

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

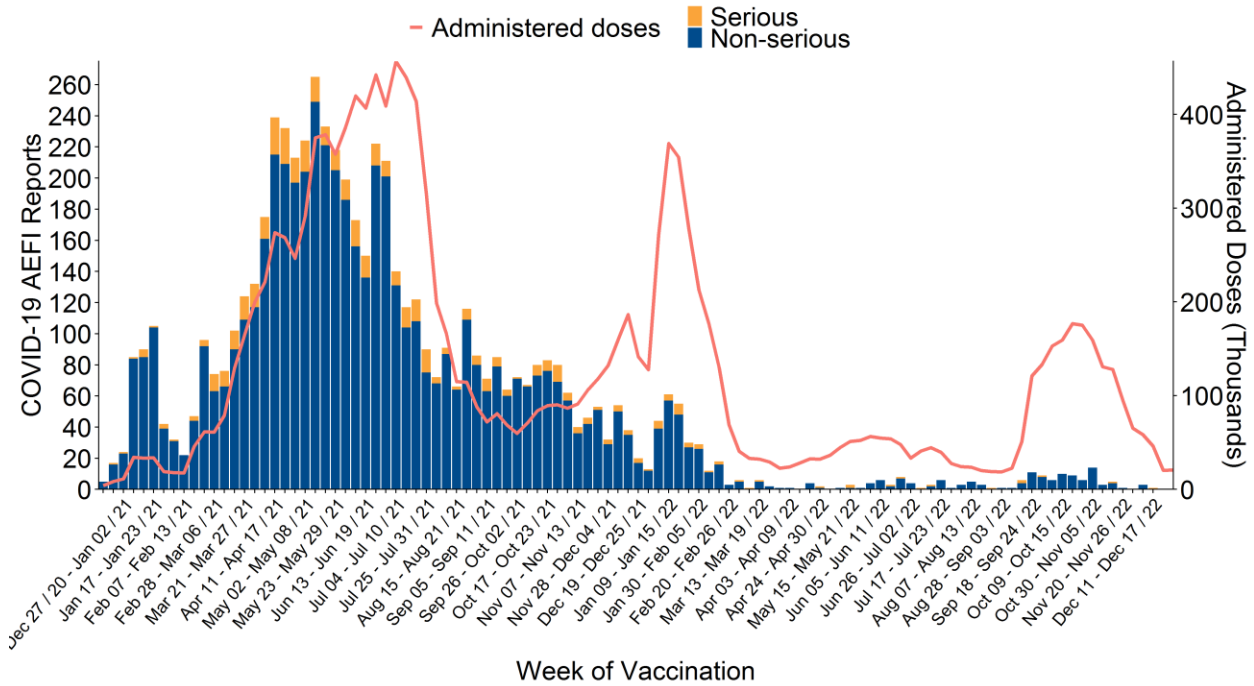
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.¹⁵
2. **Serious AEFI** - For the purpose of this report, 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)

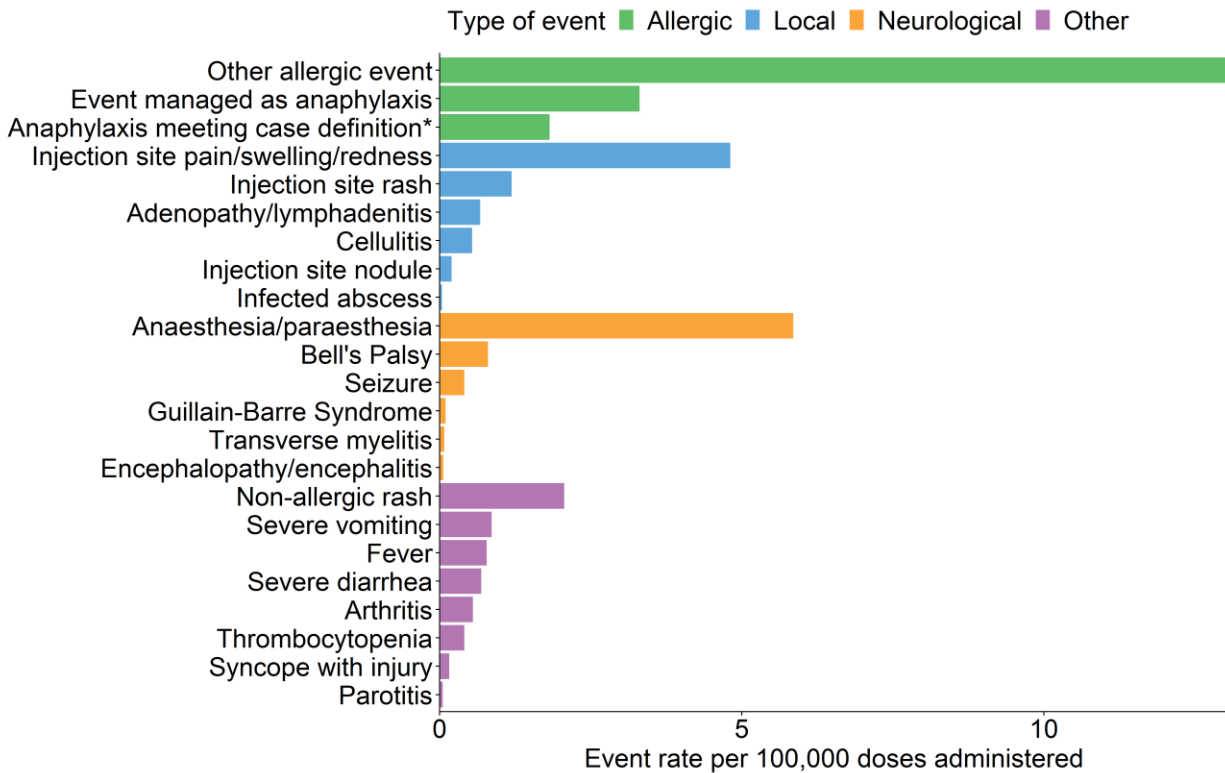
	COVID-19 Vaccine*				
	All COVID-19 Vaccines	Verity COVISHIELD	AstraZeneca Vaxzevria	J&J Janssen	Novavax NUVAXOVID
Total reports	6101	74	287	15	2
Non-serious reports	5623	68	251	13	2
Serious reports	478	6	36	2	0
Proportion serious	7.8%	8.1%	12.5%	13.3%	0%
Dose 1 reports	4124	72	256	12	2
Dose 2 reports	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)



*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 serious 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

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)

<i>Vaccine/Age Groups</i>	<i>Dose 1</i>	<i>Dose 2</i>	<i>Dose 3</i>	<i>Dose 4</i>	<i>All Doses</i>
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				
	Dose 1	Dose 2	Dose 3	Dose 4	All doses	Dose 1	Dose 2	Dose 3	Dose 4	All doses
Moderna Spikevax										
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:

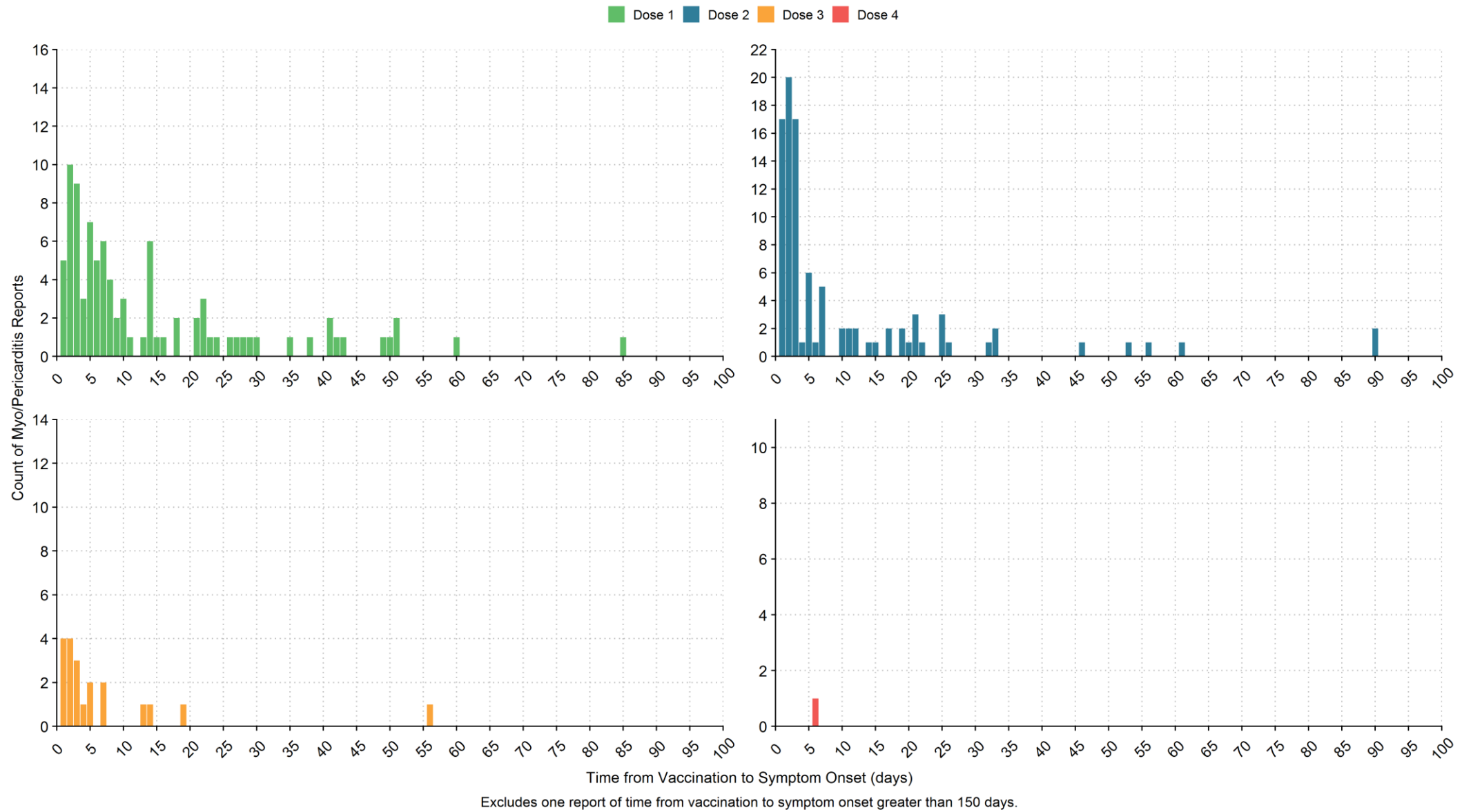
Males:

- 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)



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.

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>
3. 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>
4. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Weekly summary: adverse events following immunization (AEFIs) for COVID-19 in Ontario [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 Apr 7]. Available from: <https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-aefi-report.pdf?la=en>
5. World Health Organization. COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) reviews cases of mild myocarditis reported with COVID-19 mRNA vaccines [Internet]; 2021 [cited 2021 Jun 2]. Available from: <https://www.who.int/news/item/26-05-2021-gacvs-myocarditis-reported-with-covid-19-mrna-vaccines>
6. Centers for Disease Control and Prevention. Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination [Internet]; 2021 [cited 2021 Jun 2]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html>
7. Shimabukuro, T. Update on COVID-19 vaccine safety, including myocarditis after mRNA vaccines. Presentation to the US Advisory Committee on Immunization Practices. June 23, 2021 [Internet]; 2021 [cited 2021 Jun 30]. Available from: <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-06.html>
8. Government of the United Kingdom. Medicines & Healthcare Products Regulatory Agency. Coronavirus vaccine - weekly summary of Yellow Card reporting. [Internet]; 2021 [cited 2021 Aug 5]. Available from: <https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting>
9. European Medicines Agency. Meeting Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 5-8 July 2021. [Internet]; 2021 [cited 2021 Aug 19]. Available from: <https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-5-8-july-2021>

10. Greinacher A, Thiele T, Warkentin TE, Weisser K, Kyrle PA, Eichinger S. Thrombotic thrombocytopenia after ChAdOx1 nCov-19 vaccination. *N Engl J Med*. 2021. Available from: <https://www.nejm.org/doi/full/10.1056/NEJMoa2104840>
11. Brighton Collaboration. Case finding definition of thrombosis with thrombocytopenia syndrome (TTS) v9.0 [Internet]; 2021 [cited 2021 Apr 21]. Available from: <https://brightoncollaboration.us/thrombosis-with-thrombocytopenia-syndrome-case-finding-definition/>
12. BC Centre for Disease Control. Communicable disease control manual. Chapter 2: Immunization. Part 5 - Adverse events following immunization [Internet]; 2019 [cited 2021 Mar 23]. Available from: http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Epid/CD%20Manual/Chapter%202%20-%20Imms/Part_5_AEFI.pdf
13. Government of Canada. Canadian adverse events following immunization surveillance system (CAEFISS) [Internet]; 2019 [cited 2021 Mar 23]. Available from: <https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html>
14. Government of Canada. Reported side effects following COVID-19 vaccination in Canada [Internet]; 2021 [cited 2021 Mar 23]. Available from: <https://health-infobase.canada.ca/covid-19/vaccine-safety/>
15. Council for International Organizations of Medical Sciences (CIOMS). Definition and application of terms for vaccine pharmacovigilance [Internet]. Geneva, Switzerland: WHO Press; 2012 [cited 2021 Mar 23]. Available from: https://vaccine-safety-training.org/tl_files/vs/pdf/report-of-cioms-who-working-group.pdf
16. Ruggeberg JU, Gold MS, Bayas J-M, Blum MD, Bonhoeffer J, Friedlander S, et al. Anaphylaxis: case definition and guidelines for data collection, analysis, and presentation of immunization safety data. *Vaccine*. 2007;25(31):5675-84. Available from: <https://doi.org/10.1016/j.vaccine.2007.02.064>
17. Blumenthal KG, Freeman EE, Staff RR, Robinson LB, Wolfson AR, Foreman RK, et al. Delayed large local reactions to mRNA-1273 vaccine against SARS-CoV-2. *N Eng J Med*. 2021;384(13). Available from: <https://www.nejm.org/doi/full/10.1056/NEJMc2102131>
18. Patel SU, Khurram R, Lakhani A, Quirk B. Guillain-Barre syndrome following the first dose of the chimpanzee adenovirus-vectored COVID-19 vaccine, ChAdOx1. *BMJ Case Rep*. 2021;14:e242956. Available from: <https://casereports.bmj.com/content/bmjcr/14/4/e242956.full.pdf>
19. Waheed S, Bayas A, Hindi F, Rizvi Z, Espinosa PS. Neurological complications of COVID-19: Guillain-Barre Syndrome following Pfizer COVID-19 vaccine. *Cureus*. 2021;13(2):e13426. Available from: <https://www.cureus.com/articles/52295-neurological-complications-of-covid-19-guillain-barre-syndrome-following-pfizer-covid-19-vaccine>
20. European Medicines Agency. Vaxzevria: EMA advises against use in people with history of capillary leak syndrome [Internet]; 2021 [cited 2021 Jun 23]. Available from: <https://www.ema.europa.eu/en/news/vaxzevria-ema-advises-against-use-people-history-capillary-leak-syndrome>

21. Health Canada. AstraZeneca COVID-19 vaccine and COVIDSHIELD: risk of capillary leak syndrome [Internet]; 2021 [cited 2021 Jun 30]. Available from: <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75947a-eng.php>
22. BC Centre for Disease Control. Risk Factors for Severe COVID-19 Disease [Internet]; 2021 [cited 2022 Jan 27]. Available from: <http://www.bccdc.ca/health-professionals/clinical-resources/covid-19-care/clinical-care/risk-factors-severe-covid-19-disease>
23. Brighton Collaboration. Draft myocarditis case definition (version_1.4.2_30.May.2021) [Internet]; 2021 [cited 2021 Jun 2]. Available from: <https://brightoncollaboration.us/myocarditis-case-definition-update/>
24. Buchan S, Seo C, Johnson C, Alley S, Kwong J, Nasreen S et al. Epidemiology of Myocarditis and Pericarditis Following mRNA Vaccination by Vaccine Product, Schedule, and Interdose Interval Among Adolescents and Adults in Ontario, Canada. JAMA Network Open. 2022;5(6):e2218505. Available from: <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793551>