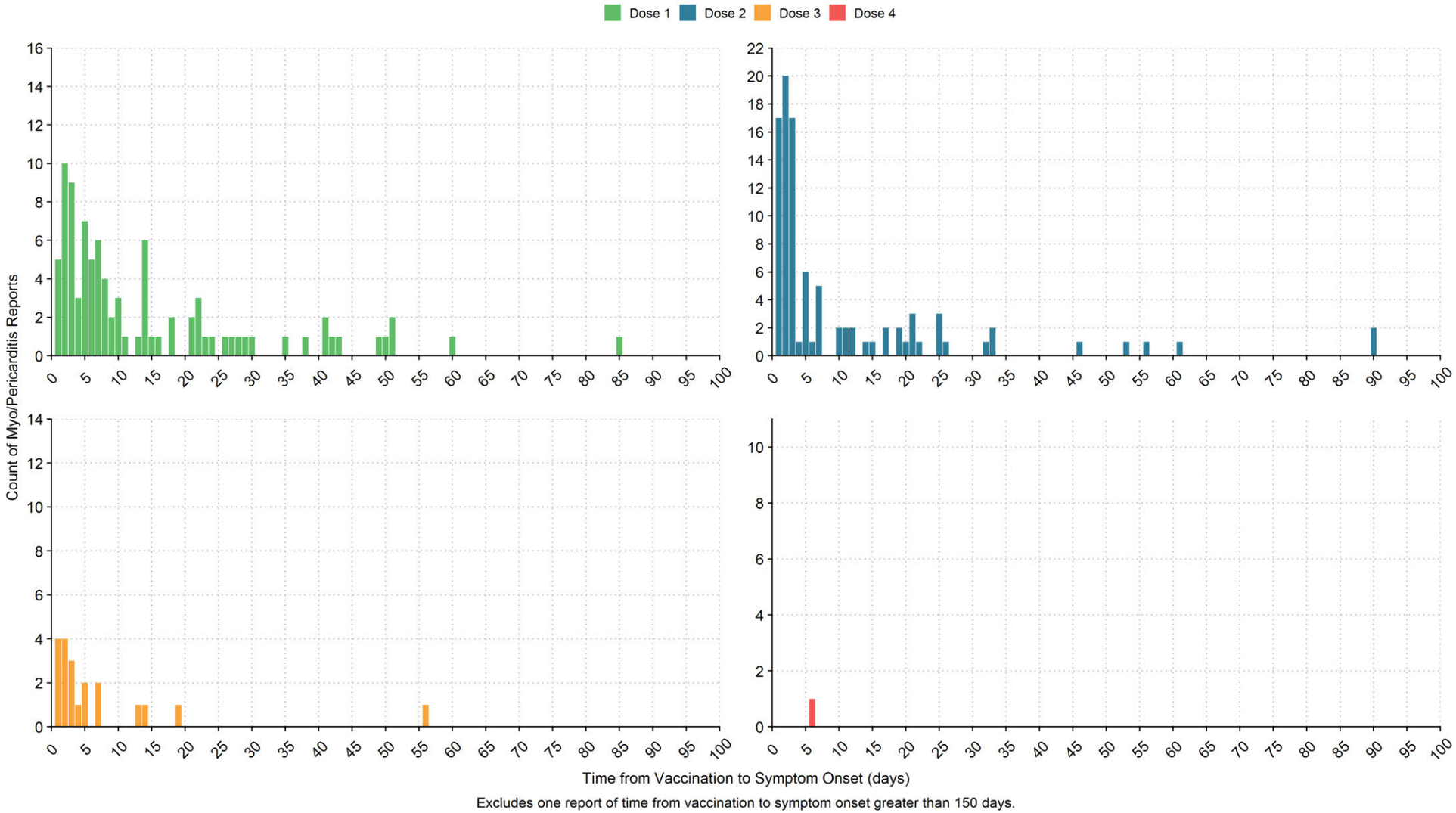
Males:

- 12-17 year olds: Dose 3 - However this is based on a single report in relation to only 1088 doses administered. This rate should be interpreted with caution.
- 18-24 years old: Dose 2 and all doses combined
- 25-29 years old: Doses 1, 2, and all doses combined
- All ages combined: Dose 2 and all doses combined

Females:

- None showed a statistically significant difference between products.

Figure 3: Time from Vaccination to Symptom Onset of Myo/Pericarditis Reports, British Columbia, Dec. 13, 2020 - Dec. 31, 2022 **(N=224)**



Excludes one report of time from vaccination to symptom onset greater than 150 days.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on January 4, 2023. Only AEFIs reported and doses administered up to December 31, 2022 were included in this report. Any AEFI report with a status of “Does not meet reporting criteria” or “Disregard - Entered in error” was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress, there may be changes to the data, or reports may be removed from analysis if events upon review are deemed not reportable (e.g., expected local reaction). This may lead to some fluctuations in AEFI counts and rates in subsequent reporting periods.

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From: Amos, Heather [BCCDC]
To: MNDS.Assist [BCCDC]
Cc: Dalati, Hadi [BCCDC]; Naus, Monika [BCCDC]
Subject: RE: Monthly COVID-19 AEFI Report
Date: Thursday, January 05, 2023 4:54:04 PM

Hi Jess,
Sorry for the delay. I think it's okay to move ahead with these reports as per usual processes unless there is anything significant/new.
Heather

From: Taylor, Jessica [BCCDC] <Jessica.Taylor@bccdc.ca> **On Behalf Of** MNDS.Assist [BCCDC]
Sent: Thursday, January 05, 2023 3:10 PM
To: Amos, Heather [BCCDC] <heather.amos@bccdc.ca>
Cc: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>; MNDS.Assist [BCCDC] <mnds.assist@bccdc.ca>; Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: FW: Monthly COVID-19 AEFI Report
Hi Heather,
Permission to post the following below to the website?
This is a reoccurring report that we update every 4 weeks, since it's merely an updated report that we post, do you think it would be possible to get a blanket reoccurring permission for us to simply post this monthly report? If there were any other changes we wanted to make we would of course ask for permission first?
Thanks
Jess

Jessica Taylor
(Mon-Thurs) Admin Assistant Dr. Monika Naus, Medical Director, Immunization Program Vaccine Preventable Diseases
BC Centre for Disease Control / Provincial Health Services Authority

From: Dalati, Hadi [BCCDC] <hadi.dalati@bccdc.ca>
Sent: Thursday, January 05, 2023 2:04 PM
To: MNDS.Assist [BCCDC] <mnds.assist@bccdc.ca>; Taylor, Jessica [BCCDC] <Jessica.Taylor@bccdc.ca>
Cc: Naus, Monika [BCCDC] <Monika.Naus@bccdc.ca>
Subject: Monthly COVID-19 AEFI Report
Hi Jess,
Please find attached the newest Monthly COVID AEFI report to be posted here:
http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccine-safety
Under "B.C.'s Reports on Adverse Events".
Also, you wanted me to remind you to remove the note that says: "The next report will be available the first week of January 2023." from
http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccine-safety#aefi
Thank you very much,

Hadi Dalati, MPH (he/his)
Communicable Disease Epidemiologist
Immunization Programs and Vaccine Preventable Diseases Service

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I respectfully acknowledge my place of work is within the ancestral, traditional and unceded territory of the Coast Salish peoples, including the territories of the xʷməθkwəy̓ əm (Musqueam), Skwxwú7mesh (Squamish), and Səl ̓ílwətaʔ/Selilwitulh (TsleilWaututh) Nations.

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