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

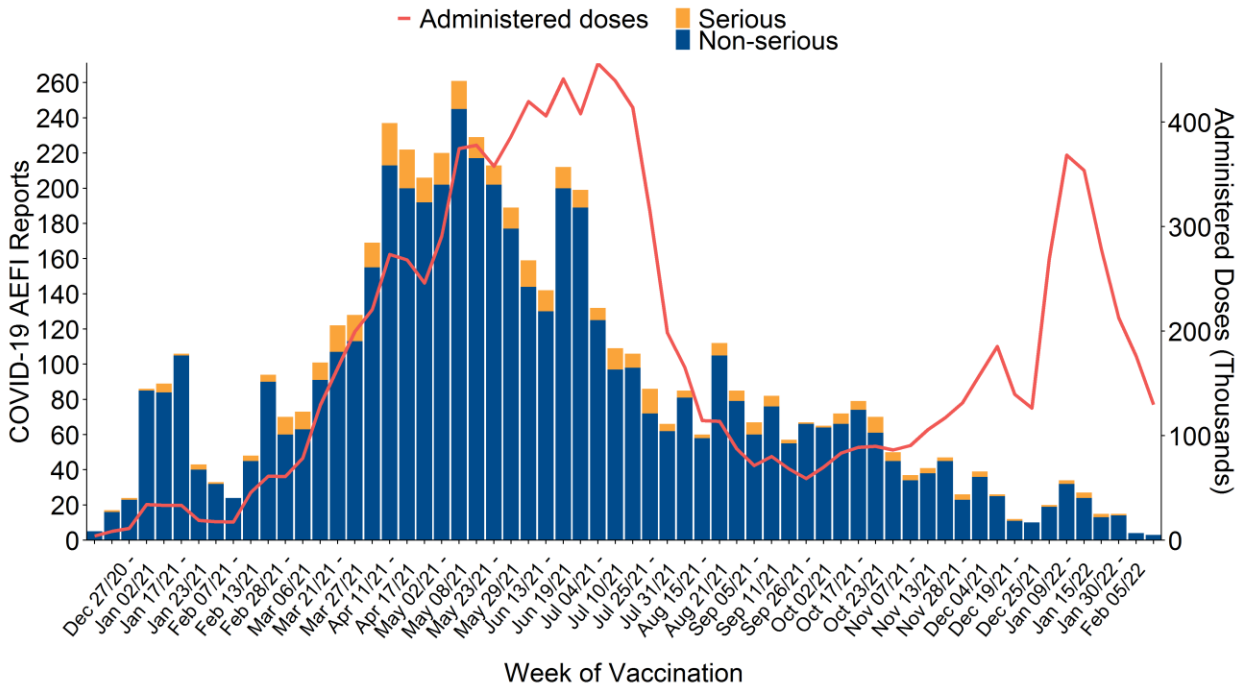
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[15]
2. **Serious AEFI** - For the purpose of this report,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

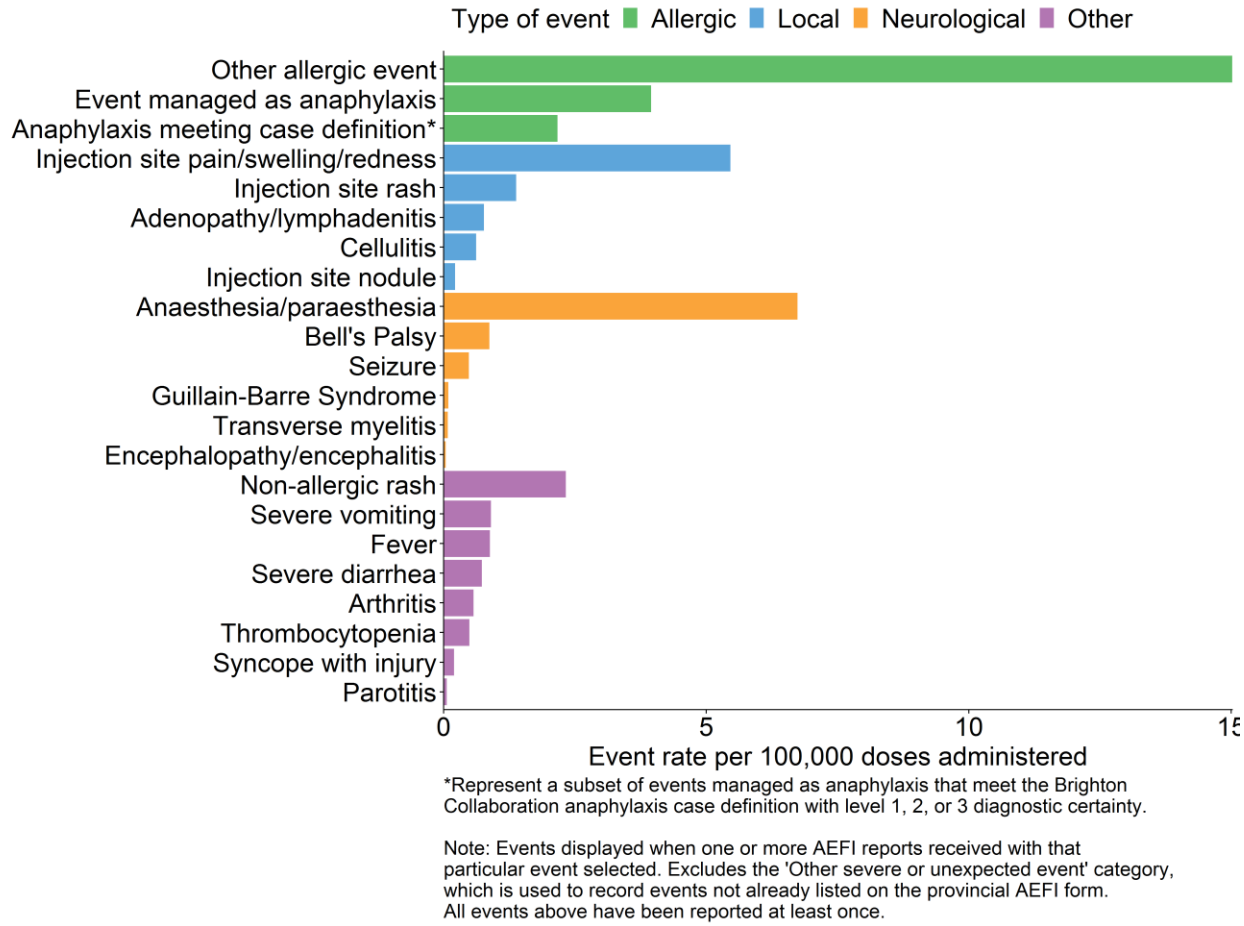
		COVID-19 Vaccine*					
	All COVID-19 Vaccines	**AstraZeneca Vaxzevria**	**Verity COVISHIELD**	**J&J Janssen**	**Moderna Spikevax**	**Pfizer-BioNTech Comirnaty**	**Pfizer-BioNTech Comirnaty Pediatric**
Total reports	**5527**	**282**	**71**	**9**	**1943**	**3200**	**22**
Non-serious reports	5124	247	65	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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