British Columbia Report

Adverse Events Following Immunization with COVID-19 Vaccines

December 13, 2020 to May 15, 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 15, 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. There have been two reports of thrombosis with thrombocytopenia syndrome reported in BC to date in association with over 250,000 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.[5,6]

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.[7] 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.[8] The Public Health Agency of Canada also produces a weekly COVID-19 AEFI report.[9]

Definitions

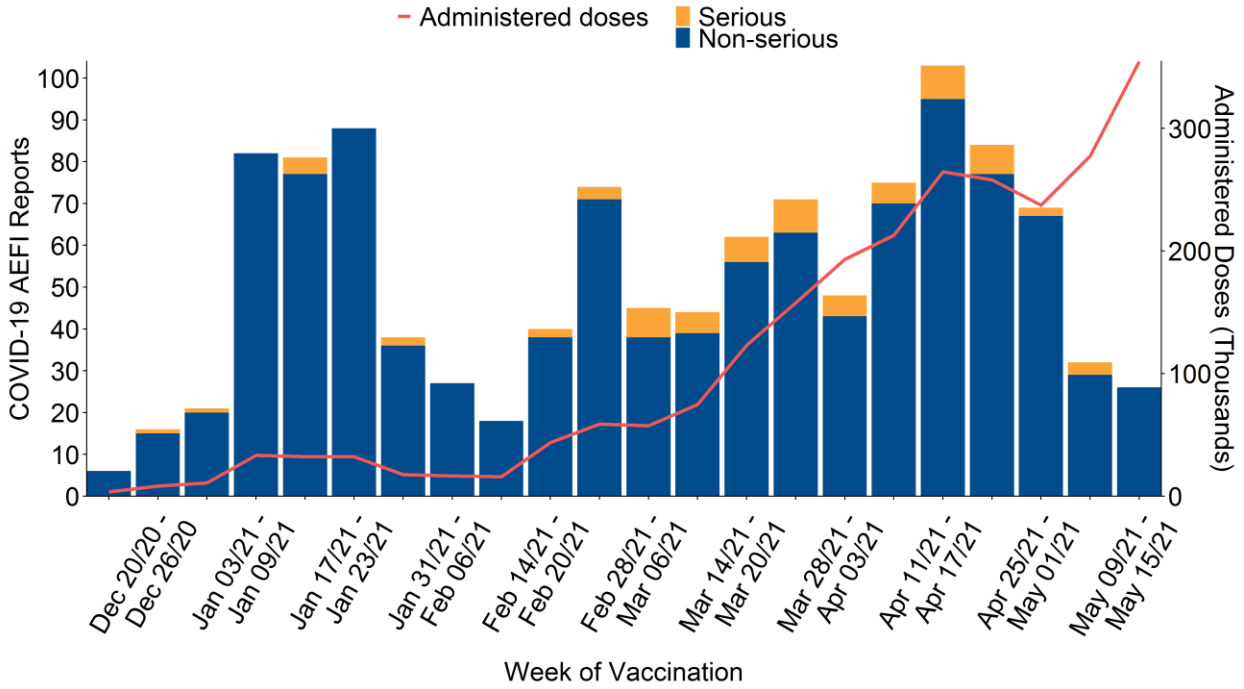
1. **Adverse event following immunization (AEFI)** - Any untoward medical event following immunization that is temporally (i.e., occurs within a biologically plausible timeframe after receipt of vaccine) but not necessarily causally associated.[10]
2. **Serious AEFI** - For the purpose of this report, a serious AEFI is one that resulted in hospitalization or a prolongation of hospitalization, permanent disability/incapacity, or death.

Key Findings

- As of May 15, 2021, there have been 2,483,293 COVID-19 vaccine doses administered in BC and 1,150 COVID-19 AEFI reports (46.3 reports per 100,000 doses administered)
- 69 reports (6%) 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 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 15, 2021 **(N=1,150)**



COVID-19 vaccinations of British Columbians began the week of December 13, 2020, and up to and including May 15, 2021, a total of 2,483,293 doses have been administered. During this

period, there have been 1,150 AEFI reports following a COVID-19 vaccine, for a reporting rate of 46.3 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 15, 2021 **(N=1,150)**

	COVID-19 Vaccine*				
	All COVID-19 Vaccines	**AstraZeneca**	**COVISHIELD**	**Moderna**	**Pfizer**
Total reports	**1,150**	**92**	**42**	**376**	**638**
Non-serious reports	1,081	85	38	357	599
Serious reports	69	7	4	19	39
Proportion serious	6%	7.6%	9.5%	5.1%	6.1%
Dose 1 reports	1,051	92	42	346	569
Dose 2 reports	99	0	0	30	69
Total doses administered	**2,483,293**	**214,359**	**58,760**	**490,242**	**1,719,932**
Dose 1 administered	2,353,760	214,308	58,677	454,342	1,626,433
Dose 2 administered	129,533	51	83	35,900	93,499
Total reporting rate	**46.3**	**42.9**	**71.5**	**76.7**	**37.1**
Serious rate	2.8	3.3	6.8	3.9	2.3
Dose 1 rate	44.7	42.9	71.6	76.2	35.0
Dose 2 rate	76.4	0.0	0.0	83.6	73.8

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

Sixty-nine reports (6%) were considered serious (refer to serious AEFI definition above). Of these, 63 individuals were admitted to hospital. These included 16 individuals hospitalized after anaphylaxis or other allergic event, 23 for neurological investigations/monitoring (including two for transverse myelitis, three for seizure, nine for stroke, two hemorrhage with one associated encephalopathy, one meningitis, and six for undiagnosed weakness, numbness, syncope, lethargy, or altered level of consciousness), 10 for chest pain/cardiac events, eight pulmonary embolism, one respiratory distress, one for a pregnancy related complication, two for thrombocytopenia, and two for thrombosis with thrombocytopenia syndrome (described further below).

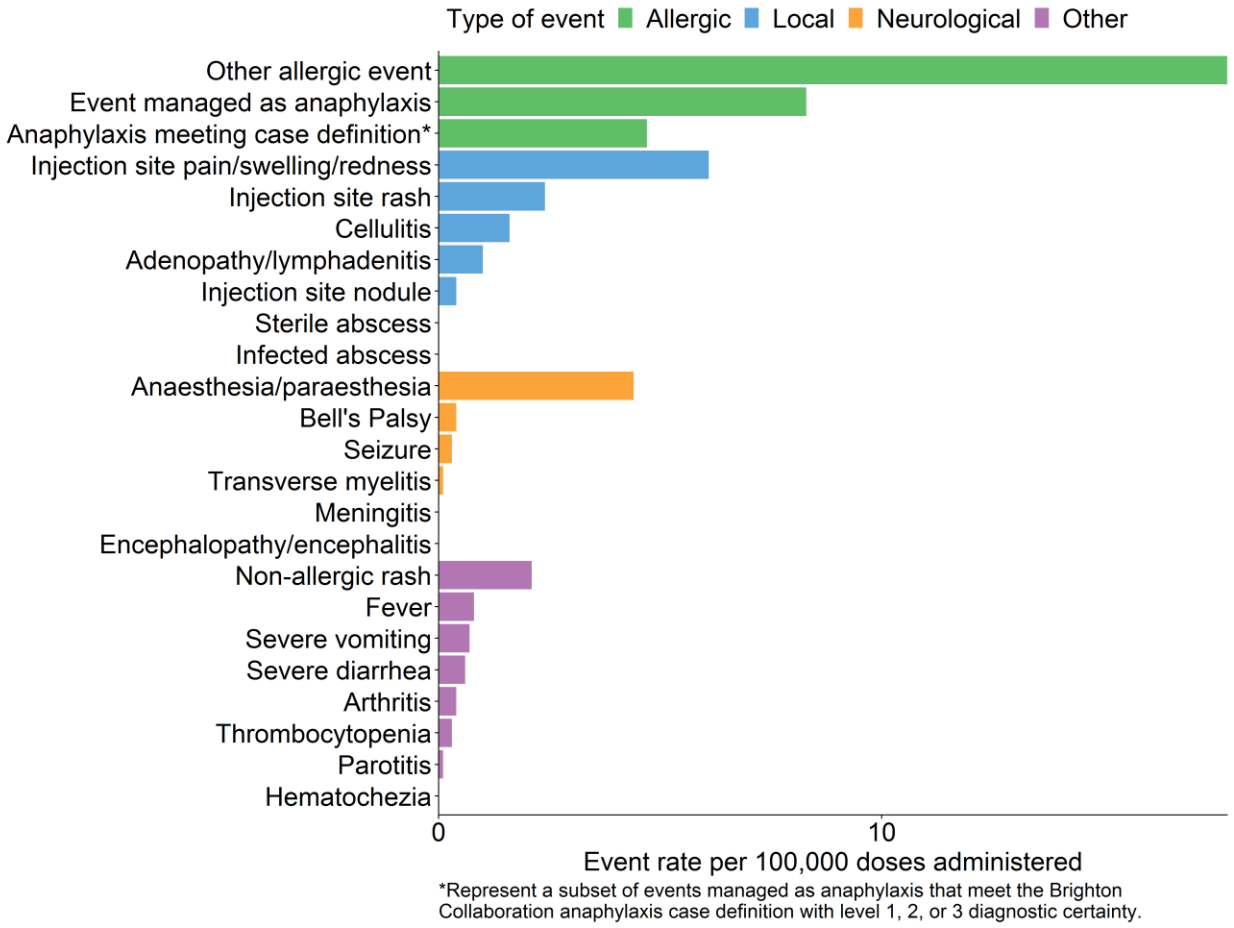
Death is reportable as an adverse event when it occurs within 30 days of vaccination and no

other clear cause of death has been established.[7] Death may also be recorded as the outcome of a specific reportable event. Seven 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. 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 1,150 AEFI reports received up to May 15, 2021 contained a total of 1,515 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.[11]

Figure 2: Adverse events following receipt of a COVID-19 vaccine, British Columbia, Dec. 13, 2020 - May 15, 2021 **(N=1,515)**



Event Descriptions

Two hundred six reports were received for events managed as anaphylaxis (i.e., the client received epinephrine for a suspected anaphylactic reaction). Of these, 117 (57%) met the Brighton Collaboration definition for anaphylaxis with diagnostic certainty levels of 1, 2, or 3.[11] Upon further review of these reports, many may reflect events such as anxiety or pre-syncopal (fainting) events.

Thirty-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.[12] None of these reports were confirmed by microbial testing.

Twenty four reports contained a diagnosed neurological event. Eleven 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. Finally, one individual

was hospitalized for aseptic meningitis.

There were five 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. None of these three were associated with receipt of AstraZeneca/COVISHIELD vaccine. The fourth 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. The final report was for an individual with a concurrent blood condition that could have contributed to development of thrombocytopenia. Investigation was still ongoing for this report.

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, 45 were for various thrombotic/thromboembolic conditions. These included nine strokes, eight myocardial infarctions, 15 pulmonary embolisms, 11 deep vein thromboses, and two superficial vein thromboses. None of these events met the TTS criteria as none were associated with new onset thrombocytopenia.[5,6]

There have been two non-fatal confirmed cases of TTS reported in BC to date, both in adults in their 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.

Data Notes

Data on COVID-19 AEFI reports and doses administered were extracted from Panorama, the provincial public health information system, on May 19, 2021. Only AEFIs reported and doses administered up to May 15, 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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