Public Health Ontario | Santé publique Ontario

Weekly Summary

Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to April 10, 2021

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

This weekly summary includes reports of AEFIs reported in the Public Health Case and Contact Management Solution (CCM) as of **April 10, 2021**. Doses administered up to and including April 10, 2021 are extracted from the $COVax_{ON}$ application (see technical notes for details on data sources).

Background

In Ontario, AEFIs are primarily 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]
- The COVID-19 vaccine webpage for resources and data on Ontario's COVID-19 vaccine program

Highlights

- There are a total of 1,367 AEFI reports received following 3,141,288 doses of COVID-19 vaccines administered in Ontario to date (Dec 13, 2020 – Apr 10, 2021) with a reporting rate of 43.5 per 100,000 doses administered
    - 176 new AEFI reports were received this week (Apr 4 – Apr 10, 2021)
- Of the total 1,367 AEFI reports received to date (Dec 13, 2020 – Apr 10, 2021):
    - 1,331 AEFI reports are non-serious (97.4% of total AEFI reports)
    - 36 AEFI reports meet the serious definition (2.6% of total AEFI reports)
    - The most commonly reported adverse events are allergic skin reactions and pain/redness/swelling at the injection site, reported in 29.4% and 26.6% of the total AEFI reports respectively
    - 52 reports of events managed as anaphylaxis are reported, in which six reports also meet the serious definition (see Adverse Event Descriptions for description of events)
    - 18 reports include a COVID-19 vaccine-specific adverse event of special interest, in which nine reports also meet the serious definition (see Adverse Event Descriptions for description of event)

> 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.

AEFI Report Characteristics

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).

Table 1. Summary of all AEFI reports received to date by COVID-19 vaccine in Ontario, December 13, 2020 to April 10, 2021

	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine	COVISHIELD COVID-19 vaccine	AstraZeneca COVID-19 vaccine	All vaccine products combined
Total number of AEFI reports	885	407	66	1	1,367
Number of non-serious reports	866	395	61	1	1,331
Number of serious reports	19	12	5	0	36
Proportion of total AEFI reports that are serious	2.1	2.9	7.6	0.0	2.6
Doses administered	2,380,937	451,157	199,990	109,204	3,141,288
Total reporting rate per 100,000 doses administered	37.2	90.2	33.0	0.9	43.5
Serious reporting rate per 100,000 doses administered	0.8	2.7	2.5	0.0	1.1

Note: Eight 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. Doses administered data are subject to reporting delays.
Data Source: CCM, COVax$_{ON}$ (see technical notes for details on data sources)

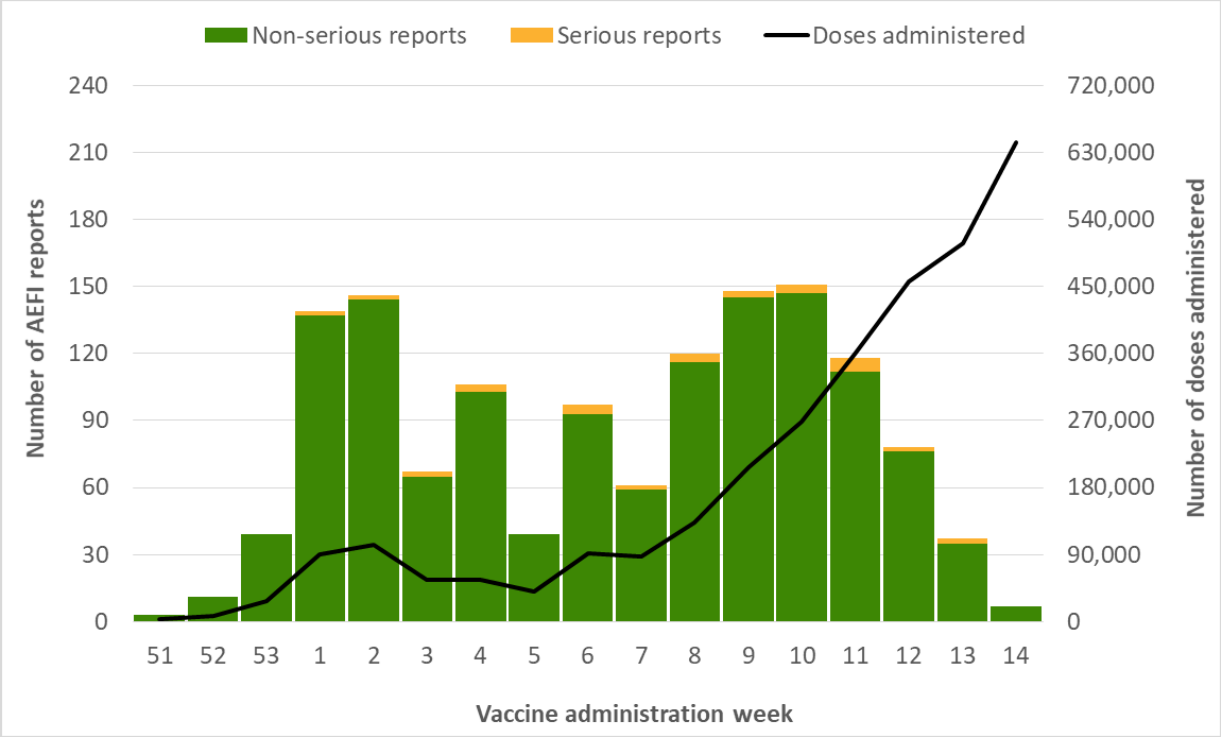
Table 2. Summary of all AEFI reports received to date by age group and gender in Ontario, December 13, 2020 to April 10, 2021

	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Gender: Female	1,188	63.0
Gender: Male	164	13.2
Ages: 18-49 years	622	92.2
Ages: 50-64 years	393	53.4
Ages: 65 years and over	346	20.1

Note: Age represents age at time of immunization. Some AEFI reports and doses administered records have unknown gender or age; these reports are excluded from gender and age-specific counts and reporting rate. Age group of 17 years and under has been excluded due to low number of reports and doses administered in this age group. 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. Doses administered data are subject to reporting delays.
Data Source: CCM, $COVax_{ON}$ (see technical notes for details on data sources)

Time

Figure 1. Number of AEFI reports and doses administered by week of COVID-19 vaccine administration in Ontario, December 13, 2020 to April 10, 2021



Note: AEFI reports are assessed based on date of vaccine administration. The administration week ranges from week 51 (Dec 13 to 19, 2020) to week 14 (April 4 to 10, 2021). 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. Doses administered data are subject to reporting delays.
Data Source: CCM, COVax$_{ON}$ (see technical notes for details on data sources)

Adverse Event Descriptions

The most commonly reported adverse events for all vaccine products combined are allergic skin reactions and pain/redness/swelling at the injection site, reported in 29.4% and 26.6% of the total AEFI reports respectively. Allergic skin reaction was the most frequently reported adverse event for the Pfizer-BioNTech vaccine (12.9 per 100,000 doses administered) while pain/redness/swelling at the injection site was the most frequently reported adverse event for the Moderna vaccine (44.8 per 100,000 doses administered). The 'other severe or unusual events' category was the third most frequently reported event for all vaccine products combined, which includes reports of adverse events that do not meet any other pre-defined events outlined in the Infectious Diseases Protocol: Appendix B.[1] These events do not necessarily meet the serious AEFI definition. Of the 218 reports of other severe or unusual events received to date, ten reports met the definition of a serious AEFI (described in the Serious AEFIs below). The number of AEFI reports and reporting rate for each adverse event are presented in Appendix A.

There were also 20 reports of Bell's Palsy with symptom onset ranging from 18 hours to 34 days post-immunization. At the time of reporting, two individuals were fully recovered, seventeen individuals were still symptomatic and one report had an unknown outcome. The outcome for AEFI reports is determined at the time the PHU completes the case investigation and may not reflect the current status of the client's symptoms.

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 list of medically important events are listed in the technical notes. There were 58 AEFIs reported that were classified as medically important events, representing 4.2% of all reports. Eleven of these reports met the definition of a serious AEFI.

Of the 58 reports of medically important events, 52 were reports of events managed as anaphylaxis, in which six met the definition of a serious AEFI (described in the Serious AEFIs below). Of all 52 reports of events managed as anaphylaxis: 45 received epinephrine, 45 were seen in the emergency department and 44 were fully recovered at the time of reporting. A preliminary assessment using the Brighton Collaboration standard definition of anaphylaxis was applied to cases which include clinical information required to conduct an assessment.[6] Sixteen met Brighton definition at level I of diagnostic certainty, seven met Brighton definition at level II of diagnostic certainty and 25 reports did not have sufficient documented evidence to meet levels I, II or III of diagnostic certainty. Four reports are still under investigation and have not yet been assigned a level of diagnostic certainty.

Of the remaining six reports of medically important events, there was one report of myelitis/transverse myelitis following the Pfizer-BioNTech vaccine, one report of Guillain-Barré syndrome (GBS) following the COVISHIELD vaccine and four reports of thrombocytopenia (two following Moderna, one following Pfizer-BioNTech and one following COVISHIELD). Five of these six events met the definition of a serious AEFI (described in the Serious AEFIs below).

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 18 reports with COVID-19 vaccine-specific AESIs, in which nine reports also met the definition of a serious AEFI (described in the Serious AEFIs below). The nine reports that did not meet the definition of a serious AEFI were:

- three reports of "acute cardiovascular injury"
    - one report in an individual that developed chest pain 21 days following receipt of COVID-19 vaccine and was subsequently diagnosed with pericarditis. (Pfizer-BioNTech)
    - one report of in an individual who developed shortness of breath and chest pain shortly after receiving COVID-19 vaccine, that was subsequently diagnosed with a cardiac conduction disorder. (Pfizer-BioNTech)
    - one report in an individual who developed left occipital lobe infarct five days after receiving their first dose of COVID -19 vaccine. (Moderna)
- two reports of "coagulation disorder"
    - one report in an individual who developed internal jugular vein thrombosis ten days after receiving their first dose of COVID-19 vaccine. (COVISHIELD)
    - one report in an individual who developed popliteal deep vein thrombosis six days after receiving their first dose of COVID-19 vaccine. (Pfizer)
- one report of "coagulation disorder" and "acute respiratory distress syndrome" in an individual with suspected congestive heart failure (CHF) and pulmonary emboli after receiving their second dose of COVID-19 vaccine. (Pfizer)
- one report of "Chilblain-like lesions" which were diagnosed prior to immunization and reported as an exacerbation temporally associated with receipt of COVID-19 vaccine. (Pfizer-BioNTech)
- one report of physician-diagnosed "erythema multiforme" in an individual who developed erythematous macules three days following receipt of COVID-19 vaccine. (Moderna)
- one report of "anosmia and/or ageusia" in an individual who lost their sense of taste 2 hours following receipt of COVID-19 vaccine. (Pfizer)

Serious AEFIs

There were 36 AEFI reports classified as serious, representing 2.6% of all AEFI reports and a serious AEFI reporting rate of 1.1 per 100,000 doses administered for all vaccine products combined. As a comparison, the proportion of AEFIs defined as serious for all vaccines administered in Ontario ranged from 2.8% and 5.0% between 2012 and 2018.[7] The serious reporting rate was 0.8 and 2.7 per 100,000 doses administered for the Pfizer-BioNTech vaccine and the Moderna vaccine, respectively. Five serious

reports were received for the COVISHIELD vaccine (reporting rate of 2.5 per 100,000 doses administered). No serious reports were received for the AstraZeneca vaccine.

Thirty-five of the 36 clients were hospitalized related to the reported events. Of the 35 clients, seventeen were reported to be recovered, fourteen were still symptomatic at the time of reporting and four had unknown outcome. When a serious report contained multiple adverse events, one event that was the prominent reason for reporting was chosen to describe the serious report. The 35 reports with hospitalization were:

- six reports of events managed as anaphylaxis
- eight other severe or unusual events
- nine reports of COVID-19 AESI: two "acute cardiovascular injury", six "coagulation disorder" including two with thrombocytopenia, and one "acute kidney injury" (see below)
- three reports of severe vomiting/diarrhea
- three reports of anaesthesia/paraesthesia
- one each of GBS, myelitis/transverse myelitis, arthritis/arthralgia, convulsion/seizure, thrombocytopenia, and allergic skin reaction.

The nine reported AESIs that were classified as serious include:

- one report of "acute kidney injury" in an individual who received COVID-19 vaccine but subsequently tested positive for COVID-19. The individual had risk factors for renal disease prior to vaccination. (Pfizer-BioNTech)
- two reports of "acute cardiovascular injury"
    - one report in an individual who developed myocarditis following their second dose of COVID-19 vaccine. (Pfizer-BioNTech)
    - one report in an individual with underlying cardiovascular risk factors diagnosed with a myocardial infarction the day after receiving their first dose of COVID-19 vaccine. (COVISHIELD)
- six reports of "coagulation disorder"
    - one report in an individual with multiple co-morbidities including cardiovascular disease who tested positive for COVID-19 prior to receipt of a mRNA COVID-19 vaccine. The individual subsequently developed pulmonary embolisms following their first dose of COVID-19 vaccine. (Moderna)
    - one report in an individual who suffered a stroke one day following their first dose of COVID-19 vaccine. (COVISHIELD)
    - one report in an individual who developed shortness of breath the day after receiving their first dose of COVID-19 vaccine and two days later was diagnosed with pulmonary embolisms. (Pfizer-BioNTech)

- one report in an individual with underlying cardiovascular risk factors who was diagnosed with a pulmonary embolus two days after receiving their first dose of COVID-19 vaccine. (Moderna)
- one report in an individual who was diagnosed with deep vein thrombosis the day after receiving their first COVID-19 vaccine. (Moderna)
- one report in an individual with an exacerbation of thrombotic thrombocytopenic purpura (TTP) six days after receiving his first COVID-19 vaccine. (Pfizer)

The remaining serious AEFI was a report of death following receipt of COVID-19 vaccine that met the provincial surveillance definition (i.e., other severe/unusual event). The individual was a resident of a health-care institution with significant co-morbidities. The cause of death was not attributed to the vaccine.

Reports of death temporally associated with receipt of vaccine

In Ontario, all deaths temporally associated with receipt of vaccines that have been reported to public health units are thoroughly investigated and reported to PHO. As of April 10, 2021, there are seven reports of deaths temporally associated with receipt of COVID-19 vaccine that are currently classified as 'persons under investigation' as they do not currently meet the provincial surveillance definition. These investigations are ongoing and additional information including a cause of death (e.g., autopsy or Coroner's report) is expected. Preliminary information suggests that these events occurred in individuals with multiple co-morbidities which may be related to the cause of death. Five of the seven reports are in long-term care home (LTCH)/retirement home residents. There has been no association with vaccine identified at this time. Reports of death that meet the provincial case definition are events temporally associated with vaccine that have not been clearly attributed to other causes; these reports should not be interpreted as causally related with vaccine.

During the first few months of the COVID-19 vaccination campaign, LTCH/retirement home residents have been a focus for vaccination efforts. In this population, it was expected that deaths may occur close to the time of vaccination and require further evaluation to determine the cause of death. After reviewing reports of deaths of very frail elderly individuals vaccinated with Pfizer-BioNTech COVID-19 vaccine, the Global Advisory Committee on Vaccine Safety (GACVC) COVID-19 Vaccine Safety subcommittee concluded that "the current reports do not suggest any unexpected or untoward increase in fatalities in frail, elderly individuals or any unusual characteristics of adverse events following administration of Pfizer-BioNTech COVID-19 vaccine".[8] The Centres for Disease Control (CDC) also presented a similar assessment of their analysis at the January 27, 2021 meeting of the Advisory Committee on Immunization Practices (ACIP) in the United States that mortality in LTCH residents is high and substantial numbers of deaths in this population are expected, unrelated to vaccination.[9] PHO continues to conduct continuous monitoring of the safety of COVID-19 vaccines in collaboration with its partners, including individual case review of all serious AEFIs including reports of death temporally association with receipt of vaccine, daily analysis of surveillance data for vaccine safety signals and weekly reporting on the PHO website and to the Public Health Agency of Canada.

Geography

Table 3. Number of AEFI reports received to date by public health unit and region in Ontario, December 13, 2020 to April 10, 2021

Public Health Unit Name	Number of AEFI reports received to date
Northwestern Health Unit	37
Thunder Bay District Health Unit	12
TOTAL NORTH WEST	49
Algoma Public Health	18
North Bay Parry Sound District Health Unit	22
Porcupine Health Unit	27
Public Health Sudbury & Districts	41
Timiskaming Health Unit	16
TOTAL NORTH EAST	124
Eastern Ontario Health Unit	16
Hastings Prince Edward Public Health	18
Kingston, Frontenac and Lennox & Addington Public Health	33
Leeds, Grenville & Lanark District Health Unit	25
Ottawa Public Health	9
Renfrew County and District Health Unit	19
TOTAL EASTERN	120
Durham Region Health Department	106
Haliburton, Kawartha, Pine Ridge District Health Unit	43
Peel Public Health	111
Peterborough Public Health	36

Public Health Unit Name	Number of AEFI reports received to date
Simcoe Muskoka District Health Unit	36
York Region Public Health	61
TOTAL CENTRAL EAST	393
Toronto Public Health	242
TOTAL TORONTO	242
Chatham-Kent Public Health	11
Grey Bruce Health Unit	12
Huron Perth Public Health	17
Lambton Public Health	53
Middlesex-London Health Unit	30
Southwestern Public Health	26
Windsor-Essex County Health Unit	57
TOTAL SOUTH WEST	206
Brant County Health Unit	19
City of Hamilton Public Health Services	55
Haldimand-Norfolk Health Unit	4
Halton Region Public Health	35
Niagara Region Public Health	24
Region of Waterloo Public Health and Emergency Services	66
Wellington-Dufferin-Guelph Public Health	30
TOTAL CENTRAL WEST	233
TOTAL ONTARIO	1,367

Note: Orientation of AEFI reports by geography is based the case's public health unit of residence at the time of adverse event. This does not represent the location of vaccine administration.
Data Source: CCM

Technical Notes

Data Sources

- The data for this report were based on:
    - AEFI information from the Public Health Case and Contact Management Solution (CCM) extracted on **April 12, 2021 at approximately 9:00 a.m.**
    - Doses administered data from the $COVax_{ON}$ application extracted on **April 12 at approximately 9:45 a.m**. Methodology used to calculate the number of doses administered are documented in PHO's COVID-19 Vaccine Uptake in Ontario report.[10]

Data Caveats

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

Methods

- For provincial surveillance reporting, an adverse event must occur after receiving the vaccine and meet the MOH AEFI case definition.[1] Data presented in this report only includes AEFI reports with a confirmed case classification and an association with a COVID-19 vaccine in CCM at the time of data extraction.
- AEFI reports from CCM where the Disposition was reported as ENTERED IN ERROR, DOES NOT MEET DEFINITION, EXPOSURE RULED OUT or DUPLICATE – DO NOT USE, or any variation on these values have been excluded. AEFI reports from CCM where the Status was reported as MERGED-OBSOLETE have also been excluded.
- AEFI reports with a missing date of vaccine administration have been excluded.
- Each AEFI report refers to an individual who reported an adverse event after receiving a dose of COVID-19 vaccine. An AEFI report may contain multiple adverse events. Therefore, the total number of adverse events can exceed the number of individual AEFI reports reported in a given time frame. AEFI reports that did not have an adverse event reported at the time of data extraction have been excluded.
- AEFI reporting rates are calculated using the number of COVID-19 vaccine-specific AEFIs reported in a given time period in Ontario divided by doses of COVID-19 vaccines administered in the same time period in Ontario.
- Serious AEFIs are defined using the World Health Organization (WHO) standard definition:[11] 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 date 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 and thrombocytopenia.

- All reports of events managed as anaphylaxis are further assessed using the internationally recognized case definition for anaphylaxis following vaccination from the Brighton Collaboration.[6] 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 I 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.[12] These are: vaccine-associated enhanced disease, multisystem inflammatory syndrome in children, acute respiratory distress syndrome, acute cardiovascular injury, coagulation disorder, acute kidney injury, acute liver injury, anosmia and/or ageusia, chilblain like lesions, single organ cutaneous vasculitis, and erythema multiforme.

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

References

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

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

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

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

5. Government of Canada. COVID-19 vaccine safety in Canada [Internet]. Ottawa, ON: Government of Canada; 2021 [modified 2021 Jan 15; cited 2021 Jan 16]. Available from: https://health-infobase.canada.ca/covid-19/vaccine-safety/

6. 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

7. 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

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

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

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

11. 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

12. 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 Jan 25]. 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 adverse events reported to date by COVID-19 vaccine in Ontario, December 13, 2020 to April 10, 2021

Adverse event	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine	COVISHIELD COVID-19 vaccine	Astra-Zeneca COVID-19 vaccine	All vaccine products combined
Allergic skin reactions	307	76	16	0	402
Pain/redness/swelling at the injection site	146	202	14	0	364
Other severe or unusual events	161	39	18	0	218
Rash	123	72	6	0	202
Fever in conjunction with another reportable event	63	31	5	0	100
Anaesthesia/paraesthesia	70	16	6	0	92
Severe vomiting/diarrhea	54	21	7	1	84
Adenopathy/lymphadenopathy	65	14	2	0	81
Cellulitis	14	39	0	0	53
Arthritis/arthralgia	45	5	2	0	52
Event managed as anaphylaxis	45	7	0	0	52
Bell's Palsy	11	8	0	0	20
Convulsions/seizure	6	5	1	0	12
AESI – Coagulation disorder	4	3	2	0	9
Nodule	1	8	0	0	9
AESI – Acute cardiovascular injury	3	1	1	0	5
Oculorespiratory syndrome (ORS)	3	2	0	0	5

Adverse event	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine	COVISHIELD COVID-19 vaccine	Astra-Zeneca COVID-19 vaccine	All vaccine products combined
Syncope (fainting) with injury	4	0	0	0	4
Thrombocytopenia	1	2	1	0	4
AESI – Acute kidney injury	1	0	0	0	1
AESI – Acute respiratory distress syndrome	1	0	0	0	1
AESI – Anosmia, ageusia	1	0	0	0	1
AESI – Chilblain-like lesions	1	0	0	0	1
AESI – Erythema multiforme	0	1	0	0	1
Guillian-Barré syndrome (GBS)	0	0	1	0	1
Myelitis/transverse myelitis	1	0	0	0	1
Parotitis	1	0	0	0	1

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

Table A2. Reporting rate per 100,000 doses administered for adverse events reported to date by COVID-19 vaccine in Ontario, December 13, 2020 to April 10, 2021

Adverse event	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine	COVISHIELD COVID-19 vaccine	Astra-Zeneca COVID-19 vaccine	All vaccine products combined
Allergic skin reactions	12.9	16.8	8.0	0.0	12.8
Pain/redness/swelling at the injection site	6.1	44.8	7.0	0.0	11.6
Other severe or unusual events	6.8	8.6	9.0	0.0	6.9
Rash	5.2	16.0	3.0	0.0	6.4
Fever in conjunction with another reportable event	2.6	6.9	2.5	0.0	3.2
Anaesthesia/paraesthesia	2.9	3.5	3.0	0.0	2.9
Severe vomiting/diarrhea	2.3	4.7	3.5	0.9	2.7
Adenopathy/lymphadenopathy	2.7	3.1	1.0	0.0	2.6
Arthritis/arthralgia	1.9	1.1	1.0	0.0	1.7
Cellulitis	0.6	8.6	0.0	0.0	1.7
Event managed as anaphylaxis	1.9	1.6	0.0	0.0	1.7
Bell's Palsy	0.5	1.8	0.0	0.0	0.6
Convulsions/seizure	0.3	1.1	0.5	0.0	0.4
AESI – Coagulation disorder	0.2	0.7	1.0	0.0	0.3
Nodule	0.0	1.8	0.0	0.0	0.3
AESI – Acute cardiovascular injury	0.1	0.2	0.5	0.0	0.2
Oculorespiratory syndrome (ORS)	0.1	0.4	0.0	0.0	0.2
Syncope (fainting) with injury	0.2	0.0	0.0	0.0	0.1
Thrombocytopenia	0.0	0.4	0.5	0.0	0.1

Adverse event	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine	COVISHIELD COVID-19 vaccine	Astra-Zeneca COVID-19 vaccine	All vaccine products combined
AESI – Acute kidney injury	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
AESI – Anosmia, ageusia	0.0	0.0	0.0	0.0	0.0
AESI – Chilblain-like lesions	0.0	0.0	0.0	0.0	0.0
AESI – Erythema multiforme	0.0	0.2	0.0	0.0	0.0
Guillian-Barré syndrome (GBS)	0.0	0.0	0.5	0.0	0.0
Myelitis/transverse myelitis	0.0	0.0	0.0	0.0	0.0
Parotitis	0.0	0.0	0.0	0.0	0.0

Note: An AEFI report may contain multiple adverse events. Thus the sum of all adverse event-specific counts may not equal to the total number of AEFI reports. Some AEFI reports did not specify vaccine product received; these are included in the counts for all vaccine products combined.
Data Source: CCM, $COVax_{ON}$ (see technical notes for details on data sources)

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.

Citation

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Weekly summary: adverse events following immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to April 10, 2021. Toronto, ON: Queen's Printer for Ontario; 2021.

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