

SURVEILLANCE REPORT

Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to April 10, 2022

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 summary includes AEFIs reported in the Public Health Case and Contact Management Solution (CCM) as of **April 10, 2022**. Doses administered up to and including April 10, 2022 are extracted from the Ontario Ministry of Health's COVaxON application (see [technical notes](#) for details on data sources). The report is updated on a bi-weekly basis.

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 Ontario³
- The [technical annex](#) of PHO's annual vaccine safety report for technical details on vaccine safety surveillance data analysis in Ontario⁴
- The government of Canada's COVID-19 vaccine safety [webpage](#) for national data on COVID-19 vaccine safety⁵
- PHO's [COVID-19 vaccine webpage](#) for resources and data on Ontario's COVID-19 vaccine program

Highlights

There are a total of 20,033 AEFI reports received following 31,555,465 doses of COVID-19 vaccines administered in Ontario to date with a reporting rate of 63.5 per 100,000 doses administered (0.06% of all doses administered)

- This represents an increase of 105 AEFI reports compared to the previous report

Of the total 20,033 AEFI reports received to date:

- 18,912 AEFI reports are non-serious (94.4% of total AEFI reports)
- 1,121 AEFI reports meet the [serious definition](#) (5.6% of total AEFI reports)
- The most commonly reported adverse events are other severe or unusual events and allergic skin reactions, reported in 27.2% and 22.8% of the total AEFI reports, respectively
- 1,522 reports include a COVID-19 vaccine-specific adverse event of special interest, in which 675 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)
- 743 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 April 10, 2022

	Pfizer-BioNTech Comirnaty COVID-19 vaccine (10 mcg)	Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg)	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine	Janssen (Johnson & Johnson) COVID-19 vaccine	All vaccine products combined
Total number of AEFI reports	217	11,893	6,263	1,646	12	20,033
Number of non-serious reports	212	11,266	5,902	1,519	11	18,912
Number of serious reports	5	627	361	127	1	1,121
Proportion of total AEFI reports that are serious	2.3	5.3	5.8	7.7	8.3	5.6
Doses administered	1,054,415	20,576,359	8,832,889	1,088,557	3,245	31,555,465
Total reporting rate per 100,000 doses administered	20.6	57.8	70.9	151.2	369.8	63.5
Serious reporting rate per 100,000 doses administered	0.5	3.0	4.1	11.7	30.8	3.6

Notes:

- The Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg) is authorized for 5-11 year olds and the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) is indicated for 12+ years of age but also administered to eligible 11 year olds (i.e., who turned 12 years of age by the end of 2021) as per the provincial program.
- 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.
- Reporting rate for the Janssen COVID-19 vaccine should be interpreted with caution due to unstable reporting rate arising from small number of doses administered.
- 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 for people 12 years of age or older.⁶ For children 5 to 11 years of age, NACI recommends a 14 day interval before or after the administration of another vaccine before administering a COVID-19 vaccine. More information can be found in the [Canadian Immunization Guide for COVID-19 vaccines](#). To date, there have been ten AEFI reports associated with co-administration of COVID-19 vaccine and a non-COVID-19 vaccine in Ontario.

Data Source: CCM, COVaxON (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 April 10, 2022

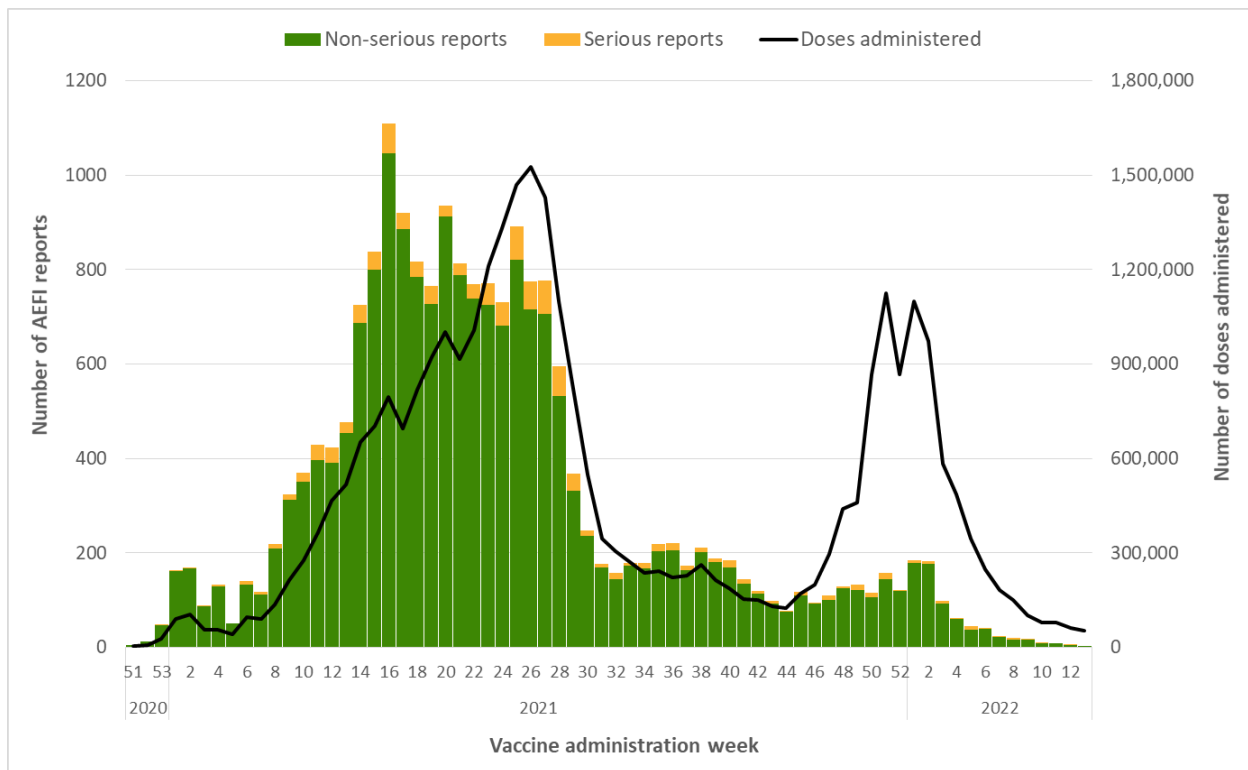
	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Sex: Female	14,678	89.9
Sex: Male	5,143	33.9
Ages: 5-11 years	229	20.3
Ages: 12-17 years	693	35.7
Ages: 18-24 years	1,334	46.5
Ages: 25-29 years	1,313	57.6
Ages: 30-39 years	3,299	73.8
Ages: 40-49 years	4,030	94.2
Ages: 50-59 years	3,916	78.7
Ages: 60-69 years	2,884	61.9
Ages: 70-79 years	1,503	48.0
Ages: 80 years and over	823	45.3

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.
- There are three AEFI reports in 4-year-olds who received the Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg) authorized for 5-11 year olds but administered to eligible 4 year olds in 2021 (i.e., who turned 5 years of age by the end of 2021). These reports are not included in the age group-specific reporting rates.
- The number of reports and reporting rate for the 5-11 year age group includes all doses administered in this age group. This includes the Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg) authorized for 5-11 year olds and the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) indicated for 12+ years of age but administered to eligible 11 year olds (i.e., who turned 12 years of age by the end of 2021) as per the provincial program.

Data Source: CCM, COVaxON (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 April 10, 2022



Note:

- AEFI reports are assessed based on date of vaccine administration. The administration week ranges from week 51 (Dec 13 – 19, 2020) to week 13 (April 3 – 9, 2022). April 10, 2022 is not included 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, COVaxON (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 April 10, 2022

	Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg)	Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg)	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine	Janssen (Johnson & Johnson) COVID-19 vaccine	All vaccine products combined
Total number of AEFI reports	217	11,893	6,263	1,646	12	20,033
Dose 1	177	7,832	3,463	1,565	11	13,048
Dose 2	40	3,524	2,220	74	1	5,861
Dose 3	0	513	543	0	0	1,056
Dose 4	0	4	22	0	0	26
Number of serious reports	5	627	361	127	1	1,121
Dose 1	3	307	101	119	1	531
Dose 2	2	279	215	8	0	504
Dose 3	0	38	38	0	0	76
Dose 4	0	2	6	0	0	8
Total reporting rate per 100,000 doses administered	20.6	57.8	70.9	151.2	369.8	63.5
Dose 1	28.5	90.1	163.4	181.0	355.2	106.1
Dose 2	9.2	46.7	61.0	33.1	1,204.8	49.5
Dose 3	0.0	12.1	18.3	0.0	0.0	14.6
Dose 4	0.0	4.5	18.8	0.0	0.0	12.7
Serious reporting rate per 100,000 doses administered	0.5	3.0	4.1	11.7	30.8	3.6
Dose 1	0.5	3.5	4.8	13.8	32.3	4.3

	Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg)	Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg)	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine	Janssen (Johnson & Johnson) COVID-19 vaccine	All vaccine products combined
Dose 2	0.5	3.7	5.9	3.6	0.0	4.3
Dose 3	0.0	0.9	1.3	0.0	0.0	1.1
Dose 4	0.0	2.3	5.1	0.0	0.0	3.9

Note:

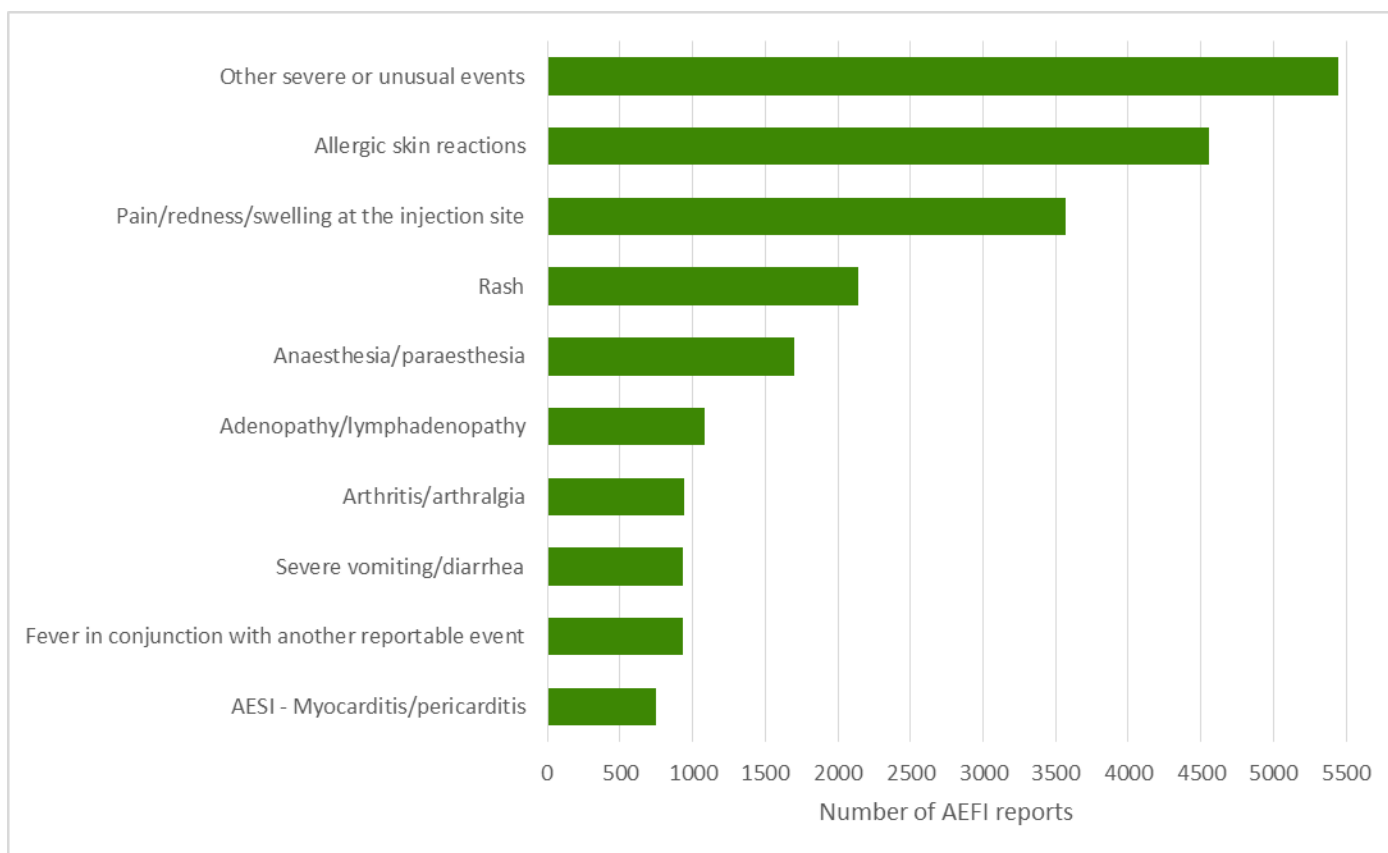
- The Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg) is authorized for 5-11 year olds and the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) is indicated for 12+ years of age but also administered to eligible 11 year olds (i.e., who turned 12 years of age by the end of 2021) as per the provincial program.
- Reporting rate for the Janssen COVID-19 vaccine should be interpreted with caution due to unstable reporting rate arising from small number of doses administered.
- 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, COVaxON (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 27.2% and 22.8% 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 April 10, 2022



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](#).

The 'other severe or unusual events' category was the most frequently reported adverse event for the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) (17.2 per 100,000 doses administered) and the AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine (40.4 per 100,000 doses administered). Pain/redness/swelling at the injection site was the most frequently reported adverse event for the Moderna Spikevax COVID-19 vaccine (21.2 per 100,000 doses administered). Allergic skin reaction was the most frequently reported adverse event for the Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg) (8.9 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 672 reports with medically important events, representing 3.4% of all reports. The 672 reports include 514 reports of events managed as anaphylaxis, of which 38 met the definition of a serious AEFI. Of all 514 reports of events managed as anaphylaxis: 460 received epinephrine, 441 were seen in the emergency department and 386 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, 39 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 1, one report met level 2 and one report met level 3 of the Brighton Collaboration case definition of GBS. Four did not meet the Brighton Collaboration case definition of GBS and 31 had insufficient evidence to meet level 1, 2 or 3 (i.e., met level 4 diagnostic certainty) of the case definition. One report has not yet been assessed due to lack of information.

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 1,522 reports with COVID-19 vaccine-specific AESIs, representing 7.6% of all reports. Of the 1,522 reports, 675 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](#) and Ontario’s COVID-19 Science Advisory Table scientific briefs on [Vaccine-Induced Immune Thrombotic Thrombocytopenia \(VITT\) Following Adenovirus Vector COVID-19 Vaccination](#).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 and later [expanded this to individuals aged 12 to 29 years of age](#) to align with the updated NACI recommendation.^{16,17} Ontario is continuing to monitor these events in collaboration with its partners and updates can be found within this report and on the PHAC [website](#).⁵ For more information on this topic please see [PHO's Focus On: Myocarditis and Pericarditis after 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 November 21, 2021](#).^{18,19}

As of April 10, 2022, there have been 743 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, 193 (26.0%) were diagnosed with myocarditis and 355 (47.8%) were diagnosed with pericarditis. The remaining 195 (26.2%) were diagnosed with perimyocarditis (n=37), myopericarditis (n=147) and myocarditis/pericarditis (n=11).

The 193 reports of myocarditis have been assessed using the [Brighton Collaboration case definition for myocarditis](#); 174 reports met Brighton levels of diagnostic certainty 1, 2 or 3 (90.2%) and 19 reports had insufficient evidence to meet level 1, 2 or 3 of the case definition (9.8%).²⁰ Of the 355 reports of pericarditis assessed using the [Brighton Collaboration case definition for pericarditis](#), 178 reports met Brighton levels of diagnostic certainty 1, 2 or 3 (50.1%) and 177 reports had insufficient evidence to meet level 1, 2 or 3 of the case definition (49.9%).²⁰ The remaining 195 reports diagnosed with perimyocarditis, myopericarditis or myocarditis/pericarditis were assessed against both Brighton Collaboration case definition for myocarditis and pericarditis to see if they meet either one of two definitions; of these, 182 (93.3%) met Brighton levels of diagnostic certainty 1, 2 or 3 for either myocarditis or pericarditis.

Based on 743 reports of myocarditis or pericarditis, the overall crude reporting rate is 25.3 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 198.6 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 November 21, 2021](#).¹⁹

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 1,121 AEFI reports classified as serious, representing 5.6% of all AEFI reports and a serious AEFI reporting rate of 3.6 per 100,000 doses administered for all vaccine products combined. Of the 1,121 reports meeting the serious definition, 1,099 reports had a hospital admission related to the adverse event and 22 were reports of deaths. The serious reporting rate was 3.0 and 4.1 per 100,000 doses administered for the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) and the Moderna Spikevax COVID-19 vaccine, respectively. The serious reporting rate for the AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine was 11.7 per 100,000 doses administered. There have been five serious reports received after the Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg), with a serious reporting rate of 0.5 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% to 5.0% between 2012 and 2018.²¹

AEFI REPORTS REQUIRING HOSPITALIZATION

Of the 1,099 reports of hospitalization, 429 were recovered at the time of reporting, 494 were not yet recovered when the investigation was completed but likely to recover, and 93 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

In Ontario, reports of death that meet the provincial AEFI surveillance case definition are those that are temporally associated with vaccination, where no other clear cause of death can be established. Similar to other events, reports of deaths are thoroughly investigated by the local PHU through the collection of relevant information including a cause of death (e.g., autopsy or Coroner's report). **It is important to note that these reports should not be interpreted as causally related with receipt of a vaccine.**

As of April 10, 2022, there are 22 reports of death temporally associated with receipt of COVID-19 vaccine that met the provincial surveillance case definition. There was one death where AEFI may have been a contributing factor of death; in this death, a Coroner's investigation determined that the immediate causes of death included VITT.

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 and daily analysis of surveillance data for vaccine safety signals.

Geography

Table 4. Number of AEFI reports and reporting rates by public health unit and region: Ontario, December 13, 2020 to April 10, 2022

Public Health Unit Name	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Northwestern Health Unit	152	86.3
Thunder Bay District Health Unit	119	35.3
TOTAL NORTH WEST	271	52.8
Algoma Public Health	148	58.0
North Bay Parry Sound District Health Unit	188	68.4
Porcupine Health Unit	142	81.5
Public Health Sudbury & Districts	397	90.1
Timiskaming Health Unit	102	146.6
TOTAL NORTH EAST	977	80.5
Eastern Ontario Health Unit	493	108.9
Hastings Prince Edward Public Health	208	57.3
Kingston, Frontenac and Lennox & Addington Public Health	420	88.2
Leeds, Grenville & Lanark District Health Unit	383	90.4
Ottawa Public Health	1,963	85.2
Renfrew County and District Health Unit	267	121.5
TOTAL EASTERN	3,734	88.1
Durham Region Health Department	2,727	178.3
Haliburton, Kawartha, Pine Ridge District Health Unit	485	117.8
Peel Public Health	1,299	41.4
Peterborough Public Health	265	82.4
Simcoe Muskoka District Health Unit	701	55.9

Public Health Unit Name	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
York Region Public Health	1,572	61.4
TOTAL CENTRAL EAST	7,049	76.5
Toronto Public Health	2,420	38.3
TOTAL TORONTO	2,420	38.3
Chatham-Kent Public Health	80	36.5
Grey Bruce Health Unit	177	49.7
Huron Perth Public Health	359	117.2
Lambton Public Health	554	207.0
Middlesex-London Health Unit	316	28.8
Southwestern Public Health	434	98.3
Windsor-Essex County Health Unit	341	38.9
TOTAL SOUTH WEST	2,261	63.4
Brant County Health Unit	148	47.3
City of Hamilton Public Health Services	553	45.8
Haldimand-Norfolk Health Unit	61	25.9
Halton Region Public Health	838	62.9
Niagara Region Public Health	495	48.5
Region of Waterloo Public Health and Emergency Services	762	60.0
Wellington-Dufferin-Guelph Public Health	464	69.5
TOTAL CENTRAL WEST	3,321	54.9
TOTAL ONTARIO	20,033	63.5

Note: Orientation of AEFI reports by geography is based the case's public health unit of residence at the time of the 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, COVaxON (see [technical notes](#) for details on data sources)

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 **April 11, 2022 at approximately 8:30 a.m.**
 - Doses administered data from the Ontario Ministry of Health's COVaxON application extracted on **April 11, 2022 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](#).²²

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 COVaxON are dynamic reporting systems which allow ongoing updates to data previous entered. As a result, data extracted from CCM and COVaxON 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. If an AEFI report has more than one vaccination entered (i.e., it was unclear if the adverse event was attributed to the first or the second dose of the series), then the administration date of the first dose was used for the analysis.
- 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. AEFIs that are reported in Ontario following vaccines that were administered outside of Canada with a Health Canada-approved vaccine are included in the calculation of reporting rates. The number of such reports are small and has minimal impact on the reporting rates.
- 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 COVaxON 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](#):²³ 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 from the Brighton Collaboration.^{7,8,10,20} 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.²⁴ 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.

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Appendix A

Table A1. Number of AEFI reports by adverse event and vaccine product: Ontario, December 13, 2020 to April 10, 2022

Adverse event	Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg)	Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg)	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine	Janssen (Johnson & Johnson) COVID-19 vaccine	All vaccine products combined
Other severe or unusual events*	45	3,546	1,410	440	6	5,448
Allergic skin reactions	94	2,945	1,245	272	3	4,559
Pain/redness/swelling at the injection site	12	1,366	1,870	318	2	3,568
Rash	27	1,183	746	180	3	2,139
Anaesthesia/paraesthesia	2	1,120	364	210	2	1,698
Adenopathy/lymphadenopathy	6	716	311	47	0	1,080
Arthritis/arthralgia	4	625	214	101	0	944
Severe vomiting/diarrhea	9	510	272	145	1	937
Fever in conjunction with another reportable event	12	412	342	169	1	936
AESI - Myocarditis/pericarditis**	3	463	271	9	0	746
Event managed as anaphylaxis†	3	369	120	22	0	514
AESI – Coagulation disorder (including thrombotic events)	0	221	88	77	1	387
Syncope (fainting) with injury	17	226	74	8	0	325

Adverse event	Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg)	Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg)	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine	Janssen (Johnson & Johnson) COVID-19 vaccine	All vaccine products combined
Bell's Palsy	0	212	86	14	0	313
Cellulitis	0	45	207	22	0	274
AESI – Acute cardiovascular injury	1	130	60	17	0	208
Convulsions/seizure	5	104	39	13	0	161
Thrombocytopenia†	2	49	12	20	1	84
Nodule	0	24	38	21	0	83
Paralysis	0	27	8	9	0	44
AESI – Anosmia, ageusia	0	29	10	4	0	43
Guillian-Barré syndrome (GBS)†	0	14	8	17	0	39
AESI - Acute liver injury	0	23	12	2	0	37
AESI - TTS/VITT	0	4	3	21	0	28
Oculorespiratory syndrome (ORS)	0	18	7	2	0	27
AESI – Acute kidney injury	0	11	8	3	0	22
Myelitis/transverse myelitis†	0	14	4	3	0	21
AESI - Subacute thyroiditis	0	13	5	1	0	19
AESI – Single organ cutaneous vasculitis	0	10	5	4	0	19
AESI – Chilblain-like lesions	1	11	3	1	0	16

Adverse event	Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg)	Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg)	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine	Janssen (Johnson & Johnson) COVID-19 vaccine	All vaccine products combined
AESI - Acute pancreatitis	0	8	4	1	0	13
AESI – Erythema multiforme	0	7	5	1	0	13
AESI - Rhabdomyolysis	0	5	6	1	0	12
Encephalopathy/encephalitis†	0	6	4	1	0	11
AESI - Multisystem inflammatory syndrome in children/adults	2	5	2	0	0	9
Infected abscess	0	2	6	0	0	8
Parotitis	1	3	1	0	0	5
AESI – Acute respiratory distress syndrome	0	3	1	0	0	4
Sterile abscess	0	2	2	0	0	4
Meningitis	0	2	0	1	0	3
Acute disseminated encephalomyelitis (ADEM)†	0	1	0	1	0	2

Notes:

- The Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg) is authorized for 5-11 year olds and the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) is indicated for 12+ years of age but also administered to eligible 11 year olds (i.e., who turned 12 years of age by the end of 2021) as per the provincial program.
- 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](#).

**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 information on the number of myocarditis or pericarditis reports based on the latter process.

†Represents a medically important event.

Data Source: CCM

Table A2. Reporting rate per 100,000 doses administered by adverse event and vaccine product: Ontario, December 13, 2020 to April 10, 2022

Adverse event	Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg)	Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg)	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine	Janssen (Johnson & Johnson) COVID-19 vaccine	All vaccine products combined
Other severe or unusual events*	4.3	17.2	16.0	40.4	184.9	17.3
Allergic skin reactions	8.9	14.3	14.1	25.0	92.4	14.4
Pain/redness/swelling at the injection site	1.1	6.6	21.2	29.2	61.6	11.3
Rash	2.6	5.7	8.4	16.5	92.4	6.8
Anaesthesia/paraesthesia	0.2	5.4	4.1	19.3	61.6	5.4
Adenopathy/lymphadenopathy	0.6	3.5	3.5	4.3	0.0	3.4
Arthritis/arthralgia	0.4	3.0	2.4	9.3	0.0	3.0
Severe vomiting/diarrhea	0.9	2.5	3.1	13.3	30.8	3.0
Fever in conjunction with another reportable event	1.1	2.0	3.9	15.5	30.8	3.0
AESI - Myocarditis/pericarditis**	0.3	2.3	3.1	0.8	0.0	2.4
Event managed as anaphylaxis†	0.3	1.8	1.4	2.0	0.0	1.6
AESI – Coagulation disorder (including thrombotic events)	0.0	1.1	1.0	7.1	30.8	1.2
Syncope (fainting) with injury	1.6	1.1	0.8	0.7	0.0	1.0
Bell's Palsy	0.0	1.0	1.0	1.3	0.0	1.0

Adverse event	Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg)	Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg)	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine	Janssen (Johnson & Johnson) COVID-19 vaccine	All vaccine products combined
Cellulitis	0.0	0.2	2.3	2.0	0.0	0.9
AESI – Acute cardiovascular injury	0.1	0.6	0.7	1.6	0.0	0.7
Convulsions/seizure	0.5	0.5	0.4	1.2	0.0	0.5
Thrombocytopenia†	0.2	0.2	0.1	1.8	30.8	0.3
Nodule	0.0	0.1	0.4	1.9	0.0	0.3
Paralysis	0.0	0.1	0.1	0.8	0.0	0.1
AESI – Anosmia, ageusia	0.0	0.1	0.1	0.4	0.0	0.1
Guillian-Barré syndrome (GBS) †	0.0	0.1	0.1	1.6	0.0	0.1
AESI - Acute liver injury	0.0	0.1	0.1	0.2	0.0	0.1
AESI - TTS/VITT	0.0	0.0	0.0	1.9	0.0	0.1
Oculorespiratory syndrome (ORS)	0.0	0.1	0.1	0.2	0.0	0.1
AESI – Acute kidney injury	0.0	0.1	0.1	0.3	0.0	0.1
Myelitis/transverse myelitis†	0.0	0.1	0.0	0.3	0.0	0.1
AESI - Subacute thyroiditis	0.0	0.1	0.1	0.1	0.0	0.1
AESI – Single organ cutaneous vasculitis	0.0	0.0	0.1	0.4	0.0	0.1
AESI – Chilblain-like lesions	0.1	0.1	0.0	0.1	0.0	0.1
AESI - Acute pancreatitis	0.0	0.0	0.0	0.1	0.0	0.0

Adverse event	Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg)	Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg)	Moderna Spikevax COVID-19 vaccine	AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine	Janssen (Johnson & Johnson) COVID-19 vaccine	All vaccine products combined
AESI – Erythema multiforme	0.0	0.0	0.1	0.1	0.0	0.0
AESI - Rhabdomyolysis	0.0	0.0	0.1	0.1	0.0	0.0
Encephalopathy/encephalitis†	0.0	0.0	0.0	0.1	0.0	0.0
AESI - Multisystem inflammatory syndrome in children/adults	0.2	0.0	0.0	0.0	0.0	0.0
Infected abscess	0.0	0.0	0.1	0.0	0.0	0.0
Parotitis	0.1	0.0	0.0	0.0	0.0	0.0
AESI – Acute respiratory distress syndrome	0.0	0.0	0.0	0.0	0.0	0.0
Sterile abscess	0.0	0.0	0.0	0.0	0.0	0.0
Meningitis	0.0	0.0	0.0	0.1	0.0	0.0
Acute disseminated encephalomyelitis (ADEM) †	0.0	0.0	0.0	0.1	0.0	0.0

Notes:

- The Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg) is authorized for 5-11 year olds and the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) is indicated for 12+ years of age but also administered to eligible 11 year olds (i.e., who will be 12 years of age by the end of 2021) as per the provincial program.
- 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.
- Reporting rates for the Janssen COVID-19 vaccine should be interpreted with caution due to unstable reporting rates arising from small number of doses administered.

*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](#).

**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 information on the number of myocarditis or pericarditis reports based on the latter process.

†Represents a medically important event.

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 April 10, 2022

Age group (years)	All sex: All doses	All sex: Dose 1	All sex: Dose 2	All sex: Dose 3	All sex: Dose 4	Females: All doses	Females: Dose 1	Females: Dose 2	Females: Dose 3	Females: Dose 4	Males: All doses	Males: Dose 1	Males: Dose 2	Males: Dose 3	Males: Dose 4
5-11*	2.9	1.6**	4.7	0.0	0.0	5.9	3.3**	9.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0
12-17	70.0	55.6	98.5	14.4	0.0	31.3	37.1	33.5	0.0	0.0	108.2	73.7	161.6	30.3	0.0
18-24	69.4	41.5	123.8	16.5	0.0	30.0	29.6	46.7	0.0	0.0	109.4	53.0	198.6	37.1	0.0
25-29	36.0	34.2	53	4.6	0.0	17.6	13.1	29.3	4.2**	0.0	54.6	54.6	76.2	5.0**	0.0
30-39	27.2	24.9	40.4	7.4	0.0	22.0	22.4	30.8	5.9	0.0	32.8	27.5	50.5	9.1	0.0
40-49	14.2	17.5	17.5	4.0	0.0	8.0	11.9	7.2	3.7	0.0	21.1	23.8	28.8	4.4	0.0
50-59	14.3	17.5	17.6	6.2	0.0	15.8	22.4	19.9	2.9	0.0	12.7	12.3	15.2	9.8	0.0
60-69	8.5	9.4	14.6	0.8**	0.0	5.8	5.5	11.5	0.0	0.0	11.4	13.8	18.1	1.6**	0.0
70-79	9.4	9.6	12.4	6.4	0.0	7.3	9.0	9.0	4.1	0.0	11.8	10.3	16.3	9.2	0.0
80+	6.1	3.3	13.3	1.9**	0.0	1.8	0.0	5.6	0.0	0.0	12.4	8.1	24.8	4.8**	0.0
Total	25.3	23.4	40.2	5.7	0.0	14.9	17.2	21.2	2.6	0.0	36.7	30.1	60.4	9.3	0.0

Note: Includes all reports of myocarditis or pericarditis identified through case-level review (n=743), regardless of the reports meeting the Brighton Collaboration case definition for myocarditis or pericarditis.

*The reporting rate for the 5-11 year age group only includes reports of myocarditis/pericarditis following Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg) authorized for this age group and doses administered of the Pfizer-BioNTech Comirnaty pediatric COVID-19 vaccine (10 mcg) product. There were three reports among those 11-year-olds (i.e., who turned 12 years of age by the end of 2021) who received the Pfizer-BioNTech Comirnaty COVID-19 vaccine (30 mcg) indicated for 12+ years of age as per the provincial program. These reports are excluded from age group-specific reporting rate calculations but included in the total reporting rate calculation.

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

Data Source: CCM, COVaxON (see [technical notes](#) for details on data sources)

Citation

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Adverse events following immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to April 10, 2022. Toronto, ON: Queen's Printer for Ontario; 2022.

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