Public Health Ontario | Santé publique Ontario

WEEKLY SURVEILLANCE SUMMARY

Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to November 21, 2021

This report provides a summary of adverse events following immunization (AEFIs) that are temporally associated (i.e., occur after receiving the vaccine) with receipt of COVID-19 vaccine and meet the provincial surveillance definitions (i.e., confirmed).[1] It is important to note that AEFIs described in this report are defined as any untoward medical occurrences that followed immunization and do not necessarily have a causal relationship with the vaccine.

This weekly summary includes AEFIs reported in the Public Health Case and Contact Management Solution (CCM) as of **November 21, 2021**. Doses administered up to and including November 21, 2021 are extracted from the COVax$_{ON}$ application (see technical notes for details on data sources).

Background

In Ontario, AEFIs are reported to local public health units (PHUs) by health care providers and vaccine recipients.[2] PHUs investigate and assess all AEFI reports, which are then entered into the provincial electronic reporting system according to provincial surveillance guidelines.[1] Please see the following resources for more information:

- Public Health Ontario's (PHO) overview of vaccine safety surveillance for more information on vaccine safety surveillance in Ontario[3]
- The technical annex of PHO's annual vaccine safety report for technical details on vaccine safety surveillance data analysis in Ontario[4]
- The government of Canada's COVID-19 vaccine safety webpage for national data on COVID-19 vaccine safety[5]
- PHO's COVID-19 vaccine webpage for resources and data on Ontario's COVID-19 vaccine program

Highlights

- There are a total of 15,496 AEFI reports received following 22,950,373 doses of COVID-19 vaccines administered in Ontario to date with a reporting rate of 67.5 per 100,000 doses administered (0.07% of all doses administered)
    - This represents an increase of 209 AEFI reports compared to previous week
- Of the total 15,496 AEFI reports received to date:
    - 14,615 AEFI reports are non-serious (94.3% of total AEFI reports)
    - 881 AEFI reports meet the serious definition (5.7% of total AEFI reports)
    - The most commonly reported adverse events are other severe or unusual events and allergic skin reactions, reported in 23.9% and 23.4% of the total AEFI reports respectively
    - 1,161 reports include a COVID-19 vaccine-specific adverse event of special interest, in which 547 reports also meet the serious definition (see Adverse events of special interest section for more information)
    - 21 reports of thrombosis with thrombocytopenia syndrome (TTS) after receipt of AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine, of which 16 are vaccine-induced immune thrombotic thrombocytopenia (VITT) (see TTS/VITT section for more information)
    - 537 reports of myocarditis or pericarditis after receipt of mRNA vaccine (see Myocarditis/pericarditis section for more information)
- Ontario is continuing to monitor all AEFIs reported following receipt of COVID-19 immunization in collaboration with its partners

> In Ontario, AEFIs that meet the serious definition are events that required hospital admission and reports of death. Please see the technical notes for a full definition of serious AEFIs.
>
> Several adverse events have been identified as COVID-19 vaccine-specific adverse events of special interest (AESIs). The list of COVID-19 specific AESIs are listed in the technical notes.

Summary of AEFI reports in Ontario

An AEFI report refers to a report received by the PHU, which pertains to one individual vaccine recipient who reported at least one adverse event after receiving the COVID-19 vaccine (i.e., temporally associated with the vaccine). See Table 1 for a summary of all AEFI reports received to date in Ontario.

Table 1. Summary of AEFI reports by vaccine product: Ontario, December 13, 2020 to November 21, 2021

	Pfizer-BioNTech Comirnaty COVID-19 vaccine	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine	All vaccine products combined
Total number of AEFI reports	9,227	4,716	1,551	15,496
Number of non-serious reports	8,745	4,433	1,435	14,615
Number of serious reports	482	283	116	881
Proportion of total AEFI reports that are serious	5.2%	6.0%	7.5%	5.7%
Doses administered	16,123,565	5,738,410	1,088,398	22,950,373
Total reporting rate per 100,000 doses administered	57.2	82.2	142.5	67.5
Serious reporting rate per 100,000 doses administered	3.0	4.9	10.7	3.8

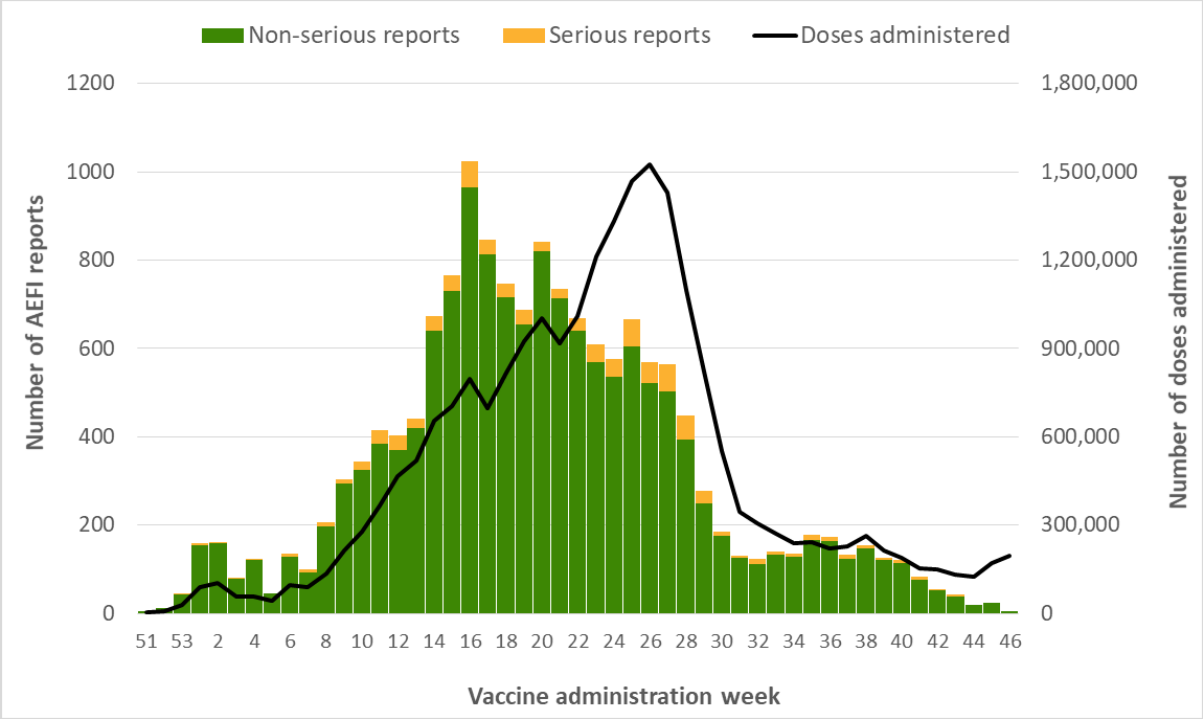
Note: Two AEFI reports did not specify vaccine product received. Data corrections or updates can result in AEFI reports being removed and/or updated from past reports and may result in counts differing from past publicly reported AEFIs. The National Advisory Committee on Immunization (NACI) now recommends that COVID-19 vaccines may be administered concomitantly with, or at any time before or after non-COVID-19 vaccines including live, non-live, adjuvanted, or unadjuvanted vaccines.[6] To date, there has been one AEFI report associated with co-administration of COVID-19 vaccine and a non-COVID-19 vaccine (influenza vaccine).
Data Source: CCM, $COVax_{ON}$ (see technical notes for details on data sources)

Table 2. Number of AEFI reports and reporting rates by age group and sex: Ontario, December 13, 2020 to November 21, 2021

	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Sex: Female	11,443	96.8
Sex: Male	3,858	34.8
Ages: 12-17 years	568	34.2
Ages: 18-24 years	1,052	46.7
Ages: 25-29 years	1,015	56.8
Ages: 30-39 years	2,483	72.4
Ages: 40-49 years	3,127	96.6
Ages: 50-59 years	3,050	83.4
Ages: 60-69 years	2,330	70.1
Ages: 70-79 years	1,157	52.5
Ages: 80 years and over	692	52.1

Note: Age represents age at time of immunization. Gender used when sex was missing. Some AEFI reports and doses administered records have unknown sex, gender or age; these reports are excluded from sex and age-specific counts and reporting rates. Data corrections or updates can result in AEFI reports being removed and/or updated from past reports and may result in counts differing from past publicly reported AEFIs.
Data Source: CCM, $COVax_{ON}$ (see technical notes for details on data sources)

Figure 1. Number of AEFI reports and doses administered by week of vaccine administration: Ontario, December 13, 2020 to November 21, 2021



Note: AEFI reports are assessed based on date of vaccine administration. The administration week ranges from week 51 (Dec 13 – 19, 2020) to week 46 (Nov 14 – 20, 2021). Week 47 which includes November 21, 2021 is not shown in the figure as it is not yet a full week. The number of AEFI reports for the recent reporting weeks are subject to reporting delays and/or delayed data entry (i.e., reports are likely to be still under investigation and yet to be reported as a confirmed AEFI report). Data corrections or updates can result in AEFI reports being removed and/or updated from past reports and may result in counts differing from past publicly reported AEFIs.
Data Source: CCM, COVax$_{ON}$ (see technical notes for details on data sources)

Table 3. Number of AEFI reports and reporting rates by vaccine product and dose number: Ontario, December 13, 2020 to November 21, 2021

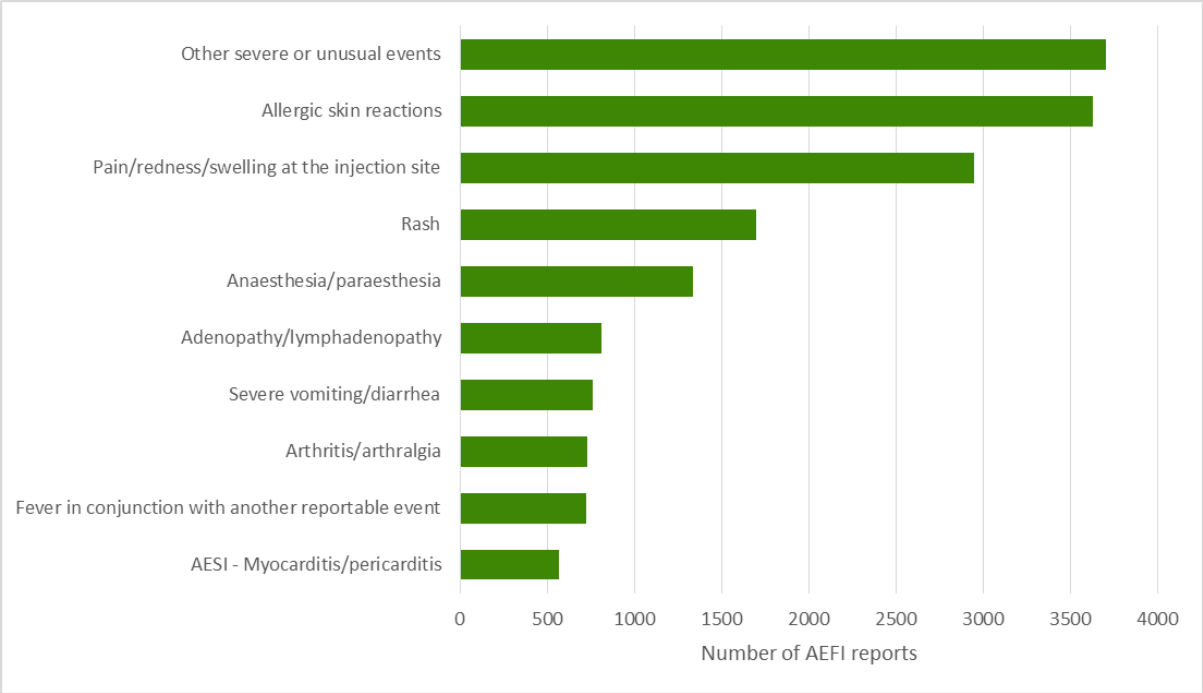
	Pfizer-BioNTech Comirnaty COVID-19 vaccine	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine	All vaccine products combined
Total number of AEFI reports	9,227	4,716	1,551	15,496
Dose 1	6,711	3,127	1,480	11,320
Dose 2	2,460	1,525	64	4,049
Dose 3	35	48	0	83
Number of serious reports	482	283	116	881
Dose 1	271	89	109	469
Dose 2	208	184	7	399
Dose 3	2	9	0	11
Total reporting rate per 100,000 doses administered	57.2	82.2	142.5	67.5
Dose 1	78.8	151.1	171.1	98.8
Dose 2	33.8	42.7	28.6	36.5
Dose 3	10.9	51.3	0.0	20.0
Serious reporting rate per 100,000 doses administered	3.0	4.9	10.7	3.8
Dose 1	3.2	4.3	12.6	4.1
Dose 2	2.9	5.1	3.1	3.6
Dose 3	0.6	9.6	0.0	2.6

Note: As some AEFI reports have unknown dose number, the sum of dose number-specific counts of AEFI reports will not equal to the total. These reports with unknown dose number are excluded from dose number-specific counts and reporting rates. Data corrections or updates can result in AEFI reports being removed and/or updated from past reports and may result in counts differing from past publicly reported AEFIs.
Data Source: CCM, $COVax_{ON}$ (see technical notes for details on data sources)

Adverse Event Descriptions

For all COVID-19 vaccine products combined, the most commonly reported adverse events are other severe or unusual events and allergic skin reactions, reported in 23.9% and 23.4% of the total AEFI reports respectively. Figure 2 shows the ten most frequently reported adverse events for all COVID-19 vaccines.

Figure 2. Ten most frequently reported adverse events for all COVID-19 vaccines: Ontario, December 13, 2020 to November 21, 2021



Note: An AEFI report may contain multiple adverse events. Thus the sum of all adverse event-specific counts may not equal to the total number of AEFI reports.
Data Source: CCM

The 'other severe or unusual events' category includes reports of adverse events that do not meet any other pre-defined events outlined in the Infectious Diseases Protocol: Appendix B but are assessed to be clinically important or epidemiologically interesting.[1] These events usually require medical attention but do not necessarily meet either the medically important event definition or the serious AEFI definition. Serious AEFIs are described in the Serious AEFI section.

Allergic skin reaction and the 'other severe or unusual events' category were the most frequently reported adverse events for the Pfizer-BioNTech Comirnaty COVID-19 vaccine (15.1 per 100,000 doses administered) while pain/redness/swelling at the injection site was the most frequently reported adverse event for the Moderna Spikevax COVID-19 vaccine (27.2 per 100,000 doses administered). The 'other severe or unusual events' category was the most frequently reported adverse event for the AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine (36.7 per 100,000 doses administered). The number of AEFI reports and reporting rate for each adverse event are presented in Appendix A.

Medically Important Events

Some selected adverse events are defined as "medically important," based on the World Health Organization's (WHO) guidance, regardless of whether they meet the serious AEFI definition. These types of events may jeopardize the patient or may require intervention to prevent an outcome described in the serious definition. The full list of medically important events are listed in the technical notes.

There were 581 reports with medically important events, representing 3.7% of all reports. The 581 reports include 445 reports of events managed as anaphylaxis, in which 31 met the definition of a serious AEFI. Of all 445 reports of events managed as anaphylaxis: 399 received epinephrine, 384 were seen in the emergency department and 336 were fully recovered at the time of reporting. All reports of events managed as anaphylaxis undergo an assessment using the Brighton Collaboration standard definition of anaphylaxis.[7] The most recent breakdown of reports by Brighton level of diagnostic certainty is available in the enhanced epidemiological summary on reports of events managed as anaphylaxis.

The Public Health Agency of Canada (PHAC) and Health Canada are actively monitoring reports of GBS following AstraZeneca Vaxzevria COVID-19 vaccination and have observed a higher number of cases than would normally be expected in the general population.[5] In Ontario, 34 reports of GBS have been reported to date, including 17 following AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine. All reports of GBS are assessed using the Brighton Collaboration standard definition of GBS.[8,9] Of all reports, one report met level 2 and one report met level 3 of the Brighton Collaboration case definition of GBS. Five did not meet the Brighton Collaboration case definition of GBS and 27 had insufficient evidence to meet level 1, 2 or 3 (i.e., met level 4 diagnostic certainty) of the case definition.

Adverse events of special interest (AESIs) for COVID-19 vaccines

Several adverse events of special interest (AESIs) for COVID-19 vaccines have been identified by international health authorities based on a theoretical rationale for a possible association with COVID-19 vaccines. Reporting of AESIs for COVID-19 vaccines enables enhanced monitoring of events which may otherwise not be captured in a passive surveillance system.

There were 1,161 reports with COVID-19 vaccine-specific AESIs, representing 7.5% of all reports. Of the 1,161 reports, 547 met the definition of a serious AEFI. The number of AEFI reports and reporting rate for each AESI by vaccine product are presented in Appendix A.

THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME (TTS) AND VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT)

Thrombosis with Thrombocytopenia Syndrome (TTS) is a condition characterized by the presence of acute venous or arterial thrombosis with new onset thrombocytopenia (low levels of platelets), and no known recent exposure to heparin.[10] Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) refers to the clinical syndrome of TTS, in addition to laboratory tests that confirm platelet activation (i.e., anti-platelet 4 antibodies). VITT has been reported following immunization with COVID-19 adenoviral vector vaccines, including AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine. Out of an abundance of caution due to an observed increase in reports of TTS/VITT in Ontario, the province announced a pause on the administration of first doses of the AstraZeneca Vaxzevria COVID-19 vaccine on May 11, 2021. More information on TTS and VITT can be found on PHO's Synthesis on COVID-19 Viral Vector Vaccines and Rare Blood Clots.[11]

To date, there have been 21 reports of TTS following the first dose of AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine in Ontario (including one probable TTS); of these, 16 are confirmed as VITT with positive anti-PF4 antibody test results. The remaining five TTS events that are

not classified as VITT have had VITT ruled out through testing (n=4) or did not have confirmatory tests ordered (n=1). The most recent event had a vaccination date of May 6, 2021. There has been one report of death recorded in CCM in an individual with VITT. A Coroner's investigation determined that the immediate causes of death included Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT). There were no reports of TTS/VITT following second dose of AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine. See Appendix A for the number of TTS/VITT reports by vaccine product.

Based on the number of first doses of AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccines administered in Ontario to date, the reporting rate of TTS based on 21 reports is 2.4 per 100,000 first doses administered (approximately 1 in 41,000). The reporting rate of VITT (as a subtype of TTS) based on 16 reports is 1.9 per 100,000 first doses administered (approximately 1 in 54,000).

MYOCARDITIS/PERICARDITIS

There have been international reports, including from the United States and Israel, of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines.[12,13] Information to date indicates that these events occur more commonly after the second dose, within the week following vaccination (typically within 4-5 days), mainly in adolescents/young adults and more often in males than females.[14]

Vaccine safety surveillance data in Canada suggest relatively higher rates of myocarditis/pericarditis reported after Moderna Spikevax COVID-19 vaccine compared to Pfizer-BioNTech Comirnaty COVID-19 vaccine.[15] Similar trends have been observed in Ontario's vaccine safety data where the reporting rates of myocarditis/pericarditis was observed to be higher following vaccination with Moderna Spikevax COVID-19 vaccine compared to Pfizer-BioNTech Comirnaty COVID-19 vaccine in the 18 to 24 year old age group, particularly among males. Out of an abundance of caution, Ontario issued a preferential recommendation of the use of Pfizer-BioNTech Comirnaty COVID-19 vaccine for individuals aged 18 to 24 year olds on September 29, 2021.[16] Ontario is continuing to monitor these events in collaboration with its partners and weekly updates can be found within this report and on the PHAC website.[5] For more information on this topic please see PHO's At A Glance: Myocarditis and Pericarditis Following COVID-19 mRNA Vaccines and additional in-depth analysis in Myocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to September 4, 2021.[17,18]

As of November 21, 2021, there have been 537 reports of myocarditis or pericarditis following receipt of COVID-19 mRNA vaccines in Ontario. These reports have been identified through case-level review of all reported AEFIs. Of these, 149 (27.7%) were diagnosed with myocarditis and 242 (45.1%) were diagnosed with pericarditis. The remaining 146 (27.2%) were diagnosed with perimyocarditis (n=28), myopericarditis (n=115) and myocarditis/pericarditis (n=3).

The 149 reports of myocarditis have been assessed using the Brighton Collaboration case definition for myocarditis; 137 reports met Brighton levels of diagnostic certainty 1, 2 or 3 (91.9%) and ten reports had insufficient evidence to meet level 1, 2 or 3 of the case definition (6.7%).[19] Two reports could not be assessed due to lack of information. Of the 242 reports of pericarditis assessed using the Brighton Collaboration case definition for pericarditis, 126 reports met Brighton levels of diagnostic certainty 1, 2 or 3 (52.1%), 104 reports had insufficient evidence to meet level 1, 2 or 3 of the case definition (43.0%), and 11 reports did not meet the Brighton Collaboration case definition for pericarditis (4.5%).[19] One report could not be assessed due to lack of information. The remaining 146 reports were assessed against both Brighton Collaboration case definition for myocarditis and pericarditis to see if they meet either one of two definitions; of these, 139 (95.2%) met Brighton levels of diagnostic certainty 1, 2 or 3 for either myocarditis or pericarditis.

Based on 537 reports of myocarditis or pericarditis, the overall crude reporting rate is 24.5 per million doses of mRNA vaccines administered. The highest reporting rates were observed in younger age groups (12-17 and 18-24 years) and among males. The highest reporting rate was observed for males aged 18-

24 years of age following dose 2, at 185.9 events per million doses administered. Table A3 in Appendix A presents the reporting rate of myocarditis or pericarditis by age group, gender and dose number. The reporting rates are calculated by including all reports of myocarditis or pericarditis identified through case-level review, regardless of whether they meet the Brighton Collaboration case definition for myocarditis or pericarditis.

The most recent in-depth analysis of myocarditis/pericarditis meeting the Brighton Collaboration case definition is available in Myocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to September 4, 2021.[18]

Serious AEFIs

In Ontario, AEFIs that meet the serious definition are events that required hospital admission and reports of death (see the technical notes for a full definition).

There were 881 AEFI reports classified as serious, representing 5.7% of all AEFI reports and a serious AEFI reporting rate of 3.8 per 100,000 doses administered for all vaccine products combined. Of the 881 reports meeting the serious definition, 873 reports had a hospital admission related to the adverse event and eight were reports of deaths. The serious reporting rate was 3.0 and 4.9 per 100,000 doses administered for the Pfizer-BioNTech Comirnaty COVID-19 vaccine and the Moderna Spikevax COVID-19 vaccine, respectively. The serious reporting rate for the AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine was 10.7 per 100,000 doses administered. As a comparison, the proportion of AEFIs defined as serious for all vaccines administered in Ontario ranged from 2.8% and 5.0% between 2012 and 2018.[20]

AEFI REPORTS REQUIRING HOSPITALIZATION

Of the 873 reports of hospitalization, 320 recovered at the time of reporting, 400 were not yet recovered when the investigation was completed but likely to recover, and 83 reported persistent or significant disability/incapacity related to the adverse event. Due to the relatively short follow-up time for AEFIs reported in CCM, it is uncertain whether these disability/incapacity will eventually resolve, but had not yet resolved at the time of reporting. The remaining reports had unknown outcome at the time of reporting.

AEFI REPORTS WITH FATAL OUTCOME

There are eight reports of death temporally associated with receipt of COVID-19 vaccine that met the provincial surveillance definition. Reports of death that meet the provincial case definition are events temporally associated with vaccine that have not been clearly attributed to other causes; these reports should not be interpreted as causally related with vaccine. The reports of deaths are as follows:

1. Resident of a health-care institution with significant comorbidities. The cause of death was not attributed to the vaccine.

2. Community dwelling senior with complex cardiovascular and renal conditions, wherein the AEFI may have contributed to but was not the underlying cause of death.

3. Community dwelling senior with multiple comorbidities including heart disease and an autoimmune disorder. The cause of death was not attributed to the vaccine.

4. An individual with VITT with death recorded in CCM (described above under Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) and Thrombosis with Thrombocytopenia Syndrome (TTS) section). A Coroner's investigation determined that the immediate causes of death included VITT.

5. Individual with hypertension, wherein the cause of death was not clearly attributed to vaccine.

6. Community dwelling senior with a complex cardiovascular history. The AEFI may have contributed to but was not the underlying cause of death.

7. Community dwelling senior with multiple comorbidities, wherein the AEFI may have contributed to but was not the underlying cause of death.

8. Community dwelling senior with severe aortic stenosis. The AEFI may have contributed to but was not underlying cause of death.

Reports of death temporally associated with receipt of vaccine

In Ontario, all deaths temporally associated with receipt of vaccines that have been reported to public health units are thoroughly investigated and reported to PHO. As of November 21, 2021, there are 27 reports of deaths temporally associated with receipt of COVID-19 vaccine that are currently classified as 'persons under investigation' as they do not currently meet the provincial surveillance definition. These investigations are ongoing and additional information including a cause of death (e.g., autopsy or Coroner's report) is expected. Preliminary information suggests that these events occurred in individuals with multiple co-morbidities which may be related to the cause of death. There has been no association with vaccine identified at this time.

During the first few months of the COVID-19 vaccination campaign, LTCH/retirement home residents have been a focus for vaccination efforts. In this population, it was expected that deaths may occur close to the time of vaccination and require further evaluation to determine the cause of death. After reviewing reports of deaths of very frail elderly individuals vaccinated with Pfizer-BioNTech Comirnaty COVID-19 vaccine, the Global Advisory Committee on Vaccine Safety (GACVC) COVID-19 Vaccine Safety subcommittee concluded that "the current reports do not suggest any unexpected or untoward increase in fatalities in frail, elderly individuals or any unusual characteristics of adverse events following administration of Pfizer-BioNTech COVID-19 vaccine".[21] The Centres for Disease Control (CDC) also presented a similar assessment of their analysis at the January 27, 2021 meeting of the Advisory Committee on Immunization Practices (ACIP) in the United States that mortality in LTCH residents is high and substantial numbers of deaths in this population are expected, unrelated to vaccination.[22] PHO continues to conduct continuous monitoring of the safety of COVID-19 vaccines in collaboration with its partners, including individual case review of all serious AEFIs including reports of death temporally association with receipt of vaccine, daily analysis of surveillance data for vaccine safety signals and weekly reporting on the PHO website and to the Public Health Agency of Canada.

Geography

Table 4. Number of AEFI reports and reporting rates by public health unit and region: Ontario, December 13, 2020 to November 21, 2021

Public Health Unit Name	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Northwestern Health Unit	134	106.6
Thunder Bay District Health Unit	98	40.6
TOTAL NORTH WEST	232	63.2
Algoma Public Health	122	67.2
North Bay Parry Sound District Health Unit	155	78.0
Porcupine Health Unit	121	94.4
Public Health Sudbury & Districts	310	97.3
Timiskaming Health Unit	91	182.4
TOTAL NORTH EAST	799	91.1
Eastern Ontario Health Unit	299	91.2
Hastings Prince Edward Public Health	164	63.4
Kingston, Frontenac and Lennox & Addington Public Health	312	93.6
Leeds, Grenville & Lanark District Health Unit	318	105.9
Ottawa Public Health	1,496	92.0
Renfrew County and District Health Unit	226	143.1
TOTAL EASTERN	2,815	93.7
Durham Region Health Department	1,897	171.7
Haliburton, Kawartha, Pine Ridge District Health Unit	372	124.5
Peel Public Health	1,041	43.9
Peterborough Public Health	239	104.1

Public Health Unit Name	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Simcoe Muskoka District Health Unit	573	62.6
York Region Public Health	1,085	58.5
TOTAL CENTRAL EAST	5,207	76.8
Toronto Public Health	1,931	41.9
TOTAL TORONTO	1,931	41.9
Chatham-Kent Public Health	70	43.9
Grey Bruce Health Unit	142	55.8
Huron Perth Public Health	203	92.3
Lambton Public Health	496	255.8
Middlesex-London Health Unit	288	36.6
Southwestern Public Health	388	122.6
Windsor-Essex County Health Unit	284	43.8
TOTAL SOUTH WEST	1,871	72.5
Brant County Health Unit	136	59.3
City of Hamilton Public Health Services	433	49.5
Haldimand-Norfolk Health Unit	48	27.6
Halton Region Public Health	671	70.7
Niagara Region Public Health	356	48.1
Region of Waterloo Public Health and Emergency Services	629	68.7
Wellington-Dufferin-Guelph Public Health	368	76.5
TOTAL CENTRAL WEST	2,641	60.5
TOTAL ONTARIO	15,496	67.5

Note: Orientation of AEFI reports by geography is based the case's public health unit of residence at the time of adverse event. This does not represent the location of vaccine administration. Reporting rates should not be interpreted as incidence rates. In the context of a passive AEFI surveillance system, a higher overall reporting rate of AEFIs does not necessarily suggest a vaccine safety concern; rather, it is an indicator of a robust passive vaccine safety surveillance system. Reporting rates are valuable estimates for comparing to other passive surveillance systems and for monitoring reporting trends over time.
Data Source: CCM

Technical Notes

Data Sources

- The data for this report were based on:
    - AEFI information from the Public Health Case and Contact Management Solution (CCM) extracted on **November 22, 2021 at approximately 9:00 a.m.**
    - Doses administered data from Ontario Ministry of Health's $COVax_{ON}$ application extracted on **November 22 at approximately 7:00 a.m**. Doses administered out of province and doses administered with non-Ontario stock were excluded from the doses administered data used for this report. Methodology used to calculate the number of doses administered are documented in PHO's COVID-19 Vaccine Uptake in Ontario report.[23]

Data Caveats

- Data presented in this report only represent AEFIs reported to public health units and recorded in CCM. As a result, all counts will be subject to varying degrees of reporting bias. Including underreporting, particularly for mild or common reportable events, as well as stimulated (elevated) reporting, which can occur in response to media coverage and increased public awareness.
- CCM and $COVax_{ON}$ are dynamic reporting systems which allow ongoing updates to data previous entered. As a result, data extracted from CCM and $COVax_{ON}$ represent a snapshot at the time of data extraction and may differ from previous or subsequent reports.

Methods

- For provincial surveillance reporting, an adverse event must occur after receiving the vaccine and meet the MOH AEFI case definition.[1] Data presented in this report only includes AEFI reports with a confirmed case classification and an association with a COVID-19 vaccine in CCM at the time of data extraction.
- AEFI reports from CCM where the Disposition was reported as ENTERED IN ERROR, DOES NOT MEET DEFINITION or DUPLICATE – DO NOT USE, or any variation on these values have been excluded. AEFI reports from CCM where the Status was reported as MERGED-OBSOLETE have also been excluded.
- AEFI reports with a missing date of vaccine administration have been excluded.
- Each AEFI report refers to an individual who reported an adverse event after receiving a dose of COVID-19 vaccine. An AEFI report may contain multiple adverse events. Therefore, the total number of adverse events can exceed the number of individual AEFI reports reported in a given time frame. AEFI reports that did not have an adverse event reported at the time of data extraction have been excluded.
- AEFI reporting rates are calculated using the number of COVID-19 vaccine-specific AEFIs reported in a given time period in Ontario divided by doses of COVID-19 vaccines administered in the same time period in Ontario.
- On October 14, 2021 changes were made in CCM to enable reporting on Sex and Gender separately; previously, sex and gender were reported interchangeably under the Gender field. Male/Female information presented in this report are sourced from the Sex field in CCM and are

intended to represent sex assigned at birth. The doses administered data from the COVaxON application are presented by gender, which is used as a proxy for doses administered by sex in calculating sex-specific reporting rates.

- Dose number is extracted from CCM. It represents the dose number of the immunization that is associated with the adverse event. Since dose number was not a system-mandatory field in CCM during the initial implementation of the system, there are records with missing dose number information. When a dose number was missing or reported as unknown in CCM, the individual's immunization records in $COVax_{ON}$ application were examined to identify the dose number of the immunization that was associated with the AEFI, if available.

- Serious AEFIs are defined using the World Health Organization (WHO) standard definition:[24] an AEFI that results in death, is life-threatening, requires in-patient hospitalization or prolongs an existing hospitalization, results in persistent or significant disability/incapacity, or in a congenital anomaly/birth defect. Due to data limitations and the relatively brief follow-up period of AEFIs reported in Ontario, AEFI reports that meet the serious definition typically have an in-patient hospitalization or death reported. In-patient hospitalization is defined as having a hospital admission recorded in CCM. Deaths are defined as reporting 'fatal' in the outcome field in CCM.

- Some selected adverse events can be defined as "medically important," based on the World Health Organization's (WHO) guidance, regardless of whether they meet the serious AEFI definition. These types of events may jeopardize the patient or may require intervention to prevent an outcome described in the serious definition (e.g., hospitalization); "medically important" events may be defined after applying medical and scientific judgement. In Ontario, the specific events under surveillance that align with this definition include: acute disseminated encephalomyelitis (ADEM), events managed as anaphylaxis, encephalitis/encephalopathy, Guillain-Barré syndrome (GBS), intussusception, meningitis, myelitis/transverse myelitis and thrombocytopenia.

- All reports of events managed as anaphylaxis, GBS, TTS/VITT and myocarditis are further assessed using the internationally recognized case definition for anaphylaxis following vaccination from the Brighton Collaboration.[7,8,10,19] An independent review of these cases is completed and a preliminary score is assigned based on this case definition. This score is not a measure of severity but rather reflects the level of diagnostic certainty, with level 1 being the most highly specific for the condition.

- Several adverse events of special interest (AESI) following administration of COVID-19 vaccine(s) were selected for surveillance.[25] These are: vaccine-associated enhanced disease, multisystem inflammatory syndrome in children and adults, acute respiratory distress syndrome, acute cardiovascular injury, myocarditis/pericarditis, coagulation disorder (including thrombotic events), thrombosis with thrombocytopenia syndrome (TTS) and vaccine-induced immune thrombotic thrombocytopenia (VITT), acute kidney injury, acute liver injury, anosmia and/or ageusia, chilblain-like lesions, single organ cutaneous vasculitis, erythema multiforme, acute pancreatitis, rhabdomyolysis, and subacute thyroiditis.

- Orientation of case counts by geography is based on the Permanent Health Unit in CCM. Permanent Health Unit refers to the case's public health unit of residence at the time of adverse event. Cases for which the Permanent Health Unit was reported as MOH-PHO (to signify a case that is not a resident of Ontario) have been excluded from the analyses.

References

1. Ontario. Ministry of Health. Infectious diseases protocol: appendix B: provincial case definitions for diseases of public health significance: disease: adverse events following immunization (AEFIs) [Internet]. Toronto, ON: Queen's Printer for Ontario; 2020 [cited 2021 Jan 16]. Available from: http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/aefi_cd.pdf

2. Ontario Agency for Health Protection and Promotion (Public Health Ontario). COVID-19 vaccines [Internet]. Toronto, ON: Queen's Printer for Ontario; 2020 [modified 2021 Jan 13; cited 2021 Jan 16]. Available from: https://www.publichealthontario.ca/en/diseases-and-conditions/infectious-diseases/respiratory-diseases/novel-coronavirus/vaccines

3. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Focus on: how vaccine safety is monitored in Canada [Internet]. Toronto, ON: Queen's Printer for Ontario; 2020 [cited 2021 Jan 16]. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/vaccines/2020/12/vaccine-safety-survelliance-canada.pdf?la=en

4. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Vaccine safety surveillance archive [Internet]. Toronto, ON: Queen's Printer for Ontario; 2020 [modified 2020 Dec 16; cited 2021 Jan 16]. Available from: https://www.publichealthontario.ca/en/data-and-analysis/infectious-disease/vaccine-safety/vaccine-safety-surveillance-archive

5. Government of Canada. COVID-19 vaccine safety in Canada [Internet]. Ottawa, ON: Government of Canada; 2021 [modified 2021 June 4; cited 2021 Jun 4]. Available from: https://health-infobase.canada.ca/covid-19/vaccine-safety/

6. Public Health Agency of Canada; National Advisory Committee on Immunization. An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI): recommendations on the use of COVID-19 vaccines [Internet]. Ottawa, ON: Government of Canada; 2021 [cited 2021 Nov 10]. Available from: https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/recommendations-use-covid-19-vaccines-en.pdf

7. Rüggeberg 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

8. Task Force for Global Health, Brighton Collaboration. Guillain Barré and Miller Fisher Syndromes: Case Definition Companion Guide [Internet]. Decatur, GA: Task Force for Global Health; 2021 [cited 2021 Jul 05]. Available from: https://brightoncollaboration.us/wp-content/uploads/2021/03/SPEAC_D2.5.2.1-GBS-Case-Definition-Companion-Guide_V1.0_format12062-1.pdf

9. Tan CY, Razali SN, Goh KJ, Shahrizaila N. Determining the Utility of the Guillain-Barré Syndrome Classification Criteria. J Clin Neurol. 2021 Apr;17(2):273-282. Available from: https://doi.org/10.3988/jcn.2021.17.2.273

10. Task Force for Global Health, Brighton Collaboration. Interim case definition of thrombosis with thrombocytopenia syndrome (TTS) [Internet]. Decatur, GA: Task Force for Global Health; 2021 [cited 2021 Apr 26]. Available from: https://brightoncollaboration.us/wp-content/uploads/2021/01/COVID-19-updated-AESI-list.pdf

11. Ontario Agency for Health Protection and Promotion (Public Health Ontario). COVID-19 viral vector vaccines and rare blood clots – vaccine safety surveillance in action. Toronto, ON: Queen's

Printer for Ontario; 2021 [cited 2021 Oct 13]. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/vaccines/2021/07/covid-19-viral-vector-vaccines-rare-blood-clots.pdf?sc_lang=en

12. 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]. Geneva: World Health Organization; 2021 [cited 2021 Jun 3]. Available from: https://www.who.int/news/item/26-05-2021-gacvs-myocarditis-reported-with-covid-19-mrna-vaccines

13. Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices (ACIP). COVID-19 VaST Work Group report – May 17, 2021 [Internet]. Atlanta, GA: Centers for Disease Control and Prevention; 2021 [cited 2021 Jun 3]. Available from: https://www.cdc.gov/vaccines/acip/work-groups-vast/report-2021-05-17.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Facip%2Fwork-groups-vast%2Ftechnical-report-2021-05-17.html

14. Centers for Disease Control and Prevention, National Center for Immunization & Respiratory Diseases. COVID-19 vaccine safety update: Advisory Committee on Immunization Practices (ACIP) [Webinar]. Atlanta, GA: Centers for Disease Control and Prevention; 2021 [presented 2021 Jun 23; cited 2021 Jun 28]. Available from: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/03-COVID-Shimabukuro-508.pdf

15. Public Health Agency of Canada. Statement from the Council of Chief Medical Officers of Health (CCMOH): update on COVID-19 vaccines and the risk of myocarditis and pericarditis [Internet]. Ottawa, ON: Government of Canada; 2021 [cited 2021 Oct 05]. Available from: https://www.canada.ca/en/public-health/news/2021/10/statement-from-the-council-of-chief-medical-officers-of-health-ccmoh-update-on-covid-19-vaccines-and-the-risk-of-myocarditis-and-pericarditis.html

16. Government of Ontario. Statement: Ontario recommends the use of Pfizer-BioNTech COVID-19 vaccine for individuals aged 18-24 years old [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 Oct 05]. Available from: https://news.ontario.ca/en/statement/1000907/ontario-recommends-the-use-of-pfizer-biontech-covid-19-vaccine-for-individuals-aged-18-24-years-old

17. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Myocarditis and pericarditis following COVID-19 mRNA vaccines. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 Jun 14]. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/vaccines/2021/06/covid-19-mrna-vaccines-myocarditis-pericarditis.pdf?la=en

18. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines in Ontario: December 13, 2020 to September 4, 2021. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2021 Oct 20]. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-myocarditis-pericarditis-vaccines-epi.pdf?sc_lang=en

19. Task Force for Global Health, Brighton Collaboration. Myocarditis/Pericarditis Case Definition (myocarditis_version_1.5.0_16.July.2021 and pericarditis_version_1.0.0_15.July.2021) [Internet]. Decatur, GA: Task Force for Global Health; 2021 [cited 2021 Jul 19]. Available from: https://brightoncollaboration.us/myocarditis-case-definition-update/

20. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Annual report on vaccine safety in Ontario, 2018 [Internet]. Toronto, ON: Queen's Printer for Ontario; 2019 [cited 2021 Jan 26]. Available from: https://www.publichealthontario.ca/-/media/documents/a/2019/annual-vaccine-safety-report-2018.pdf?la=en

21. World Health Organization. GACVS COVID-19 Vaccine Safety subcommittee meeting to review reports of deaths of very frail elderly individuals vaccinated with Pfizer BioNTech COVID-19 vaccine, BNT162b2 [Internet]. Geneva: World Health Organization; 2021 [cited 2021 Feb 22]. Available from: https://www.who.int/news/item/22-01-2021-gacvs-review-deaths-pfizer-biontech-covid-19-vaccine-bnt162b2

22. Centers for Disease Control and Prevention, National Center for Immunization & Respiratory Diseases. COVID-19 vaccine safety update: Advisory Committee on Immunization Practices (ACIP) [Webinar]. Atlanta, GA: Centers for Disease Control and Prevention; 2021 [presented 2021 Jan 27; cited 2021 Feb 22]. Available from: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-Shimabukuro.pdf

23. Ontario Agency for Health Protection and Promotion (Public Health Ontario). COVID-19 vaccine uptake in Ontario: December 14, 2020 to March 27, 2021 [cited 2021 Mar 29]. Toronto, ON: Queen's Printer for Ontario; 2021. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-vaccine-uptake-ontario-epi-summary.pdf?la=en

24. ICH Expert Working Group. ICH harmonised tripartite guideline: clinical safety data management: definitions and standards for expedited reporting E2A [Internet]. Version 4. Geneva: ICH; 1994 [cited 2021 Jan 16]. Available from: https://database.ich.org/sites/default/files/E2A_Guideline.pdf

25. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Adverse events of special interest (AESIs) for COVID-19 vaccines surveillance. Toronto, ON: Queen's Printer for Ontario; 2020 [cited 2021 Jul 19]. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/vaccines/2020/12/covid-19-guidance-aesis.pdf?la=en

Appendix A

Table A1. Number of AEFI reports by adverse event and vaccine product: Ontario, December 13, 2020 to November 21, 2021

Adverse event	Pfizer-BioNTech Comirnaty COVID-19 vaccine	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine	All vaccine products combined
Other severe or unusual events‡	2,436	870	399	3,706
Allergic skin reactions	2,430	931	267	3,628
Pain/redness/swelling at the injection site	1,088	1,560	299	2,947
Rash	941	590	170	1,701
Anaesthesia/paraesthesia	872	266	201	1,339
Adenopathy/lymphadenopathy	526	239	44	809
Severe vomiting/diarrhea	423	198	141	763
Arthritis/arthralgia	484	154	95	733
Fever in conjunction with another reportable event	320	240	165	726
AESI – Myocarditis/pericarditis†	344	213	8	565
Event managed as anaphylaxis*	326	98	21	445
AESI – Coagulation disorder (including thrombotic events)	175	69	70	314
Syncope (fainting) with injury	212	68	8	288
Bell's Palsy	171	68	13	252
Cellulitis	41	184	20	245
AESI – Acute cardiovascular injury	87	39	15	141
Convulsions/seizure	88	35	13	136
Thrombocytopenia*	42	11	20	73
Nodule	18	33	21	72

Adverse event	Pfizer-BioNTech Comirnaty COVID-19 vaccine	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine	All vaccine products combined
AESI – Anosmia, ageusia	23	8	4	35
Guillian-Barré syndrome (GBS)*	12	5	17	34
Paralysis	24	1	9	34
AESI – Acute liver injury	17	8	2	27
AESI – TTS/VITT	4	2	21	27
Oculorespiratory syndrome (ORS)	17	4	2	23
Myelitis/transverse myelitis*	14	3	3	20
AESI – Single organ cutaneous vasculitis	10	5	4	19
AESI – Acute kidney injury	8	6	2	16
AESI – Chilblain-like lesions	8	3	1	12
AESI – Erythema multiforme	6	5	1	12
AESI – Subacute thyroiditis	6	3	1	10
AESI – Rhabdomyolysis	4	4	1	9
AESI – Acute pancreatitis	4	3	1	8
Encephalopathy/encephalitis*	5	2	1	8
AESI – Multisystem inflammatory syndrome in children/adults	4	2	0	6
Infected abscess	1	5	0	6
AESI – Acute respiratory distress syndrome	3	1	0	4
Sterile abscess	1	2	0	3
Acute disseminated encephalomyelitis (ADEM)*	1	0	1	2
AESI – Vaccine-associated enhanced disease	0	1	0	1
Meningitis*	1	0	0	1

Note: An AEFI report may contain multiple adverse events. Thus the sum of all adverse event-specific counts may not equal to the total number of AEFI reports. Some AEFI reports did not specify vaccine product received; these are included in the counts for all vaccine products combined.
‡This category includes reports of death that are temporally associated with immunization and where no other clear cause of death was established; these reports should not be interpreted as causally related with vaccine. These reports are described in the Serious AEFI section.
* represents a medically important event.
† The number of reports with 'AESI – Myocarditis/pericarditis' presented in this table is based on CCM data entry and may be different from the number of myocarditis or pericarditis reports that are presented in the Myocarditis/Pericarditis section, which is based on case-level review. With the latter process, additional reports may be identified in those that are not yet classified as 'AESI – Myocarditis/pericarditis' or reports may be excluded if the case information does not support the report being classified as 'AESI – Myocarditis/pericarditis'. Refer to the Myocarditis/Pericarditis section for accurate number of myocarditis or pericarditis reports.
Data Source: CCM

Table A2. Reporting rate per 100,000 doses administered by adverse event and vaccine product: Ontario, December 13, 2020 to November 21, 2021

Adverse event	Pfizer-BioNTech Comirnaty COVID-19 vaccine	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine	All vaccine products combined
Other severe or unusual events‡	15.1	15.2	36.7	16.1
Allergic skin reactions	15.1	16.2	24.5	15.8
Pain/redness/swelling at the injection site	6.7	27.2	27.5	12.8
Rash	5.8	10.3	15.6	7.4
Anaesthesia/paraesthesia	5.4	4.6	18.5	5.8
Adenopathy/lymphadenopathy	3.3	4.2	4.0	3.5
Severe vomiting/diarrhea	2.6	3.5	13.0	3.3
Arthritis/arthralgia	3.0	2.7	8.7	3.2
Fever in conjunction with another reportable event	2.0	4.2	15.2	3.2
AESI – Myocarditis/pericarditis†	2.1	3.7	0.7	2.5
Event managed as anaphylaxis*	2.0	1.7	1.9	1.9
AESI – Coagulation disorder (including thrombotic events)	1.1	1.2	6.4	1.4
Syncope (fainting) with injury	1.3	1.2	0.7	1.3
Bell's Palsy	1.1	1.2	1.2	1.1
Cellulitis	0.3	3.2	1.8	1.1
AESI – Acute cardiovascular injury	0.5	0.7	1.4	0.6
Convulsions/seizure	0.5	0.6	1.2	0.6
Thrombocytopenia*	0.3	0.2	1.8	0.3
Nodule	0.1	0.6	1.9	0.3
AESI – Anosmia, ageusia	0.1	0.1	0.4	0.2
Guillian-Barré syndrome (GBS)*	0.1	0.1	1.6	0.1

Adverse event	Pfizer-BioNTech Comirnaty COVID-19 vaccine	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine	All vaccine products combined
Paralysis	0.1	0.0	0.8	0.1
AESI – Acute liver injury	0.1	0.1	0.2	0.1
AESI – TTS/VITT	0.0	0.0	1.9	0.1
Oculorespiratory syndrome (ORS)	0.1	0.1	0.2	0.1
Myelitis/transverse myelitis*	0.1	0.1	0.3	0.1
AESI – Single organ cutaneous vasculitis	0.1	0.1	0.4	0.1
AESI – Acute kidney injury	0.0	0.1	0.2	0.1
AESI – Chilblain-like lesions	0.0	0.1	0.1	0.1
AESI – Erythema multiforme	0.0	0.1	0.1	0.1
AESI – Subacute thyroiditis	0.0	0.1	0.1	0.0
AESI – Rhabdomyolysis	0.0	0.1	0.1	0.0
AESI – Acute pancreatitis	0.0	0.1	0.1	0.0
Encephalopathy/encephalitis*	0.0	0.0	0.1	0.0
AESI – Multisystem inflammatory syndrome in children/adults	0.0	0.0	0.0	0.0
Infected abscess	0.0	0.1	0.0	0.0
AESI – Acute respiratory distress syndrome	0.0	0.0	0.0	0.0
Sterile abscess	0.0	0.0	0.0	0.0
Acute disseminated encephalomyelitis (ADEM)*	0.0	0.0	0.1	0.0
AESI – Vaccine-associated enhanced disease	0.0	0.0	0.0	0.0
Meningitis*	0.0	0.0	0.0	0.0

Note: An AEFI report may contain multiple adverse events. Thus the sum of all adverse event-specific counts may not equal to the total number of AEFI reports. Some AEFI reports did not specify vaccine product received; these are included in the counts for all vaccine products combined.

‡This category includes reports of death that are temporally associated with immunization and where no other clear cause of death was established; these reports should not be interpreted as causally related with vaccine. These reports are described in the Serious AEFI section.
* represents a medically important event.
† The number of reports with 'AESI – Myocarditis/pericarditis' presented in this table is based on CCM data entry and may be different from the number of myocarditis or pericarditis reports that are presented in the Myocarditis/Pericarditis section, which is based on case-level review. With the latter process, additional reports may be identified in those that are not yet classified as 'AESI – Myocarditis/pericarditis' or reports may be excluded if the case information does not support the report being classified as 'AESI – Myocarditis/pericarditis'. Refer to the Myocarditis/Pericarditis section for accurate number of myocarditis or pericarditis reports.
Data Source: CCM, COVaxON (see technical notes for details on data sources)

Table A3. Myocarditis/pericarditis crude reporting rates per million doses administered following COVID-19 mRNA vaccines: Ontario, December 13, 2020 to November 21, 2021

Age group (years)	All sex: All doses	All sex: Dose 1	All sex: Dose 2	All sex: Dose 3	Females: All doses	Females: Dose 1	Females: Dose 2	Females: Dose 3	Males: All doses	Males: Dose 1	Males: Dose 2	Males: Dose 3
12-17	63.2	48.2	78.9	0.0	25.8	28.8	22.6	0.0	99.5	67.1	133.7	0.0
18-24	72.4	37.4	110.3	0.0	30.7	28.6	33.6	0.0	113.3	46.2	185.9	0.0
25-29	37.5	31.9	42.8	66.2*	18.2	15.8	18.8	93.8*	56.5	47.7	66.4	0.0
30-39	23.4	13.4	34.3	0.0	17.9	10.4	26.1	0.0	29.3	16.5	42.9	0.0
40-49	13.4	12.9	14.2	0.0	6.4	6.7	6.2	0.0	21.3	19.8	23.0	0.0
50-59	11.8	11.2	12.2	19.8*	12.8	13.9	11.2	30.8*	10.8	8.3	13.2	0.0
60-69	6.8	5.1	8.8	0.0	4.6	2.8	6.5	0.0	9.4	7.8	11.3	0.0
70-79	7.0	6.7	7.7	0.0	5.2	7.2	3.6	0.0	9.0	6.2	12.3	0.0
80+	5.3	3.3	8.4	0.0	2.5	0.0	5.7	0.0	9.5	8.1	12.5	0.0
Total	24.5	17.7	32.0	4.8	13.2	12.1	14.5	7.7	36.9	23.8	50.8	0.0

Note: Includes all reports of myocarditis or pericarditis identified through case-level review (n=537), regardless of the reports meeting the Brighton Collaboration case definition for myocarditis or pericarditis.

*Interpret with caution as this reporting rate is based on one report.

Data Source: CCM, $COVax_{ON}$ (see technical notes for details on data sources)

Citation

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Weekly summary: adverse events following immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to November 21, 2021. Toronto, ON: Queen's Printer for Ontario; 2021.

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