

## British Columbia Report

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

December 13, 2020 to April 17, 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 17, 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 safety of the mRNA vaccines elsewhere in Canada and available reports from other jurisdictions, as well as the demonstrated safety of these 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 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. There have been no reports of thrombocytopenia with thrombosis syndrome (TTS) reported in BC to date; this syndrome was identified in March in Europe in association with the ChAdOx1 (chimpanzee adenovirus vector AstraZeneca) COVID-19 vaccine, with very few cases reported in Canada to date.<sup>5,6</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>7</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>8</sup> The Public Health Agency of Canada also produces a weekly [COVID-19 AEFI report](#).<sup>9</sup>

## Definitions

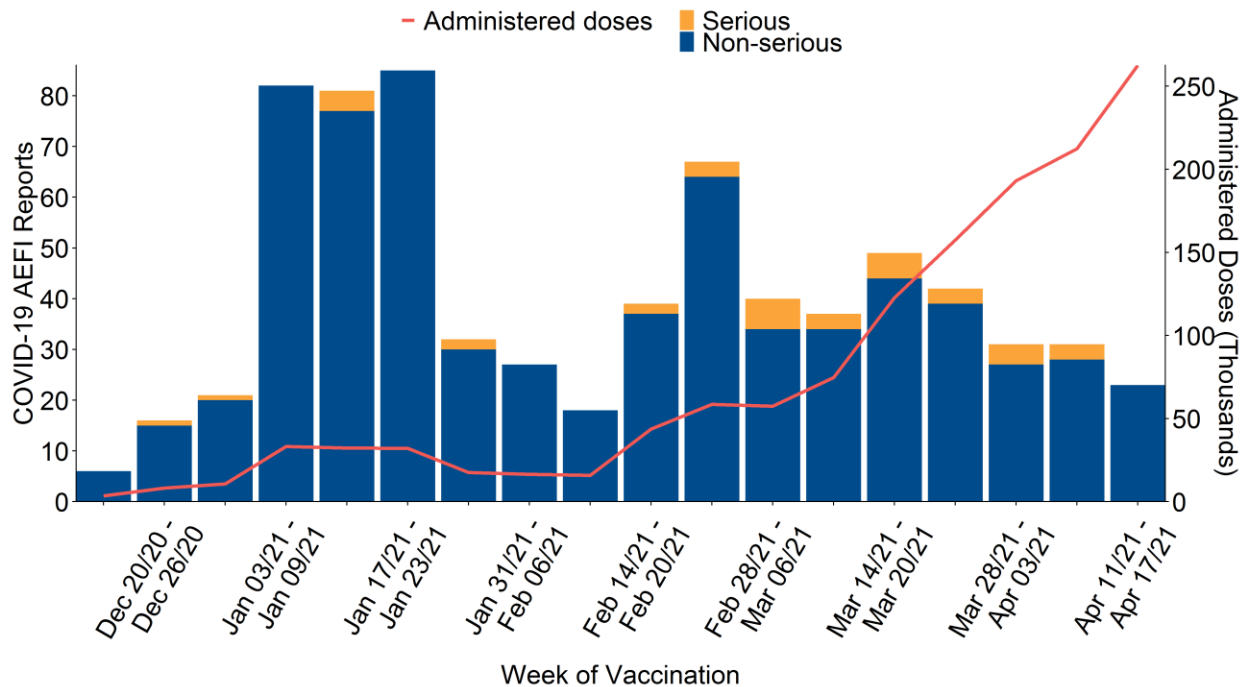
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.<sup>10</sup>
2. **Serious AEFI** - For the purpose of this 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 17, 2021, there have been 1,352,709 COVID-19 vaccine doses administered in BC and 727 COVID-19 AEFI reports (53.7 reports per 100,000 doses administered)
- 37 reports (5.1%) met the serious definition, for a rate of 2.7 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.17, 2021 (N=727)



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including April 17, 2021, a total of 1,352,709 doses have been administered. During this period, there have been 727 AEFI reports following a COVID-19 vaccine, for a reporting rate of 53.7 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.17, 2021 (N=727)

	COVID-19 Vaccine				
	All COVID-19 Vaccines	AstraZeneca	COVISHIELD	Moderna	Pfizer
<b>Total reports</b>	<b>727</b>	<b>4</b>	<b>24</b>	<b>274</b>	<b>425</b>
Non-serious reports	690	4	21	262	403
Serious reports	37	0	3	12	22
Proportion serious	5.1%	0%	12.5%	4.4%	5.2%
Dose 1 reports	638	4	24	248	362
Dose 2 reports	89	0	0	26	63
<b>Total doses administered</b>	<b>1,352,709</b>	<b>76,943</b>	<b>55,461</b>	<b>255,861</b>	<b>964,444</b>
Dose 1 administered	1,264,522	76,941	55,461	238,351	893,769
Dose 2 administered	88,187	2	0	17,510	70,675
<b>Total reporting rate</b>	<b>53.7</b>	<b>5.2</b>	<b>43.3</b>	<b>107.1</b>	<b>44.1</b>
Serious rate	2.7	0.0	5.4	4.7	2.3
Dose 1 rate	50.5	5.2	43.3	104.0	40.5
Dose 2 rate	100.9	0.0	--	148.5	89.1

Note: Rates calculated per 100,000 doses administered

### Serious Reports

Thirty-seven reports (5.1%) were considered serious (refer to serious AEFI definition above). Of these, 33 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis or other allergic event, 13 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, two for stroke, one hemorrhage and associated encephalopathy, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), four for chest pain/cardiac events, one pulmonary embolism, one respiratory distress, and one for a pregnancy related complication.

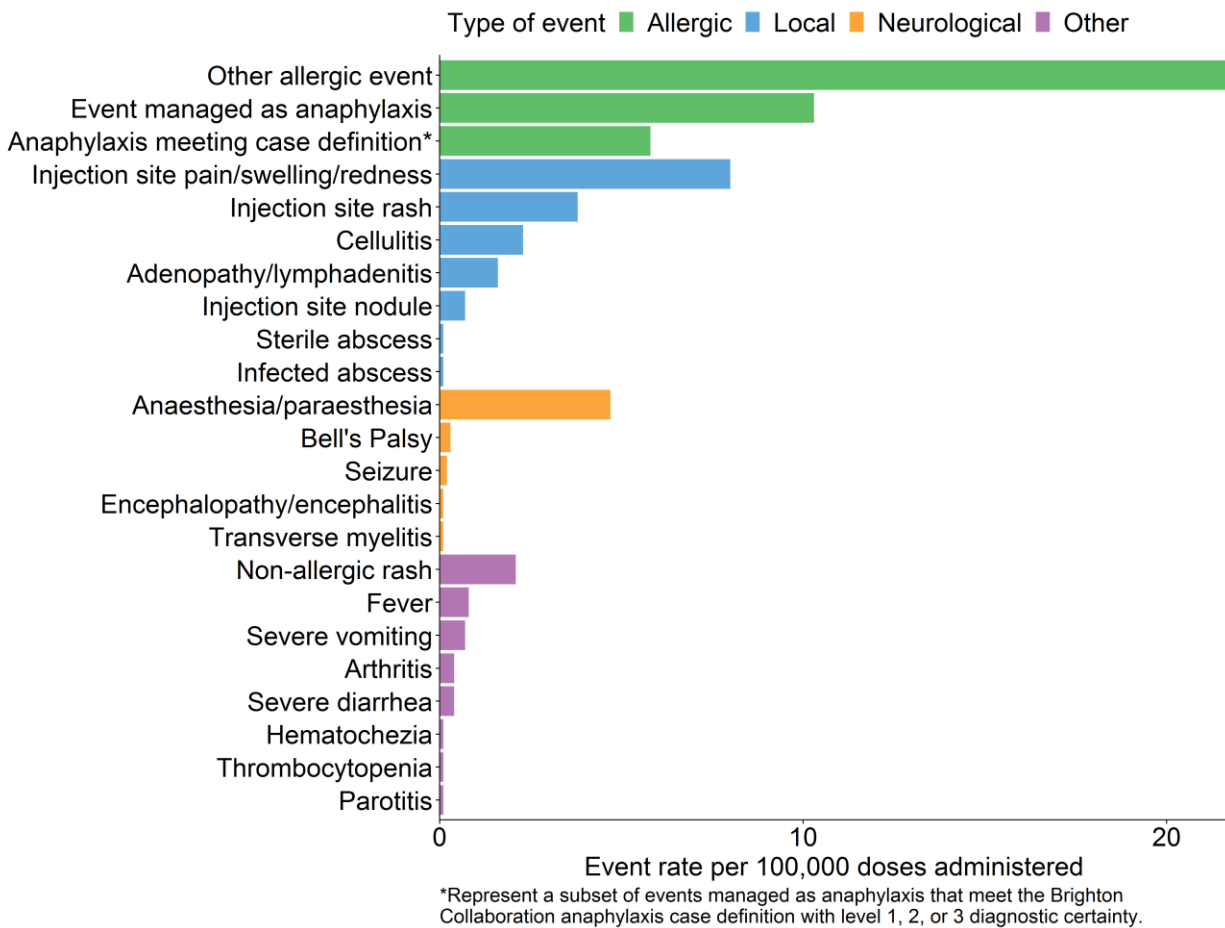
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no other clear cause of death has been established.<sup>7</sup> Death may also be recorded as the outcome of a specific reportable event. Four serious AEFI reports were received for individuals who died within 30 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 on 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; the coroner deemed this death not unexpected and further investigation into the cause of death was not conducted.

### 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 727 AEFI reports received up to April 17, 2021 contained a total of 979 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 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>11</sup>

**Figure 2:** Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 - Apr.17, 2021 (N=979)



## Event Descriptions

One hundred forty reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 79 (56%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.<sup>11</sup> Upon further review of these reports, many may reflect events such as anxiety or pre-syncope (fainting) events.

Thirty-one 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>12</sup> None of these reports were confirmed by microbial testing.

Ten 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. Three individuals were admitted to hospital for seizures, including one with a history of a seizure disorder and another that could have been related to a cardiac arrhythmia. Finally, one individual was admitted to hospital for an intracerebral hemorrhage and subsequent encephalopathy.

There were two reports of thrombocytopenia. Both were for individuals who had a prior episode of thrombocytopenia 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.

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, ten were for various thrombotic/thromboembolic conditions. These included two strokes, three myocardial infarctions, two pulmonary embolisms, two deep vein thromboses, and one peripheral vein thrombosis. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.<sup>5,6</sup>

## Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on April 21, 2021. Only AEFIs reported and doses administered up to April 17, 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

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. 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>
6. 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/>
7. 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](http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Epid/CD%20Manual/Chapter%202%20-%20Imms/Part_5_AEFI.pdf)
8. 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>
9. 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/>
10. 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](https://vaccine-safety-training.org/tl_files/vs/pdf/report-of-cioms-who-working-group.pdf)

11. 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>
12. 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>