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

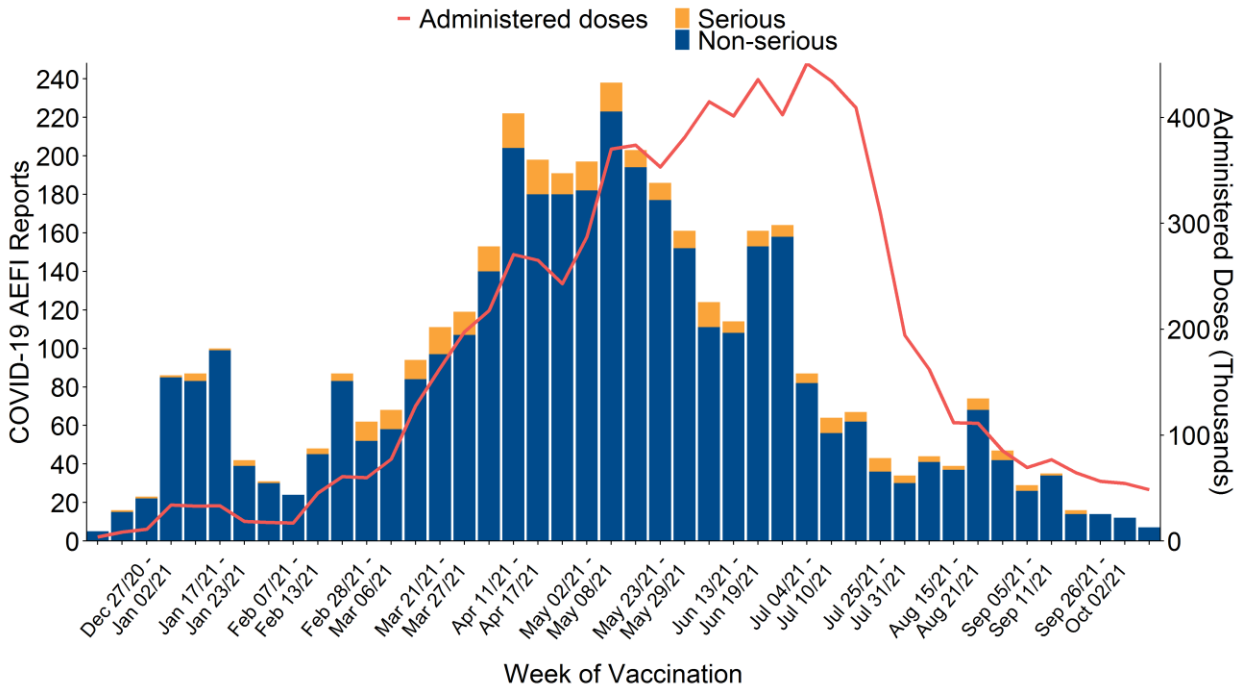
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[13]
2. **Serious AEFI** - For the purpose of this report, 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)**

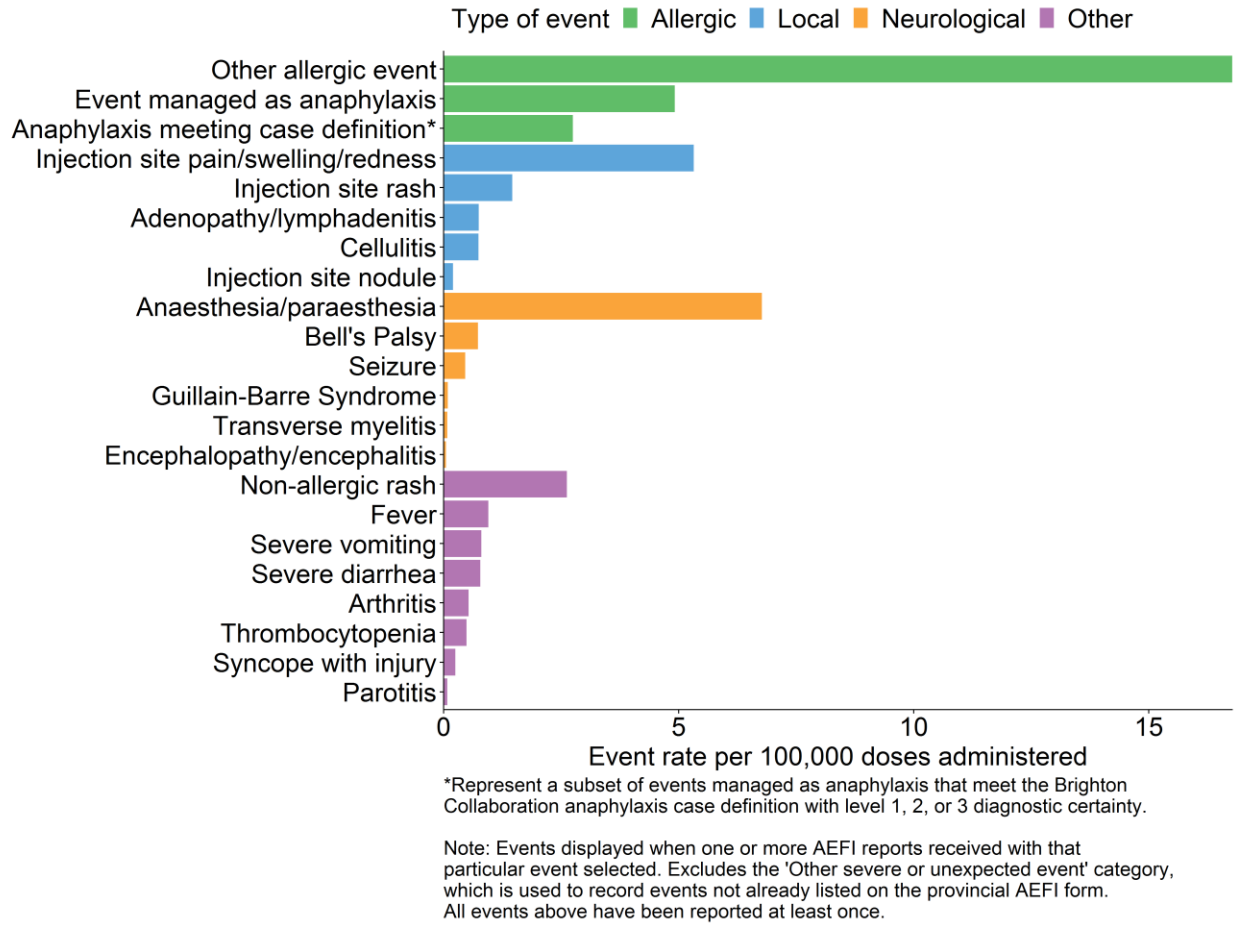
		COVID-19 Vaccine*			
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**3927**	**257**	**67**	**1297**	**2306**
Non-serious reports	3651	228	61	1213	2149
Serious reports	276	29	6	84	157
Proportion serious	7%	11.3%	9%	6.5%	6.8%
Dose 1 reports	3145	233	66	1009	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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