

## British Columbia Report

### Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to April 10, 2021

This report summarizes the reports of COVID-19 vaccine adverse events following immunization (AEFI) reported to the BC Centre for Disease Control up to and including April 10, 2021. Please refer to the [BCCDC website](#) for reporting guidelines.<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 the reports received in BC to date. These results are in keeping with observed events elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of the vaccines in clinical trials prior to authorization for use.<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 and reported as anaphylaxis out of an abundance of caution. Serious events have not been reported at rates higher than expected compared to background rates.

#### Background

AEFIs are reportable by health care providers to the local medical health officer under the regulations of the Public Health Act. Detailed reporting guidelines are available in the [BC Immunization Manual](#).<sup>5</sup> When an AEFI report is received at a local public health unit, it is reviewed and recorded in the public health information system aligned with the immunization registry which contains the information about the vaccine(s) administered on a specific date. Recommendations for further assessment and future doses are made by the medical health officer or designated public health professional. Expected side effects such as pain, redness, and swelling at the injection site which are commonly observed with many vaccines are not reportable as AEFI unless these meet specific severity thresholds.

AEFI reports are further investigated provincially with particular focus on serious AEFI and detection of potential safety signals (e.g., clusters of events, event rates occurring at a higher than expected frequency compared to background rates, or rare events with previously unknown association with vaccination). Additionally, BC submits AEFI reports to the [Canadian Adverse Event Following Immunization Surveillance System](#) where additional review and analysis for potential safety signals is performed at the national level.<sup>6</sup> The Public Health Agency of Canada also produces a weekly [COVID-19 AEFI report](#).<sup>7</sup>

## Definitions

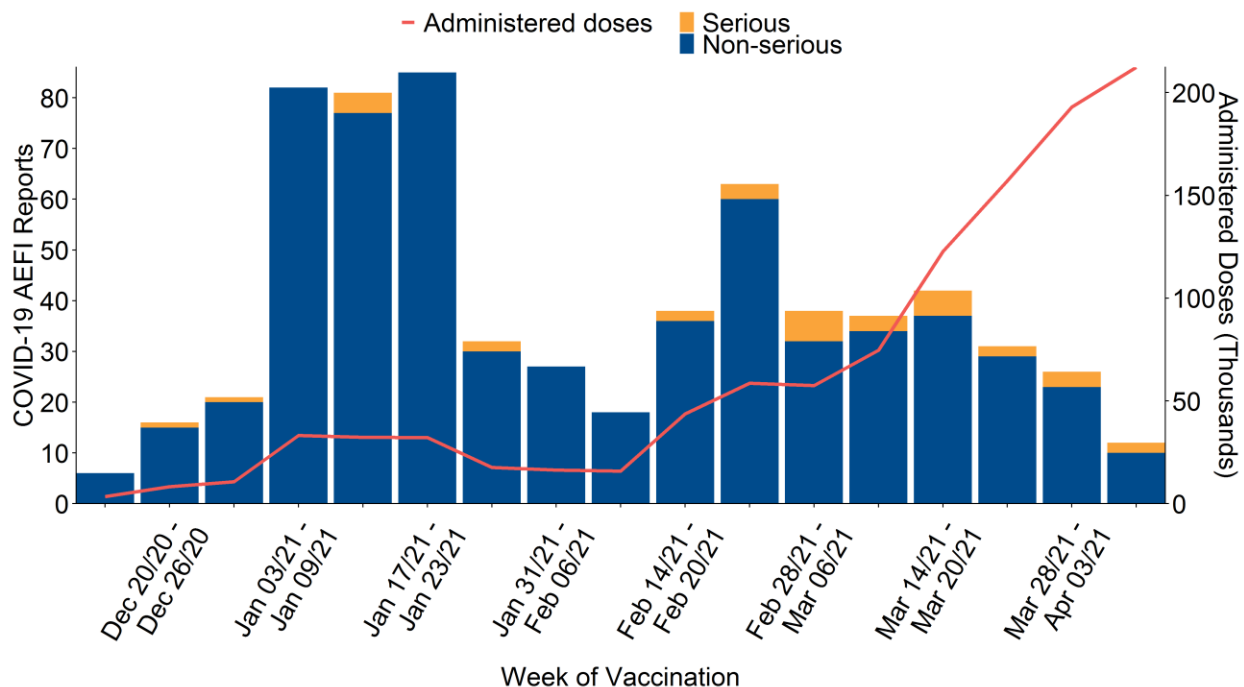
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.<sup>8</sup>
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

## Key Findings

- As of April 10, 2021, there have been 1,089,393 COVID-19 vaccine doses administered in BC and 655 COVID-19 AEFI reports (60.1 reports per 100,000 doses administered)
- 34 reports (5.2%) met the serious definition, for a rate of 3.1 per 100,000 doses administered
- The most frequently reported events were other allergic event, event managed as anaphylaxis, and injection site pain/swelling/redness

## Summary of AEFI Reports

**Figure 1:** Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec.13, 2020 - Apr.10, 2021 (N=655)



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including April 10, 2021, a total of 1,089,393 doses have been administered. During this period, there have been 655 AEFI reports following a COVID-19 vaccine, for a reporting rate of 60.1 reports per 100,000 doses administered (Table 1). Reports are delayed beyond the week of

vaccination because of time to onset that varies by event and associated time to receive, investigate and process a report for submission. Weekly report counts, especially for recent weeks, are expected to increase over time as these are submitted.

**Table 1:** Description of adverse event reports following receipt of a COVID-19 vaccine, BC, Dec.13, 2020 - Apr.10, 2021 (N=655)

	COVID-19 Vaccine				
	All COVID-19 Vaccines	AstraZeneca	COVISHIELD	Moderna	Pfizer
<b>Total reports</b>	<b>655</b>	<b>0</b>	<b>17</b>	<b>253</b>	<b>385</b>
Non-serious reports	621	0	15	241	365
Serious reports	34	0	2	12	20
Proportion serious	5.2%	0.0%	11.8%	4.7%	5.2%
Dose 1 reports	566	0	17	227	322
Dose 2 reports	89	0	0	26	63
<b>Total doses administered</b>	<b>1,089,393</b>	<b>31,240</b>	<b>53,941</b>	<b>191,787</b>	<b>812,425</b>
Dose 1 administered	1,001,582	31,240	53,941	174,434	741,967
Dose 2 administered	87,811	0	0	17,353	70,458
<b>Total reporting rate</b>	<b>60.1</b>	<b>0.0</b>	<b>31.5</b>	<b>131.9</b>	<b>47.4</b>
Serious rate	3.1	0.0	3.7	6.3	2.5
Dose 1 rate	56.5	0.0	31.5	130.1	43.4
Dose 2 rate	101.4	--	--	149.8	89.4

Note: Rates calculated per 100,000 doses administered

### Serious Reports

Thirty-four reports (5.2%) were considered serious (refer to serious AEFI definition above). Of these, 30 individuals were admitted to hospital. These included thirteen individuals hospitalized after anaphylaxis or other allergic event, eleven for neurological investigations/monitoring (including two for transverse myelitis, two for seizures, one stroke, one encephalitis/hemorrhage, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), four for chest pain/cardiac events, one respiratory distress, and one for a pregnancy related complication.

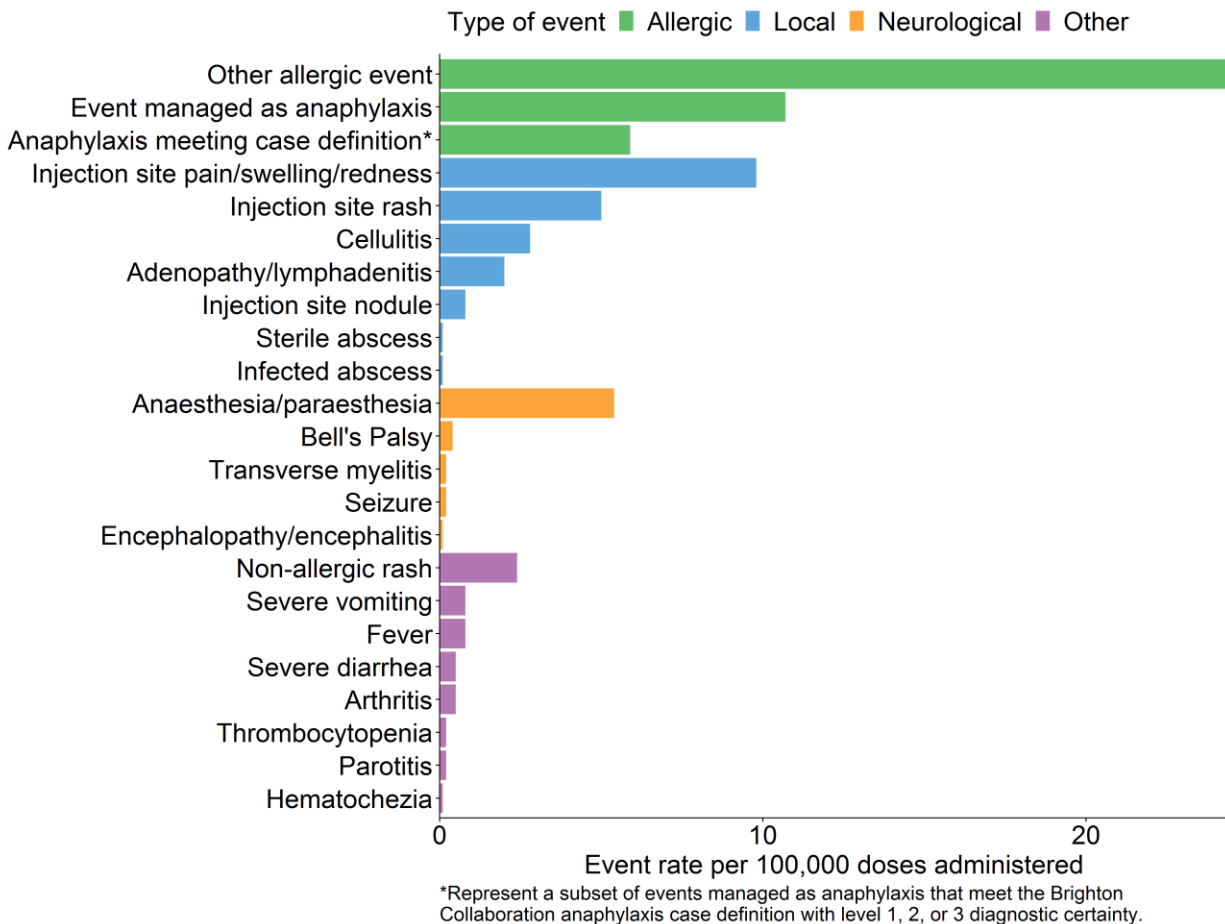
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.<sup>5</sup> Death may also be recorded as the outcome of a specific reportable event. Four serious AEFI reports were received for individuals who died within 30 days of receiving a COVID-19 vaccine. For two of the deaths, vaccination was not considered to be a contributing factor by health care providers who attended and investigated the death based off of the individuals' medical history. The third death was the outcome of a

cardiac event that occurred in an elderly individual with multiple underlying medical conditions. The fourth death also occurred in an elderly individual with underlying medical conditions but was still being investigated at the time of this report.

### Summary of Reported Events

A single AEFI report may contain one or more adverse events. Reported events are temporally associated with vaccination (i.e., occur after vaccination within a biologically plausible timeframe) but not necessarily causally associated. The 655 AEFI reports received up to April 10, 2021 contained a total of 899 adverse events for a ratio of 1.4 events per COVID-19 AEFI report. The most frequently reported events were other allergic events (e.g., allergic rash, hives, pruritus, and gastrointestinal symptoms), events managed as anaphylaxis, and injection site pain/swelling/redness (Figure 2). Of the events managed as anaphylaxis, roughly half met the Brighton Collaboration anaphylaxis case definition with level 1, 2, or 3 diagnostic certainty.<sup>9</sup>

**Figure 2:** Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 - Apr.10, 2021 (N=899)



### Event Descriptions

One hundred seventeen reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 64 (55%) met the

Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.<sup>9</sup> Upon further review of these reports, many may reflect events such as anxiety or pre-syncope (fainting) events.

Thirty reports of cellulitis were received. Although most of these reports specified that antibiotics were provided, many appeared to represent a delayed onset local inflammatory reaction rather than cellulitis, a reaction described by others.<sup>10</sup> None of these reports were confirmed by microbial testing.

Nine reports contained a diagnosed neurological event. Four individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. Two individuals were admitted to hospital for seizures, including one with a history of a seizure disorder. The other had an event that appeared to be a seizure but upon further investigation could have been related to a cardiac arrhythmia. Finally, one individual was admitted to hospital for an intracerebral hemorrhage and query encephalitis.

There were two reports of thrombocytopenia. Both were for individuals who had a prior episode of thrombocytopenia pre-vaccination and were found to have a low platelet count after vaccination when seen in the emergency department for signs of bleeding. Neither was associated with receipt of AstraZeneca/COVISHIELD vaccine.

### **Data Notes**

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on April 15, 2021. Only AEFIs reported and doses administered up to April 10, 2021 were included in this report. Any AEFI report with a status of "Does not meet reporting criteria" or "Disregard - Entered in error" was excluded.

Delays exist between the time an AEFI occurs, is reported to public health, and is entered into Panorama. As AEFI investigations progress from draft version to being submitted for review and finally completed, there may be changes to the data, or reports may be removed from analysis if reflective of events that are not reportable (e.g., expected local reaction). This may lead to fluctuations in AEFI counts and rates, and subsequent weekly reports cannot be directly compared to previous reports of AEFI reported in BC.

## References

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