

## 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.<sup>1</sup> 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.<sup>2-4</sup> 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-syncope (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.<sup>5-7</sup>

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.<sup>8,9</sup>

#### 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](#).<sup>10</sup> 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.<sup>11</sup> The Public Health Agency of Canada also produces a weekly [COVID-19 AEFI report](#).<sup>12</sup>

## Definitions

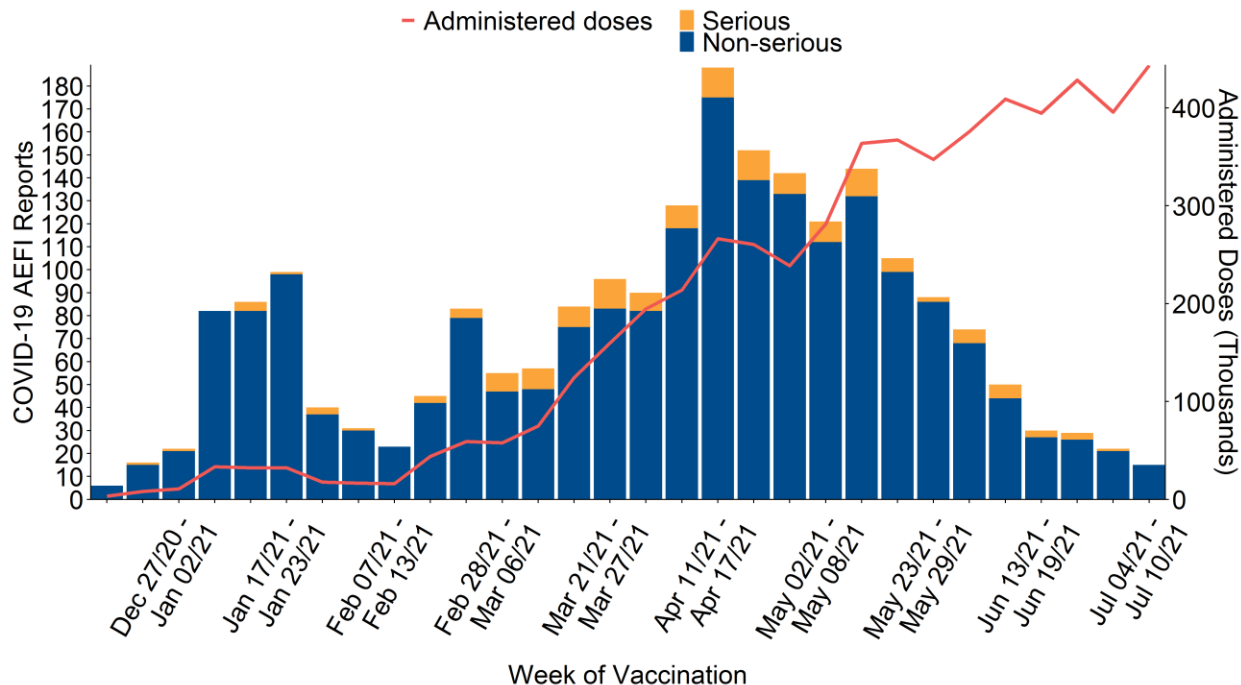
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.<sup>13</sup>
2. **Serious AEFI** - For the purpose of this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

**Table 1:** Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec. 13, 2020 - Jul. 10, 2021 (N=2,203)

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	AstraZeneca	COVISHIELD	Moderna	Pfizer
<b>Total reports</b>	<b>2,203</b>	<b>198</b>	<b>59</b>	<b>656</b>	<b>1,289</b>
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%

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	AstraZeneca	COVISHIELD	Moderna	Pfizer
Dose 1 reports	1,965	193	59	576	1,136
Dose 2 reports	237	5	0	80	152
<b>Total doses administered</b>	<b>5,671,624</b>	<b>314,593</b>	<b>67,423</b>	<b>1,350,178</b>	<b>3,939,251</b>
Dose 1 administered	3,782,932	217,261	59,771	819,059	2,686,666
Dose 2 administered	1,888,692	97,332	7,652	531,119	1,252,585
<b>Total reporting rate</b>	<b>38.8</b>	<b>62.9</b>	<b>87.5</b>	<b>48.6</b>	<b>32.7</b>
Serious rate	2.8	5.7	7.4	3.3	2.3
Dose 1 rate	51.9	88.8	98.7	70.3	42.3
Dose 2 rate	12.5	5.1	0.0	15.1	12.1

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 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.

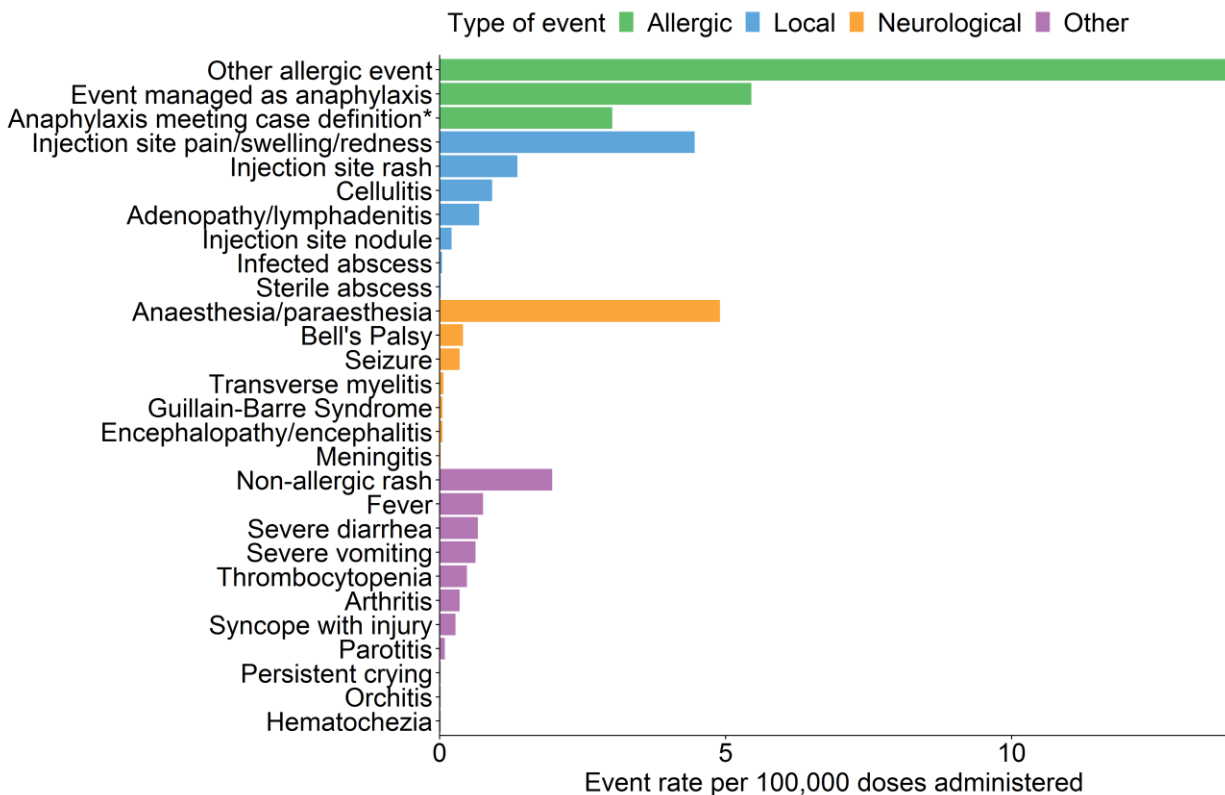
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.<sup>10</sup> Death may also be recorded as the outcome of a specific reportable event. Fourteen serious AEFI reports were received for individuals who died within 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)



\*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 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.<sup>14</sup> Upon further review of these reports, many may reflect events such as anxiety or pre-syncope (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.<sup>15</sup> 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.<sup>12,16,17</sup> 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.<sup>18</sup>

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.<sup>7,8</sup>

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.<sup>8,9</sup>

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.<sup>19</sup> Health Canada has issued an advisory for this condition and its association with AstraZeneca/COVISHIELD vaccines.<sup>20</sup>

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.<sup>21</sup> 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.<sup>5-7,12</sup>

## 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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