

British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to May 29, 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 May 29, 2021. 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

No safety signals have been identified in association with the mRNA 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.²⁻⁴ 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-syncopal (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. BC is monitoring for reports of myocarditis following mRNA vaccines, which has been identified as an adverse event of interest based on reports from Israel and is being monitored in several countries.^{5,6}

There have been three reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with roughly 275,000 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.^{7,8}

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](#).⁹ 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.¹⁰ The Public Health Agency of Canada also produces a weekly [COVID-19 AEFI report](#).¹¹

Definitions

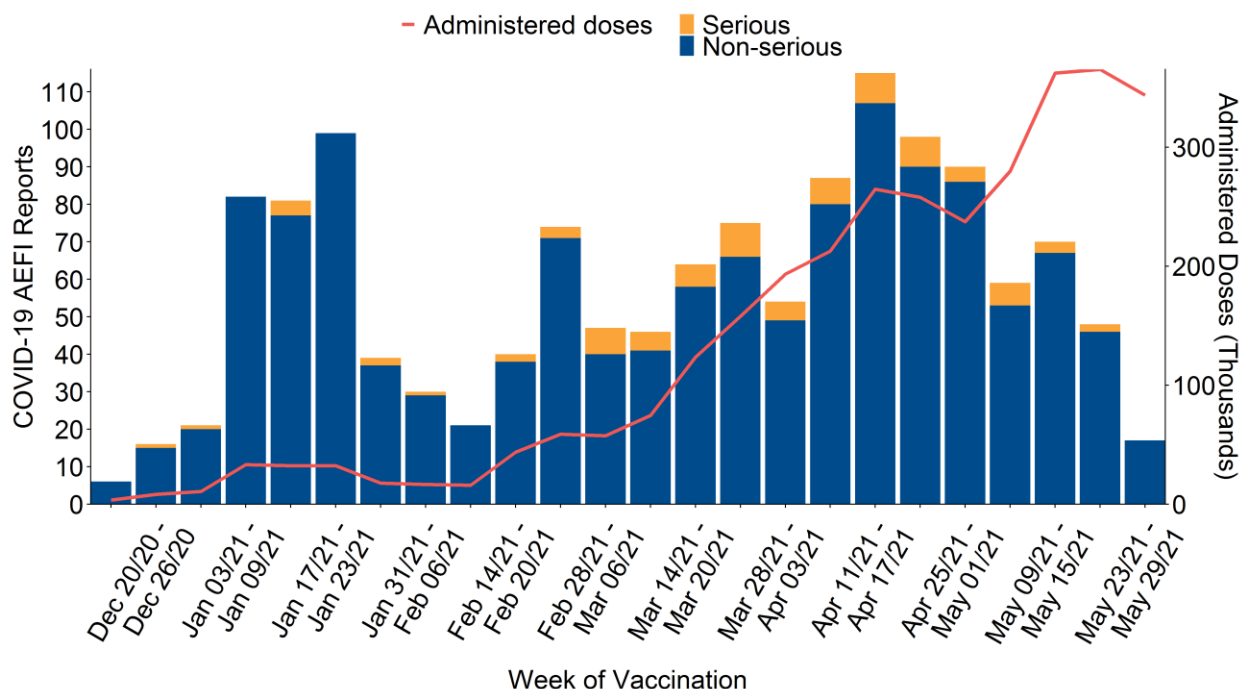
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.¹²
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of May 29, 2021, there have been 3,203,628 COVID-19 vaccine doses administered in BC and 1,379 COVID-19 AEFI reports (43.0 reports per 100,000 doses administered)
- 84 reports (6.1%) met the serious definition, for a rate of 2.6 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 - May 29, 2021 (N=1,379)



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including May 29, 2021, a total of 3,203,628 doses have been administered. During this period, there have been 1,379 AEFI reports following a COVID-19 vaccine, for a reporting rate of 43.0 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 - May 29, 2021 (N=1,379)

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	AstraZeneca	COVISHIELD	Moderna	Pfizer
Total reports	1,379	122	46	436	773
Non-serious reports	1,295	114	42	414	724
Serious reports	84	8	4	22	49
Proportion serious	6.1%	6.6%	8.7%	5%	6.3%
Dose 1 reports	1,272	122	46	403	699

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	AstraZeneca	COVISHIELD	Moderna	Pfizer
Dose 2 reports	107	0	0	33	74
Total doses administered	3,203,628	215,210	60,452	618,367	2,309,596
Dose 1 administered	3,029,224	214,669	59,103	572,630	2,182,819
Dose 2 administered	174,404	541	1,349	45,737	126,777
Total reporting rate	43.0	56.7	76.1	70.5	33.5
Serious rate	2.6	3.7	6.6	3.6	2.1
Dose 1 rate	42.0	56.8	77.8	70.4	32.0
Dose 2 rate	61.4	0.0	0.0	72.2	58.4

Note: Rates calculated per 100,000 doses administered

* Some reports had an unspecified COVID-19 vaccine (n=2). Therefore, the total reports for all COVID-19 vaccines do not equal the sum of reports for each specific vaccine

Serious Reports

Eighty-four reports (6.1%) were considered serious (refer to serious AEFI definition above). Of these, 77 individuals were admitted to hospital. These included 13 individuals hospitalized after anaphylaxis, 19 for a neurological diagnosis (including two for transverse myelitis, three for seizure, 10 for stroke, two cerebral hemorrhage with one associated encephalopathy, one meningitis, and one Guillain-Barre Syndrome), 11 for cardiac events (including eight for myocardial infarction and three for perimyocarditis), 10 pulmonary embolism, one respiratory distress, one for a pregnancy related complication, four for thrombocytopenia, and three 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.⁹ Death may also be recorded as the outcome of a specific reportable event. Eight 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. One death 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. Another death occurred in a long term care resident following deterioration with reduction in oral intake, without a clear underlying cause of death identified. Finally, one death occurred in an individual with an underlying lung condition who passed away 24 days after vaccination. Investigation into the cause of death was still underway.

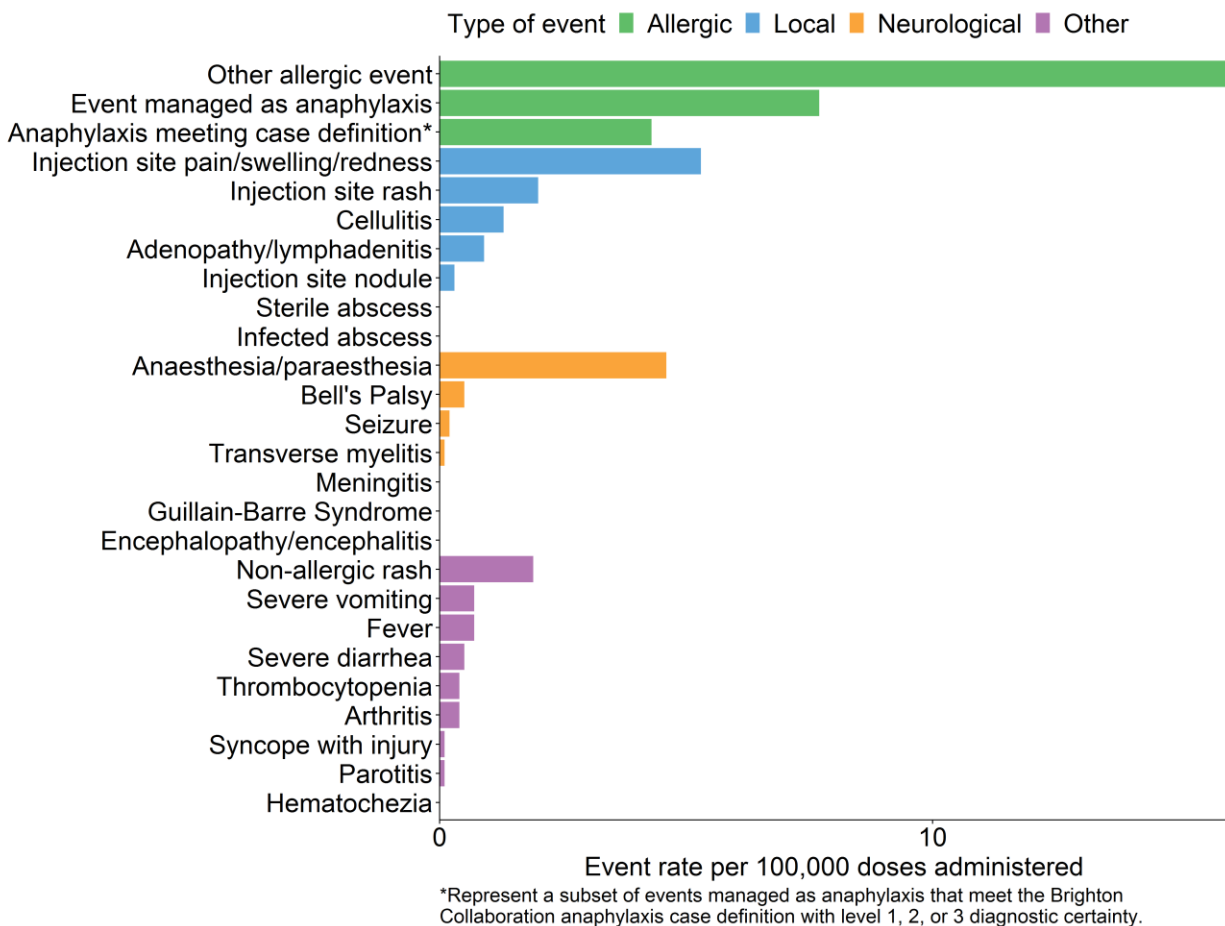
For two individuals, death was the outcome of cardiac arrest. Both were elderly individuals with multiple underlying medical conditions. The third death occurred in an elderly individual

following a stroke and hospital admission (included in hospitalized count above). This individual had previous history of stroke along with other medical conditions.

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 1,379 AEFI reports received up to May 29, 2021 contained a total of 1,794 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.¹³

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - May 29, 2021 (N=1,794)



Event Descriptions

Two hundred forty-eight reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 138 (56%) met the

Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.¹³ Upon further review of these reports, many may reflect events such as anxiety or pre-syncope (fainting) events.

Forty-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.¹⁴ None of these reports were confirmed by microbial testing.

Twenty-nine reports contained a diagnosed neurological event. Fifteen individuals experienced Bell's Palsy within 30 days following COVID-19 vaccination. Two individuals were admitted to hospital and diagnosed with transverse myelitis. Eight individuals reported seizures, including five 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. Finally, there was one report for an individual hospitalized with Guillain-Barre Syndrome (GBS) who has since been discharged and is recovering with rehabilitation therapy. A possible infectious cause of GBS was not identified. GBS cases following COVID-19 vaccines have been identified in Canada and internationally, but rarely.^{11,15,16}

There were nine reports of thrombocytopenia without concurrent thrombosis. One occurred in an individual with a single low platelet result followed subsequently by normal results in the days after. The one low result was deemed indicative of a laboratory error as it was not seen in subsequent testing. Two were in 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. Five reports were for individuals who had a concurrent medical condition or who were taking medications that could contribute to development of thrombocytopenia. None of these reports were associated with receipt of AstraZeneca/COVISHIELD vaccine. The last report was for an individual with a low platelet count admitted to hospital eight days after the AstraZeneca vaccine for abdominal pain and bruising. This individual was treated with full recovery.

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, 52 were for various thrombotic/thromboembolic conditions. These included 10 strokes and one cerebral venous sinus thrombosis without thrombocytopenia (i.e., not a TTS case), eight myocardial infarctions, 14 pulmonary embolisms, 17 deep vein thromboses, and two superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.^{7,8}

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 seven reports of pericarditis/myocarditis. Three individuals had a diagnosis of pericarditis alone, two had myocarditis, and two had perimyocarditis. Ages ranged from 29 to 95, and five were male. Four had received Moderna vaccine and three had Pfizer vaccine; two of the events occurred after second dose of Pfizer. Many 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.¹⁷ 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 in Canada and internationally, but at this time a confirmed association has not been made and event rates reported in Canada have been well within the expected background rates for these conditions.^{5,6,11}

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on June 2, 2021. Only AEFIs reported and doses administered up to May 29, 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. World Health Organization. COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) reviews cases of mild myocarditis reported with COVID-19 mRNA vaccines [Internet]. 2021 [cited 2021 Jun 2]. Available from: <https://www.who.int/news/item/26-05-2021-gacvs-myocarditis-reported-with-covid-19-mrna-vaccines>
6. Centers for Disease Control and Prevention. Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination [Internet]. 2021 [cited 2021 Jun 2]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html>
7. 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>
8. 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/>
9. 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%20-%20-%20Imms/Part_5_AEFI.pdf
10. 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>

11. 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/>
12. 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
13. 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>
14. 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>
15. Patel SU, Khurram R, Lakhani A, Quirk B. Guillain-Barre syndrome following the first dose of the chimpanzee adenovirus-vectored COVID-19 vaccine, ChAdOx1. *BMJ Case Rep* 2021;14:e242956. Available from: <https://casereports.bmj.com/content/bmjcr/14/4/e242956.full.pdf>
16. Waheed S, Bayas A, Hindi F, Rizvi Z, Espinosa PS. Neurological complications of COVID-19: Guillain-Barre Syndrome following Pfizer COVID-19 vaccine. *Cureus*. 2021;13(2):e13426. Available from: <https://www.cureus.com/articles/52295-neurological-complications-of-covid-19-guillain-barre-syndrome-following-pfizer-covid-19-vaccine>
17. Brighton Collaboration. Draft myocarditis case definition (version_1.4.2_30.May.2021) [Internet]. 2021 [cited 2021 Jun 2]. Available from: <https://brightoncollaboration.us/myocarditis-case-definition-update/>