Public Health Ontario | Santé publique Ontario

SURVEILLANCE REPORT

# Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to January 29, 2023

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 **January 29, 2023**. Doses administered up to and including **January 29, 2023** are extracted from the Ontario Ministry of Health's COVaxON application (see technical notes for details on data sources).

Starting February 3, PHO is moving to monthly reporting of COVID-19 vaccine information. This report is updated **every four weeks**.

## 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 22,521 AEFI reports received following 37,232,835 doses of COVID-19 vaccines administered in Ontario to date with a reporting rate of 60.5 per 100,000 doses administered (0.06% of all doses administered). This represents an increase of 75 AEFI reports compared to the previous report.

Of the total 22,521 AEFI reports received to date:

- 21,284 AEFI reports are non-serious (94.5% of total AEFI reports)
- 1,237 AEFI reports meet the serious definition (5.5% of total AEFI reports)
- The most commonly reported adverse events are other severe or unusual events and allergic skin reactions, reported in 28.1% and 22.7% of the total AEFI reports, respectively
- 1,700 reports include a COVID-19 vaccine-specific adverse event of special interest, in which 741 reports also meet the serious definition (see Adverse events of special interest section for more information)
- 808 reports of myocarditis or pericarditis after receipt of mRNA vaccine (see Myocarditis/pericarditis 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)

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 January 29, 2023**

| | Pfizer-BioNTech Comirnaty COVID-19 vaccine | Pfizer-BioNTech Comirnaty Bivalent BA.4/5 COVID-19 vaccine | Moderna Spikevax COVID-19 vaccine | Moderna Spikevax Bivalent BA.1 COVID-19 vaccine | AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine | Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine | Novavax Nuvaxovoid COVID-19 vaccine | All vaccine products combined |
|---|---|---|---|---|---|---|---|---|
| **Total number of AEFI reports** | 13,437 | 94 | 7,155 | 88 | 1,687 | 20 | 30 | 22,521 |
| **Number of non-serious reports** | 12,742 | 84 | 6,762 | 81 | 1,556 | 20 | 30 | 21,284 |
| **Number of serious reports** | 695 | 10 | 393 | 7 | 131 | 0 | 0 | 1,237 |
| **Proportion of total AEFI reports that are serious** | 5.2 | 10.6 | 5.5 | 8.0 | 7.8 | 0.0 | 0.0 | 5.5 |
| **Doses administered** | 23,597,574 | 1,695,359 | 9,619,948 | 1,213,218 | 1,087,696 | 3,953 | 13,632 | 37,232,835 |
| **Total reporting rate per 100,000 doses administered** | 56.9 | 5.5 | 74.4 | 7.3 | 155.1 | 505.9 | 220.1 | 60.5 |
| **Serious reporting rate per 100,000 doses administered** | 2.9 | 0.6 | 4.1 | 0.6 | 12.0 | 0.0 | 0.0 | 3.3 |

**Notes**:

- The columns above for Pfizer BioNTech Comirnaty COVID-19 vaccine and Moderna Spikevax COVID-19 vaccine include AEFIs associated with all indicated dosages: 3 mcg, 10 mcg and 30 mcg for Pfizer BioNTech Comirnaty and 25, 50 and 100 mcg for Moderna Spikevax AEFIs are combined into one column each the above table. Moderna Spikevax Bivalent BA.1 (50 mcg) COVID-19 vaccine and Pfizer-BioNTech Comirnaty Bivalent BA.4/5 (10 mcg and 30 mcg) COVID-19 vaccine are presented separately and are only approved and recommended for use as a booster.
- Three AEFI reports did not specify a vaccine product received.
- Seven AEFI reports followed vaccination with Moderna Spikevax Bivalent BA.4/5 (50 mcg) COVID-19. As this vaccine product is approved by Health Canada, but not currently being administered in Ontario, these AEFIs are included in this report but not reported out separately.
- Reporting rate for the Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine and Novavax Nuvaxovid COVID-19 vaccine should be interpreted with caution due to unstable reporting rate arising from the relatively small number of doses administered.
- To date, there have been twenty nine AEFI reports associated with co-administration of COVID-19 vaccine and a non-COVID-19 vaccine in Ontario. The majority of vaccines co-administered with COVID-19 vaccine have been Influenza (n=24). The National Advisory Committee on Immunization (NACI) 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 6 months of age or older.[6] More information can be found in the Canadian Immunization Guide for COVID-19 vaccines.

**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 January 29, 2023**

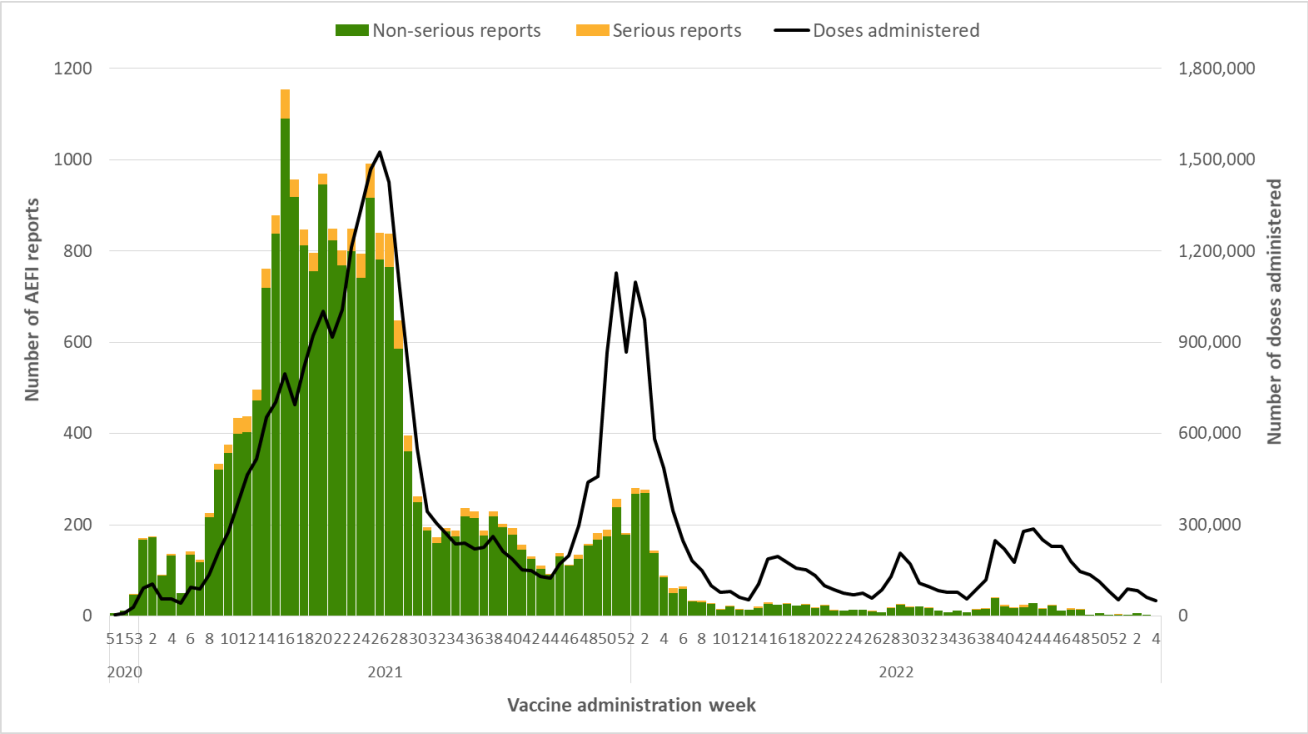
| | Number of AEFI reports received to date | Reporting rate per 100,000 doses administered |
|---|---|---|
| **Sex: Female** | 16,487 | 85.0 |
| **Sex: Male** | 5,808 | 32.7 |
| **Ages: 0-4 years** | 47 | 43.5 |
| **Ages: 5-11 years** | 318 | 25.0 |
| **Ages: 12-17 years** | 788 | 38.4 |
| **Ages: 18-24 years** | 1,426 | 46.9 |
| **Ages: 25-29 years** | 1,417 | 57.8 |
| **Ages: 30-39 years** | 3,654 | 74.6 |
| **Ages: 40-49 years** | 4,437 | 94.0 |
| **Ages: 50-59 years** | 4,305 | 76.4 |
| **Ages: 60-69 years** | 3,346 | 55.4 |
| **Ages: 70-79 years** | 1,841 | 41.7 |
| **Ages: 80 years and over** | 939 | 36.6 |

**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 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 January 29, 2023**




**Note**:

- AEFI reports are assessed based on date of vaccine administration. The administration week ranges from week 51 (Dec 13 – 19, 2020) to week 4 (January 22 –28, 2023). January 29, 2023 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 still be under investigation and yet to be reported as a confirmed AEFI report).

**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 January 29, 2023**

| | Pfizer-BioNTech Comirnaty COVID-19 vaccine | Pfizer-BioNTech Comirnaty Bivalent BA.4/5 COVID-19 vaccine | Moderna Spikevax COVID-19 vaccine | Moderna Spikevax Bivalent BA.1 COVID-19 vaccine | AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine | Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine | Novavax Nuvaxovoid COVID-19 vaccine | All vaccine products combined |
|---|---|---|---|---|---|---|---|---|
| **Total number of AEFI reports** | 13,437 | 94 | 7,155 | 88 | 1,687 | 20 | 30 | 22,521 |
| **Dose 1** | 8,454 | 3 | 3,631 | 4 | 1,602 | 19 | 17 | 13,733 |
| **Dose 2** | 3,977 | 0 | 2,472 | 0 | 78 | 1 | 11 | 6,540 |
| **Dose 3** | 854 | 4 | 853 | 2 | 0 | 0 | 1 | 1,714 |
| **Dose 4** | 127 | 40 | 170 | 39 | 0 | 0 | 1 | 380 |
| **Dose 5** | 4 | 44 | 15 | 43 | 0 | 0 | 0 | 108 |
| **Number of serious reports** | 695 | 10 | 393 | 7 | 131 | 0 | 0 | 1,237 |
| **Dose 1** | 325 | 1 | 109 | 2 | 122 | 0 | 0 | 560 |
| **Dose 2** | 299 | 0 | 218 | 0 | 9 | 0 | 0 | 526 |
| **Dose 3** | 64 | 0 | 49 | 1 | 0 | 0 | 0 | 114 |
| **Dose 4** | 6 | 3 | 16 | 1 | 0 | 0 | 0 | 26 |
| **Dose 5** | 0 | 5 | 1 | 3 | 0 | 0 | 0 | 9 |
| **Total reporting rate per 100,000 doses administered** | 56.9 | 5.5 | 74.4 | 7.3 | 155.1 | 505.9 | 220.1 | 60.5 |
| **Dose 1** | 89.9 | 17.1 | 165.8 | 54.3 | 185.5 | 503.8 | 331.7 | 109.9 |
| **Dose 2** | 49.0 | 0.0 | 67.1 | 0.0 | 34.9 | 980.4 | 228.1 | 54.4 |

| | Pfizer-BioNTech Comirnaty COVID-19 vaccine | Pfizer-BioNTech Comirnaty Bivalent BA.4/5 COVID-19 vaccine | Moderna Spikevax COVID-19 vaccine | Moderna Spikevax Bivalent BA.1 COVID-19 vaccine | AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine | Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine | Novavax Nuvaxovoid COVID-19 vaccine | All vaccine products combined |
|---|---|---|---|---|---|---|---|---|
| **Dose 3** | 18.6 | 4.0 | 28.3 | 5.6 | 0.0 | 0.0 | 108.6 | 22.2 |
| **Dose 4** | 8.5 | 5.0 | 23.3 | 6.7 | 0.0 | 0.0 | 55.5 | 10.6 |
| **Dose 5** | 41.2 | 5.7 | 276.3 | 7.4 | 0.0 | 0.0 | 0.0 | 7.9 |
| **Serious reporting rate per 100,000 doses administered** | 2.9 | 0.6 | 4.1 | 0.6 | 12.0 | 0.0 | 0.0 | 3.3 |
| **Dose 1** | 3.5 | 5.7 | 5.0 | 27.1 | 14.1 | 0.0 | 0.0 | 4.5 |
| **Dose 2** | 3.7 | 0.0 | 5.9 | 0.0 | 4.0 | 0.0 | 0.0 | 4.4 |
| **Dose 3** | 1.4 | 0.0 | 1.6 | 2.8 | 0.0 | 0.0 | 0.0 | 1.5 |
| **Dose 4** | 0.4 | 0.4 | 2.2 | 0.2 | 0.0 | 0.0 | 0.0 | 0.7 |
| **Dose 5** | 0.0 | 0.6 | 18.4 | 0.5 | 0.0 | 0.0 | 0.0 | 0.7 |

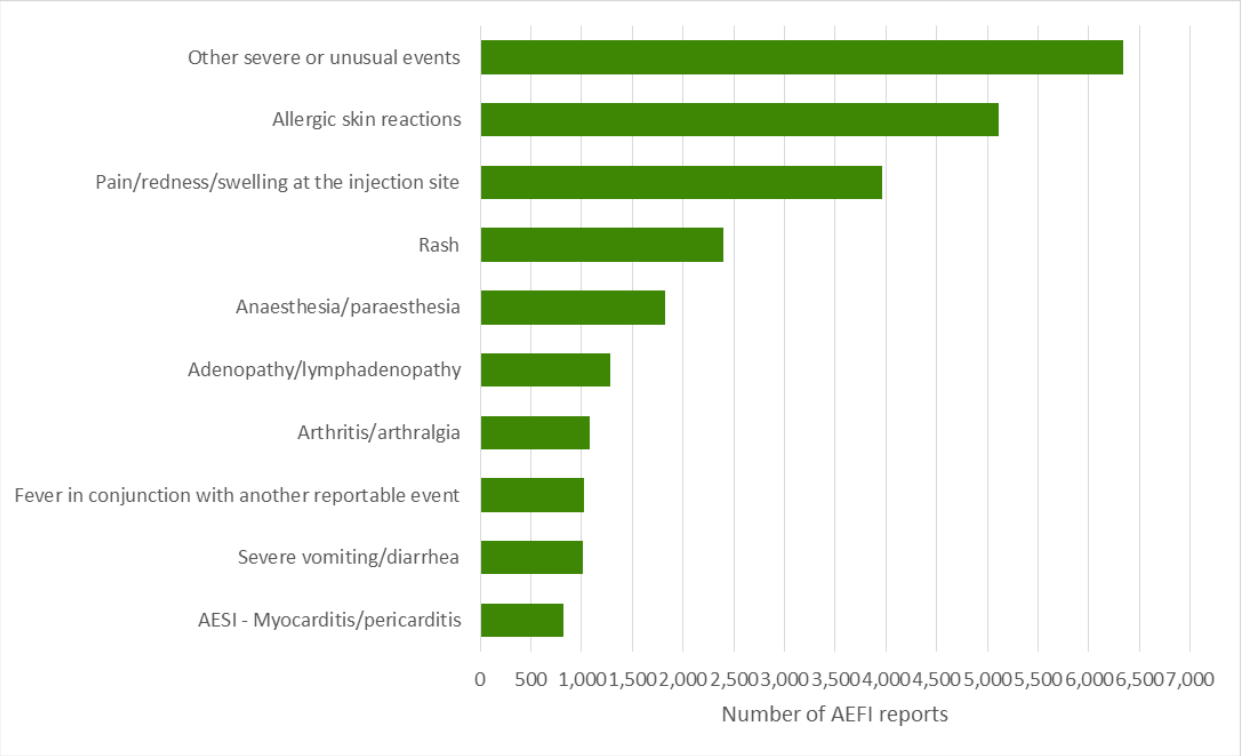
**Note**:

- The columns above for Pfizer BioNTech Comirnaty COVID-19 vaccine and Moderna Spikevax COVID-19 vaccine include AEFIs associated with all indicated dosages: 3 mcg, 10 mcg and 30 mcg for Pfizer BioNTech Comirnaty and 25, 50 and 100 mcg for Moderna Spikevax AEFIs are combined into one column each the above table. Moderna Spikevax Bivalent BA.1 (50 mcg) COVID-19 vaccine and Pfizer-BioNTech Comirnaty Bivalent BA.4/5 (10 mcg and 30 mcg) COVID-19 vaccine are presented separately and are only approved and recommended for use as a booster.
- Reporting rate for the Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine and Novavax Nuvaxovid COVID-19 vaccine should be interpreted with caution due to unstable reporting rate arising from a relatively 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 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 28.2% and 22.7% 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 January 29, 2023**




**Note**: An AEFI report may contain multiple adverse events. Thus the sum of all adverse event-specific counts will 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 1 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) (17.3 per 100,000 doses administered), the Pfizer-BioNTech Comirnaty Bivalent BA.4/5 (30 mcg) COVID-19 vaccine (1.4 per 100,000 doses administered), the Moderna Spikevax Bivalent BA.1 (50 mcg) COVID-19 vaccine 2.1 per 100,000 doses administered), and the AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine (42.2 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 (21.5 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 684 reports with medically important events, representing 3.0% of all reports. The 684 reports include 505 reports of events managed as anaphylaxis, of which 39 met the definition of a serious AEFI. Of all 505 reports of events managed as anaphylaxis: 489 received epinephrine, 458 were seen in the emergency department and 374 were fully recovered at the time of reporting. All reports of events managed as anaphylaxis have been assessed using the Brighton Collaboration standard definition of anaphylaxis.[7] Of all reports, 94 reports met level 1 of the Brighton Collaboration case definition of anaphylaxis, 156 reports met level 2, 10 reports met level 3, and 245 reports had insufficient evidence to meet level 1, 2 or 3 (i.e., met level 4 of diagnostic certainty) of the case definition.

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, 44 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, four reports 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 33 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 1,700 reports with COVID-19 vaccine-specific AESIs, representing 7.5% of all reports. Of the 1,700 reports, 741 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.

In Ontario, 12 reports of multisystem inflammatory syndrome in children and adults (MIS-C/A) have been reported to date, including 9 following Pfizer-BioNTech Comirnaty COVID-19 vaccine and 3 following Moderna Spikevax COVID-19 vaccine. All reports of MIS-C/A are assessed using the Brighton Collaboration standard definition of MIS-C/A.[10] Six reports among persons under 21 years of age met level 1 of the Brighton Collaboration case definition of MIS-C and two reports met level 2A. Among persons 21 years of age and older, based on the clinical presentation and other indicators, three reports met level 1 of the Brighton Collaboration case definition of MIS-A and one report had insufficient evidence to meet level 1,2 or 3 (i.e., met level 4 diagnostic certainty) of the case definition.

## 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.[11] 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.[12]

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.[13,14] 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.[15]

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.[16] 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 as a primary series 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.[17,18] More recently, Moderna Spikevax Bivalent BA.1 (50 mcg) and Pfizer Comirnaty Bivalent BA.4/5 (30 mcg) COVID-19 vaccines have been authorized and recommended for use as a booster dose only for individuals 18 years and older and 12 years and older, respectively. Ontario COVID-19 vaccine guidance provides more detailed information on eligibility for booster doses by age and product. 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.[19,20]

As of January 29, 2023, there have been 808 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, 211 (26.1%) were diagnosed with myocarditis and 395 (48.8%) were diagnosed with pericarditis. The remaining 202 (25.0%) were diagnosed with perimyocarditis (n=37), myopericarditis (n=154) and myocarditis/pericarditis (n=11).

The 211 reports of myocarditis have been assessed using the Brighton Collaboration case definition for myocarditis; 189 reports met Brighton levels of diagnostic certainty 1, 2 or 3 (89.5%), 21 reports had insufficient evidence to meet level 1, 2 or 3 of the case definition (10.0%).[21] One report has yet to be assessed. Of the 395 reports of pericarditis assessed using the Brighton Collaboration case definition for pericarditis, 198 reports met Brighton levels of diagnostic certainty 1, 2 or 3 (50.1%) and 197 reports had insufficient evidence to meet level 1, 2 or 3 of the case definition (49.9%).[21] The remaining 202 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, 191 (94.0%) met Brighton levels of diagnostic certainty 1, 2 or 3 for either myocarditis or pericarditis, and 11 reports had insufficient evidence to meet level 1, 2 or 3 (5.9%).

Based on 808 reports of myocarditis or pericarditis, the overall crude reporting rate is 22.4 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 201.8 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.[20]

## 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 1,237 AEFI reports classified as serious, representing 5.5% of all AEFI reports and a serious AEFI reporting rate of 3.3 per 100,000 doses administered for all vaccine products combined. Of the 1,237 reports meeting the serious definition, 1,203 reports had a hospital admission related to the adverse event and 34 were reports of deaths. The serious reporting rate was 2.9, and 0.6 per 100,000 doses administered for the Pfizer BioNTech Comirnaty COVID-19 vaccine (3 mcg, 10 mcg and 30 mcg), and the Pfizer BioNTech Comirnaty Bivalent BA.4/5 (10 mcg and 30 mcg) COVID-19 vaccines, respectively. The serious reporting rate was 4.1 and 0.6 per 100,000 doses administered for the Moderna Spikevax COVID-19 vaccine (25 mcg, 50 mcg, and 100mcg), and the Moderna Spikevax Bivalent BA.1 (50 mcg) COVID-19 vaccine, respectively. The serious reporting rate for the AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine was 12.0 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.[22]

### AEFI REPORTS REQUIRING HOSPITALIZATION

Of the 1,203 reports of hospitalization, 472 were recovered at the time of reporting, 540 were not yet recovered when the investigation was completed but likely to recover, and 102 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 January 29, 2023, there are 34 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 January 29, 2023**

| Public Health Unit Name | Number of AEFI reports received to date | Reporting rate per 100,000 doses administered |
|---|---|---|
| Northwestern Health Unit | 183 | 88.9 |
| Thunder Bay District Health Unit | 134 | 33.0 |
| **TOTAL NORTH WEST** | 317 | 51.8 |
| Algoma Public Health | 159 | 52.2 |
| North Bay Parry Sound District Health Unit | 199 | 60.4 |
| Porcupine Health Unit | 147 | 73.4 |
| Public Health Sudbury & Districts | 445 | 85.7 |
| Timiskaming Health Unit | 106 | 130.3 |
| **TOTAL NORTH EAST** | 1,056 | 73.6 |
| Eastern Ontario Health Unit | 578 | 106.9 |
| Hastings Prince Edward Public Health | 222 | 50.7 |
| Kingston, Frontenac and Lennox & Addington Public Health | 475 | 80.8 |
| Leeds, Grenville & Lanark District Health Unit | 417 | 80.2 |
| Ottawa Public Health | 2,327 | 81.5 |
| Renfrew County and District Health Unit | 285 | 109.2 |
| **TOTAL EASTERN** | 4,304 | 82.7 |
| Durham Region Health Department | 3,186 | 178.5 |
| Haliburton, Kawartha, Pine Ridge District Health Unit | 551 | 109.5 |
| Peel Public Health | 1,461 | 41.3 |
| Peterborough Public Health | 295 | 75.6 |

| Public Health Unit Name | Number of AEFI reports received to date | Reporting rate per 100,000 doses administered |
|---|---|---|
| Simcoe Muskoka District Health Unit | 824 | 55.3 |
| York Region Public Health | 1,814 | 60.9 |
| **TOTAL CENTRAL EAST** | 8,131 | 76.1 |
| Toronto Public Health | 2,635 | 35.3 |
| **TOTAL TORONTO** | 2,635 | 35.3 |
| Chatham-Kent Public Health | 81 | 31.3 |
| Grey Bruce Health Unit | 190 | 44.2 |
| Huron Perth Public Health | 406 | 107.0 |
| Lambton Public Health | 591 | 185.2 |
| Middlesex-London Health Unit | 345 | 26.4 |
| Southwestern Public Health | 465 | 88.9 |
| Windsor-Essex County Health Unit | 392 | 38.6 |
| **TOTAL SOUTH WEST** | 2,470 | 58.4 |
| Brant County Health Unit | 157 | 43.1 |
| City of Hamilton Public Health Services | 610 | 43.0 |
| Haldimand-Norfolk Health Unit | 66 | 23.6 |
| Halton Region Public Health | 941 | 59.3 |
| Niagara Region Public Health | 538 | 44.5 |
| Region of Waterloo Public Health and Emergency Services | 792 | 53.6 |
| Wellington-Dufferin-Guelph Public Health | 504 | 63.3 |
| **TOTAL CENTRAL WEST** | 3,608 | 50.6 |
| **TOTAL ONTARIO** | 22,521 | 60.5 |

**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 **January 30, 2023 at approximately 8:30 a.m.**
    - Doses administered data from the Ontario Ministry of Health's COVaxON application extracted on **January 30, 2023 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.
- 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.

## 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.

- Methods for calculating age-based denominators for AEFI reporting rates use the age at the time of dose administration. For example, the date of dose 1 administration is used to calculate age at dose 1, the date of dose 2 administration is used to calculate age at dose 2, etc. Previously age at the time of dose 1 administration was used for all age-based AEFI rates. This change was made on May 8, 2022 and as a result age-based rates in previous reports are not comparable.

- 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 from the Brighton Collaboration.[7,8,11,21] 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 1: provincial case definitions for diseases of public health significance: disease: adverse events following immunization (AEFIs) [Internet]. Toronto, ON: Queen's Printer for Ontario; 2022 [cited 2022 Jun 22]. Available from: https://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/aefi_chapter.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. Vogel TP, Top KA, Karatzios C, Hilmers DC, Tapia LI, Moceri P, et al. Multisystem inflammatory syndrome in children and adults (MIS-C/A): Case definition and guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine. 2021;39(22):3037-49. Available from: https://doi.org/10.1016/j.vaccine.2021.01.054

11. 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 2022 Mar 26]. Available from: https://brightoncollaboration.us/thrombosis-with-thrombocytopenia-syndrome-interim-case-definition/

12. 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

13. 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

14. 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

15. 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

16. 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

17. 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

18. Ontario. Ministry of Health. COVID-19 Vaccine Information Sheet (age 12+) [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021 [cited 2022 Jan 12]. Available from: https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_info_sheet.pdf

19. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Myocarditis and pericarditis after COVID-19 mRNA vaccines. 1st revision, March 2022. Toronto, ON: Queen's Printer for Ontario; 2022 [cited 2022 Mar 30]. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/vaccines/2021/11/myocarditis-pericarditis-mrna-vaccines.pdf?sc_lang=en%20

20. 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 November 21, 2021. Toronto, ON: Queen's Printer for Ontario; 2022 [cited 2022 Feb 8]. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-myocarditis-pericarditis-vaccines-epi.pdf?sc_lang=en

21. Tejtel SKS, Munoz FM et al. Myocarditis and pericarditis: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine. 2022 Mar;40(10):1499-1511. Available from: https://doi.org/10.1016/j.vaccine.2021.11.074.

22. 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

23. Ontario Agency for Health Protection and Promotion (Public Health Ontario). COVID-19 vaccine uptake in Ontario: December 14, 2020 to January 3, 2022 [cited 2022 Jan 10]. Toronto, ON: Queen's Printer for Ontario; 2022. 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 January 29, 2023**

| Adverse event | Pfizer-BioNTech Comirnaty COVID-19 vaccine | Pfizer-BioNTech Comirnaty Bivalent BA.4/5 COVID-19 vaccine | Moderna Spikevax COVID-19 vaccine | Moderna Spikevax Bivalent BA.1 COVID-19 vaccine | AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine | Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine | Novavax Nuvaxovoid COVID-19 vaccine | All vaccine products combined |
|---|---|---|---|---|---|---|---|---|
| Other severe or unusual events* | 4,092 | 23 | 1,711 | 25 | 460 | 11 | 14 | 6,337 |
| Allergic skin reactions | 3,339 | 16 | 1,450 | 17 | 276 | 4 | 9 | 5,113 |
| Pain/redness/swelling at the injection site | 1,544 | 12 | 2,070 | 9 | 320 | 3 | 3 | 3,962 |
| Rash | 1,337 | 8 | 852 | 9 | 185 | 3 | 2 | 2,398 |
| Anaesthesia/paraesthesia | 1,190 | 5 | 390 | 6 | 216 | 6 | 7 | 1,820 |
| Adenopathy/lymphadenopathy | 857 | 11 | 363 | 3 | 50 | 0 | 0 | 1,284 |
| Arthritis/arthralgia | 702 | 5 | 250 | 11 | 106 | 0 | 0 | 1,076 |
| Fever in conjunction with another reportable event | 464 | 2 | 381 | 4 | 170 | 1 | 3 | 1,026 |
| Severe vomiting/diarrhea | 555 | 3 | 301 | 6 | 149 | 1 | 2 | 1,017 |
| AESI - Myocarditis/pericarditis** | 519 | 2 | 293 | 1 | 9 | 0 | 1 | 825 |
| Event managed as anaphylaxis† | 363 | 1 | 121 | 0 | 22 | 1 | 1 | 509 |
| AESI – Coagulation disorder (including thrombotic events) | 247 | 5 | 103 | 4 | 76 | 0 | 0 | 437 |

| Adverse event | Pfizer-BioNTech Comirnaty COVID-19 vaccine | Pfizer-BioNTech Comirnaty Bivalent BA.4/5 COVID-19 vaccine | Moderna Spikevax COVID-19 vaccine | Moderna Spikevax Bivalent BA.1 COVID-19 vaccine | AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine | Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine | Novavax Nuvaxovoid COVID-19 vaccine | All vaccine products combined |
|---|---|---|---|---|---|---|---|---|
| Syncope (fainting) with injury | 256 | 3 | 72 | 3 | 8 | 0 | 0 | 342 |
| Bell's Palsy | 225 | 6 | 94 | 1 | 15 | 0 | 0 | 341 |
| Cellulitis | 47 | 0 | 212 | 0 | 23 | 0 | 0 | 282 |
| AESI – Acute cardiovascular injury | 141 | 1 | 72 | 3 | 18 | 0 | 0 | 235 |
| Convulsions/seizure | 112 | 1 | 39 | 0 | 13 | 0 | 1 | 167 |
| Thrombocytopenia† | 54 | 0 | 15 | 2 | 20 | 1 | 0 | 92 |
| Nodule | 27 | 0 | 38 | 1 | 21 | 0 | 0 | 87 |
| Paralysis | 30 | 0 | 10 | 1 | 9 | 0 | 0 | 50 |
| AESI – Anosmia, ageusia | 31 | 0 | 10 | 0 | 4 | 0 | 0 | 45 |
| Guillian-Barré syndrome (GBS)† | 16 | 0 | 11 | 0 | 17 | 0 | 0 | 44 |
| AESI - Acute liver injury | 24 | 0 | 12 | 0 | 2 | 0 | 0 | 38 |
| Oculorespiratory syndrome (ORS) | 18 | 0 | 8 | 0 | 2 | 0 | 0 | 28 |
| AESI - TTS/VITT | 4 | 0 | 3 | 0 | 21 | 0 | 0 | 28 |
| AESI – Acute kidney injury | 16 | 0 | 8 | 0 | 3 | 0 | 0 | 27 |
| Myelitis/transverse myelitis† | 15 | 0 | 5 | 0 | 3 | 0 | 0 | 23 |

| Adverse event | Pfizer-BioNTech Comirnaty COVID-19 vaccine | Pfizer-BioNTech Comirnaty Bivalent BA.4/5 COVID-19 vaccine | Moderna Spikevax COVID-19 vaccine | Moderna Spikevax Bivalent BA.1 COVID-19 vaccine | AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine | Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine | Novavax Nuvaxovoid COVID-19 vaccine | All vaccine products combined |
|---|---|---|---|---|---|---|---|---|
| AESI - Subacute thyroiditis | 14 | 1 | 5 | 0 | 1 | 0 | 0 | 21 |
| AESI – Single organ cutaneous vasculitis | 11 | 0 | 5 | 0 | 4 | 0 | 0 | 20 |
| AESI – Chilblain-like lesions | 14 | 0 | 3 | 0 | 1 | 0 | 0 | 18 |
| AESI - Acute pancreatitis | 11 | 0 | 4 | 0 | 1 | 0 | 0 | 16 |
| AESI - Rhabdomyolysis | 7 | 0 | 7 | 1 | 1 | 0 | 0 | 16 |
| AESI – Erythema multiforme | 8 | 0 | 6 | 0 | 1 | 0 | 0 | 15 |
| Encephalopathy/encephalitis† | 7 | 1 | 4 | 0 | 1 | 0 | 0 | 13 |
| AESI - Multisystem inflammatory syndrome in children/adults | 9 | 0 | 3 | 0 | 0 | 0 | 0 | 12 |
| Infected abscess | 7 | 1 | 4 | 0 | 1 | 0 | 0 | 13 |
| Parotitis | 2 | 0 | 6 | 0 | 0 | 0 | 0 | 8 |
| AESI – Acute respiratory distress syndrome | 6 | 0 | 1 | 0 | 0 | 0 | 0 | 7 |
| Sterile abscess | 3 | 0 | 2 | 0 | 0 | 0 | 0 | 5 |
| AESI – Vaccine-Associated Enhanced Disease | 2 | 0 | 2 | 0 | 0 | 0 | 0 | 4 |
| Kawasaki Disease | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |

| Adverse event | Pfizer-BioNTech Comirnaty COVID-19 vaccine | Pfizer-BioNTech Comirnaty Bivalent BA.4/5 COVID-19 vaccine | Moderna Spikevax COVID-19 vaccine | Moderna Spikevax Bivalent BA.1 COVID-19 vaccine | AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine | Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine | Novavax Nuvaxovoid COVID-19 vaccine | All vaccine products combined |
|---|---|---|---|---|---|---|---|---|
| Meningitis | 2 | 0 | 1 | 0 | 0 | 0 | 0 | 3 |
| Acute disseminated encephalomyelitis (ADEM)† | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |

**Notes:**

- The columns above for Pfizer BioNTech Comirnaty COVID-19 vaccine and Moderna Spikevax COVID-19 vaccine include AEFIs associated with all indicated dosages: 3 mcg, 10 mcg and 30 mcg for Pfizer BioNTech Comirnaty and 25, 50 and 100 mcg for Moderna Spikevax AEFIs are combined into one column each the above table. Moderna Spikevax BA.1 Bivalent (50 mcg) COVID-19 vaccine and Pfizer-BioNTech Comirnaty Bivalent BA.4/5 (10 mcg and 30 mcg) COVID-19 vaccine are presented separately and are only approved and recommended for use as a booster.
- 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 18, 2020 to January 29, 2023**

| Adverse event | Pfizer-BioNTech Comirnaty COVID-19 vaccine | Pfizer-BioNTech Comirnaty Bivalent BA.4/5 COVID-19 vaccine | Moderna Spikevax COVID-19 vaccine | Moderna Spikevax Bivalent BA.1 COVID-19 vaccine | AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine | Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine | Novavax Nuvaxovoid COVID-19 vaccine | All vaccine products combined |
|---|---|---|---|---|---|---|---|---|
| Other severe or unusual events* | 17.3 | 1.4 | 17.8 | 2.1 | 42.3 | 278.3 | 102.7 | 17.0 |
| Allergic skin reactions | 14.1 | 0.9 | 15.1 | 1.4 | 25.4 | 101.2 | 66.0 | 13.7 |
| Pain/redness/swelling at the injection site | 6.5 | 0.7 | 21.5 | 0.7 | 29.4 | 75.9 | 22.0 | 10.6 |
| Rash | 5.7 | 0.5 | 8.9 | 0.7 | 17.0 | 75.9 | 14.7 | 6.4 |
| Anaesthesia/paraesthesia | 5.0 | 0.3 | 4.1 | 0.5 | 19.9 | 151.8 | 51.3 | 4.9 |
| Adenopathy/lymphadenopathy | 3.6 | 0.6 | 3.8 | 0.2 | 4.6 | 0.0 | 0.0 | 3.4 |
| Arthritis/arthralgia | 3.0 | 0.3 | 2.6 | 0.9 | 9.7 | 0.0 | 0.0 | 2.9 |
| Fever in conjunction with another reportable event | 2.0 | 0.1 | 4.0 | 0.3 | 15.6 | 25.3 | 22.0 | 2.8 |
| Severe vomiting/diarrhea | 2.4 | 0.2 | 3.1 | 0.5 | 13.7 | 25.3 | 14.7 | 2.7 |
| AESI - Myocarditis/pericarditis** | 2.2 | 0.1 | 3.0 | 0.1 | 0.8 | 0.0 | 7.3 | 2.2 |
| Event managed as anaphylaxis† | 1.5 | 0.1 | 1.3 | 0.0 | 2.0 | 25.3 | 7.3 | 1.4 |
| AESI – Coagulation disorder (including thrombotic events) | 1.0 | 0.3 | 1.1 | 0.3 | 7.0 | 0.0 | 0.0 | 1.2 |
| Syncope (fainting) with injury | 1.1 | 0.2 | 0.7 | 0.2 | 0.7 | 0.0 | 0.0 | 0.9 |

| Adverse event | Pfizer-BioNTech Comirnaty COVID-19 vaccine | Pfizer-BioNTech Comirnaty Bivalent BA.4/5 COVID-19 vaccine | Moderna Spikevax COVID-19 vaccine | Moderna Spikevax Bivalent BA.1 COVID-19 vaccine | AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine | Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine | Novavax Nuvaxovoid COVID-19 vaccine | All vaccine products combined |
|---|---|---|---|---|---|---|---|---|
| Bell's Palsy | 1.0 | 0.4 | 1.0 | 0.1 | 1.4 | 0.0 | 0.0 | 0.9 |
| Cellulitis | 0.2 | 0.0 | 2.2 | 0.0 | 2.1 | 0.0 | 0.0 | 0.8 |
| AESI – Acute cardiovascular injury | 0.6 | 0.1 | 0.7 | 0.2 | 1.7 | 0.0 | 0.0 | 0.6 |
| Convulsions/seizure | 0.5 | 0.1 | 0.4 | 0.0 | 1.2 | 0.0 | 7.3 | 0.4 |
| Thrombocytopenia† | 0.2 | 0.0 | 0.2 | 0.2 | 1.8 | 25.3 | 0.0 | 0.2 |
| Nodule | 0.1 | 0.0 | 0.4 | 0.1 | 1.9 | 0.0 | 0.0 | 0.2 |
| Paralysis | 0.1 | 0.0 | 0.1 | 0.1 | 0.8 | 0.0 | 0.0 | 0.1 |
| AESI – Anosmia, ageusia | 0.1 | 0.0 | 0.1 | 0.0 | 0.4 | 0.0 | 0.0 | 0.1 |
| Guillian-Barré syndrome (GBS) † | 0.1 | 0.0 | 0.1 | 0.0 | 1.6 | 0.0 | 0.0 | 0.1 |
| AESI - Acute liver injury | 0.1 | 0.0 | 0.1 | 0.0 | 0.2 | 0.0 | 0.0 | 0.1 |
| Oculorespiratory syndrome (ORS) | 0.1 | 0.0 | 0.1 | 0.0 | 0.2 | 0.0 | 0.0 | 0.1 |
| AESI - TTS/VITT | 0.0 | 0.0 | 0.0 | 0.0 | 1.9 | 0.0 | 0.0 | 0.1 |
| AESI – Acute kidney injury | 0.1 | 0.0 | 0.1 | 0.0 | 0.3 | 0.0 | 0.0 | 0.1 |
| Myelitis/transverse myelitis† | 0.1 | 0.0 | 0.1 | 0.0 | 0.3 | 0.0 | 0.0 | 0.1 |
| AESI - Subacute thyroiditis | 0.1 | 0.1 | 0.1 | 0.0 | 0.1 | 0.0 | 0.0 | 0.1 |

| Adverse event | Pfizer-BioNTech Comirnaty COVID-19 vaccine | Pfizer-BioNTech Comirnaty Bivalent BA.4/5 COVID-19 vaccine | Moderna Spikevax COVID-19 vaccine | Moderna Spikevax Bivalent BA.1 COVID-19 vaccine | AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine | Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine | Novavax Nuvaxovoid COVID-19 vaccine | All vaccine products combined |
|---|---|---|---|---|---|---|---|---|
| AESI – Single organ cutaneous vasculitis | 0.0 | 0.0 | 0.1 | 0.0 | 0.4 | 0.0 | 0.0 | 0.1 |
| AESI – Chilblain-like lesions | 0.1 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.0 | 0.0 |
| AESI - Acute pancreatitis | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.0 | 0.0 |
| AESI - Rhabdomyolysis | 0.0 | 0.0 | 0.1 | 0.1 | 0.1 | 0.0 | 0.0 | 0.0 |
| AESI – Erythema multiforme | 0.0 | 0.0 | 0.1 | 0.0 | 0.1 | 0.0 | 0.0 | 0.0 |
| Encephalopathy/encephalitis† | 0.0 | 0.1 | 0.0 | 0.0 | 0.1 | 0.0 | 0.0 | 0.0 |
| AESI - Multisystem inflammatory syndrome in children/adults | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Infected abscess | 0.0 | 0.0 | 0.1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Parotitis | 0.0 | 0.0 | 0.0 | 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 | 0.0 | 0.0 |
| Sterile abscess | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| AESI – Vaccine-Associated Enhanced Disease | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Kawasaki Disease | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Meningitis | 0.0 | 0.0 | 0.0 | 0.0 | 0.1 | 0.0 | 0.0 | 0.0 |

| Adverse event | Pfizer-BioNTech Comirnaty COVID-19 vaccine | Pfizer-BioNTech Comirnaty Bivalent BA.4/5 COVID-19 vaccine | Moderna Spikevax COVID-19 vaccine | Moderna Spikevax Bivalent BA.1 COVID-19 vaccine | AstraZeneca Vaxzevria/ COVISHIELD COVID-19 vaccine | Janssen Jcovden (Johnson & Johnson) COVID-19 vaccine | Novavax Nuvaxovoid COVID-19 vaccine | All vaccine products combined |
|---|---|---|---|---|---|---|---|---|
| Acute disseminated encephalomyelitis (ADEM) † | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

**Notes**:

- The columns above for Pfizer BioNTech Comirnaty COVID-19 vaccine and Moderna Spikevax COVID-19 vaccine include AEFIs associated with all indicated dosages: 3 mcg, 10 mcg and 30 mcg for Pfizer BioNTech Comirnaty and 25, 50 and 100 mcg for Moderna Spikevax AEFIs are combined into one column each the above table. Moderna Spikevax BA.1 Bivalent (50 mcg) COVID-19 vaccine and Pfizer-BioNTech Comirnaty Bivalent BA.4/5 (10 mcg and 30 mcg) COVID-19 vaccine are presented separately and are only approved and recommended for use as a booster.
- 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 Jcovden (Johnson & Johnson) COVID-19 vaccine and Novavax Nuvaxovid 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 January 29, 2023**

| 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 | 3.9 | 3.0 | 5.8 | 0.0 | 0.0 | 3.2 | 3.0* | 4.0* | 0.0 | 0.0 | 4.6 | 2.9* | 7.6 | 0.0 | 0.0 |
| 12-17 | 70.7 | 56.1 | 98.0 | 41.0 | 0.0 | 29.7 | 36.7 | 32.9 | 0.0 | 0.0 | 111.1 | 75.1 | 161.2 | 84.8 | 0.0 |
| 18-24 | 68.1 | 43.6 | 125.4 | 20.4 | 0.0 | 30.0 | 31.0 | 46.7 | 6.2 | 0.0 | 107.5 | 55.9 | 201.8 | 38.2 | 0.0 |
| 25-29 | 37.1 | 37.0 | 55.7 | 10.6 | 0.0 | 17.8 | 13.0 | 31.3 | 7.9 | 0.0 | 57.1 | 60.3 | 79.7 | 14.0 | 0.0 |
| 30-39 | 26.0 | 26.3 | 41.8 | 6.9 | 0.0 | 21.1 | 23.3 | 32.8 | 5.6 | 0.0 | 31.4 | 29.5 | 51.2 | 8.6 | 0.0 |
| 40-49 | 15.2 | 19.4 | 20.6 | 5.8 | 3.0* | 10.2 | 13.2 | 10.8 | 7.2 | 5.4* | 21.0 | 26.5 | 31.2 | 4.2 | 0.0 |
| 50-59 | 14.4 | 20.0 | 19.3 | 8.3 | 0.0 | 15.2 | 26.0 | 20.9 | 2.9 | 0.0 | 13.6 | 13.5 | 17.5 | 14.4 | 0.0 |
| 60-69 | 8.0 | 10.1 | 15.2 | 5.7 | 0.0 | 5.7 | 5.5 | 11.4 | 5.5 | 0.0 | 10.5 | 15.2 | 19.3 | 6.0 | 0.0 |
| 70-79 | 7.1 | 9.5 | 13.2 | 7.0 | 0.0 | 5.2 | 8.9 | 8.8 | 3.8 | 0.0 | 9.3 | 10.2 | 18.1 | 10.7 | 0.0 |
| 80+ | 5.1 | 3.3 | 13.0 | 3.5 | 2.2* | 2.0 | 0.0 | 5.5 | 2.9* | 0.0 | 9.6 | 8.1 | 24.0 | 4.2* | 5.3* |
| Total | 22.4 | 23.3 | 39.6 | 8.8 | 0.6 | 13.3 | 17.1 | 21.2 | 4.8 | 0.5* | 32.4 | 30.1 | 59.2 | 13.4 | 0.6* |

**Note**: Includes all reports of myocarditis or pericarditis identified through case-level review (n=805), regardless of the reports meeting the Brighton Collaboration case definition for myocarditis or pericarditis. There are no myocarditis/pericarditis AEFIs reported in age group 0-4 years, or following vaccination with dose 5.

*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 January 29, 2023. Toronto, ON: Queen's Printer for Ontario; 2023.

# Disclaimer

This document was developed by Public Health Ontario (PHO). PHO provides scientific and technical advice to Ontario's government, public health organizations and health care providers. PHO's work is guided by the current best available evidence at the time of publication.

The application and use of this document is the responsibility of the user. PHO assumes no liability resulting from any such application or use.



# For Further Information

For more information, email ivpd@oahpp.ca.

# Public Health Ontario

Public Health Ontario is an agency of the Government of Ontario dedicated to protecting and promoting the health of all Ontarians and reducing inequities in health. Public Health Ontario links public health practitioners, front-line health workers and researchers to the best scientific intelligence and knowledge from around the world.

For more information about PHO, visit publichealthontario.ca.

Ontario