British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to April 03, 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 03, 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 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.[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 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.[5] 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.[6] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[7]

Definitions

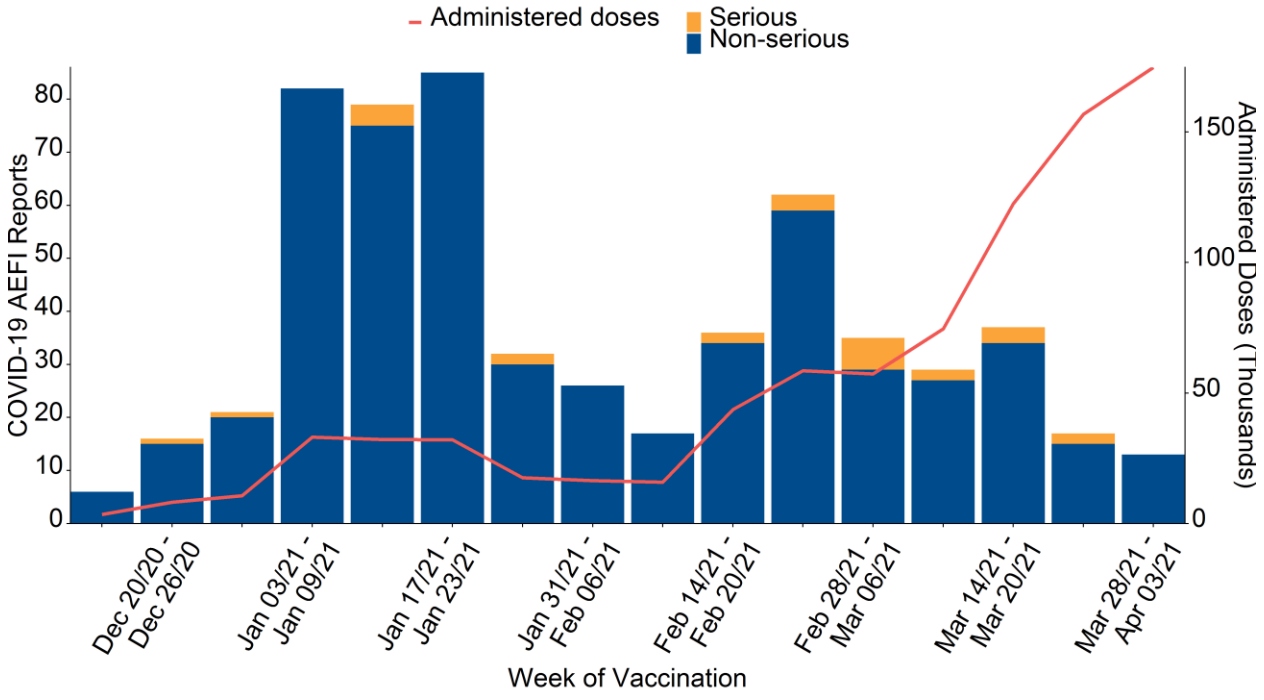
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[8]
2. **Serious AEFI** - For the purpose of this report,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

Key Findings

- As of April 03, 2021, there have been 857,644 COVID-19 vaccine doses administered in BC and 593 COVID-19 AEFI reports (69.1 reports per 100,000 doses administered)
- 26 reports (4.4%) met the serious definition, for a rate of 3.0 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.03, 2021 **(N=593)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including April 03, 2021, a total of 857,644 doses have been administered. During this period, there have been 593 AEFI reports following a COVID-19 vaccine, for a reporting rate of 69.1 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.03, 2021 **(N=593)**

		COVID-19 Vaccine		
	All COVID-19 Vaccines	**COVISHIELD**	**Moderna mRNA**	**Pfizer mRNA**
Total reports	**593**	**10**	**239**	**344**
Non-serious reports	567	9	230	328
Serious reports	26	1	9	16
Proportion serious	4.4%	10%	3.8%	4.7%
Dose 1 reports	507	10	213	284
Dose 2 reports	86	0	26	60
Total doses administered	**857,644**	**34,058**	**144,338**	**679,248**
Dose 1 administered	770,236	34,058	127,228	608,950
Dose 2 administered	87,408	0	17,110	70,298
Total reporting rate	**69.1**	**29.4**	**165.6**	**50.6**
Serious rate	3.0	2.9	6.2	2.4
Dose 1 rate	65.8	29.4	167.4	46.6
Dose 2 rate	98.4	--	152.0	85.4

Note: Rates calculated per 100,000 doses administered

Serious Reports

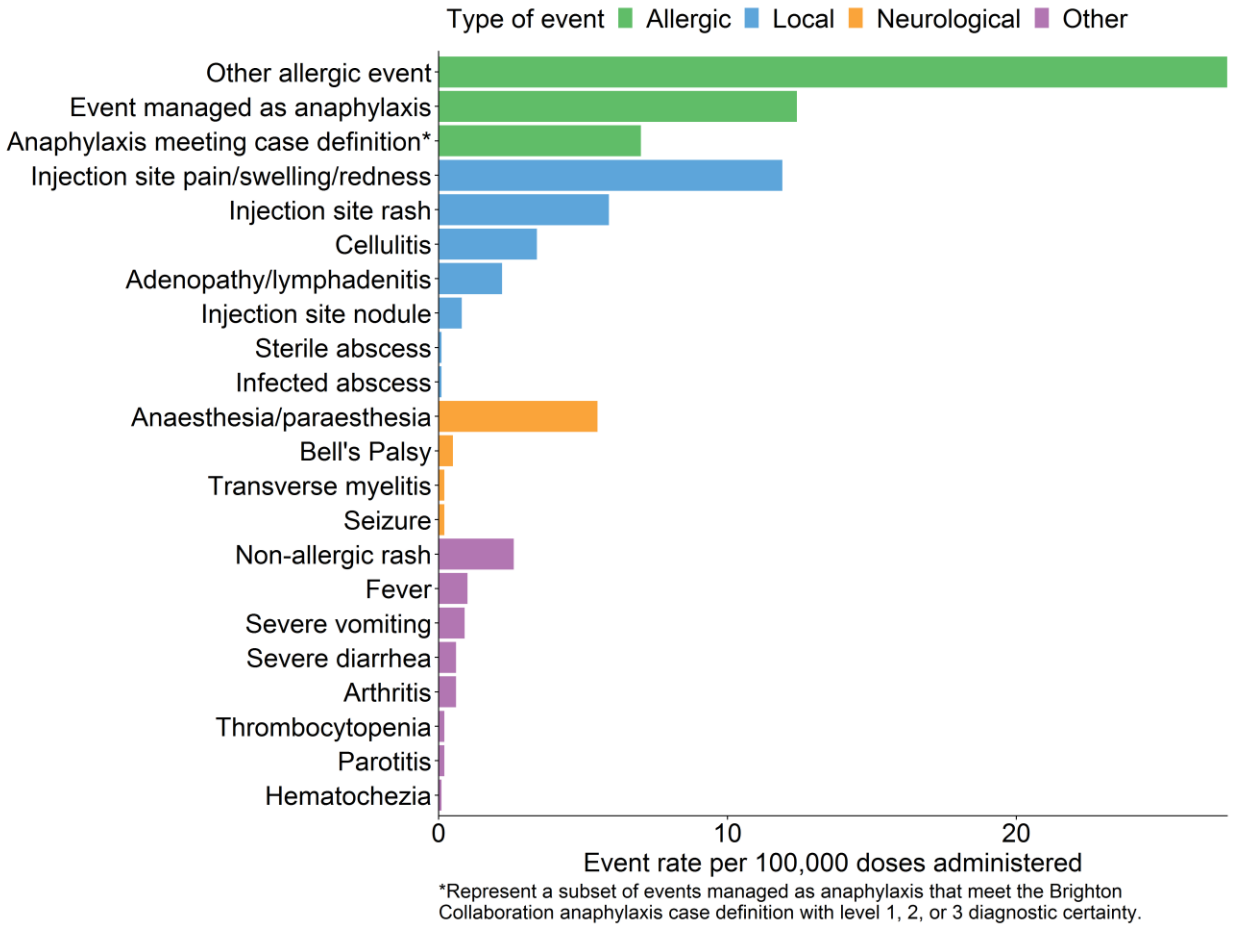
Twenty-six reports (4.4%) were considered serious (refer to serious AEFI definition above). Of these, 23 individuals were admitted to hospital. These included nine individuals hospitalized after anaphylaxis or other allergic event, eight for neurological investigations/monitoring (including two for transverse myelitis, one for a seizure, and five for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), five for chest pain/cardiac events, 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.[5] Death may also be recorded as the outcome of a specific reportable event. Three 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. The other death, which was still being investigated at the time of this report, was the outcome of a cardiac event that occurred in an elderly individual with multiple underlying 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 593 AEFI reports received up to April 03, 2021 contained a total of 809 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.[9]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec.13, 2020 - Apr.03, 2021 **(N=809)**



Event Descriptions

One hundred six reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 60 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[9] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Twenty-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, a reaction described by others.[10] None of these reports were confirmed by microbial testing.

Seven 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. One individual, with a history of a seizure disorder, was admitted to hospital for seizures.

There were two reports of thrombocytopenia, although one was unconfirmed with no platelet count provided and still under investigation at the time of this report. The other report was for an individual who had a prior episode of thrombocytopenia pre-vaccination and was found to have a low platelet count roughly two weeks after vaccination when seen in the emergency department for signs of bleeding.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on April 08, 2021. Only AEFIs reported and doses administered up to April 03, 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. 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
6. 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
7. 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/
8. 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
9. 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

10. 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