Public Health Ontario | Santé publique Ontario

WEEKLY SUMMARY

Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to May 1, 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 **May 1, 2021**. Doses administered up to and including May 1, 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 2,280 AEFI reports received following 5,327,254 doses of COVID-19 vaccines administered in Ontario to date with a reporting rate of 42.8 per 100,000 doses administered
    - This represents an increase of 402 AEFI reports compared to previous week
- Of the total 2,280 AEFI reports received to date:
    - 2,205 AEFI reports are non-serious (96.7% of total AEFI reports)
    - 75 AEFI reports meet the serious definition (3.3% of total AEFI reports)
    - The most commonly reported adverse events are allergic skin reactions and pain/redness/swelling at the injection site, reported in 27.3% and 25.5% of the total AEFI reports respectively
    - 91 reports of events managed as anaphylaxis are reported, in which nine reports also meet the serious definition (see Events Managed As Anaphylaxis for description of events)
    - 47 reports include a COVID-19 vaccine-specific adverse event of special interest, in which 20 reports also meet the serious definition (see Adverse events of special interest for description of events)
    - Three reports of thrombosis with thrombocytopenia syndrome (TTS)/vaccine-induced immune thrombotic thrombocytopenia (VITT) after receipt of COVISHIELD/AstraZeneca vaccine

> 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 May 1, 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	1,330	680	138	126	2,280
Number of non-serious reports	1,286	665	126	122	2,205
Number of serious reports	44	15	12	4	75
Proportion of total AEFI reports that are serious	3.3%	2.2%	8.7%	3.2%	3.3%
Doses administered	3,629,953	901,287	202,889	593,125	5,327,254
Total reporting rate per 100,000 doses administered	36.6	75.4	68.0	21.2	42.8
Serious reporting rate per 100,000 doses administered	1.2	1.7	5.9	0.7	1.4

Note: Six 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)

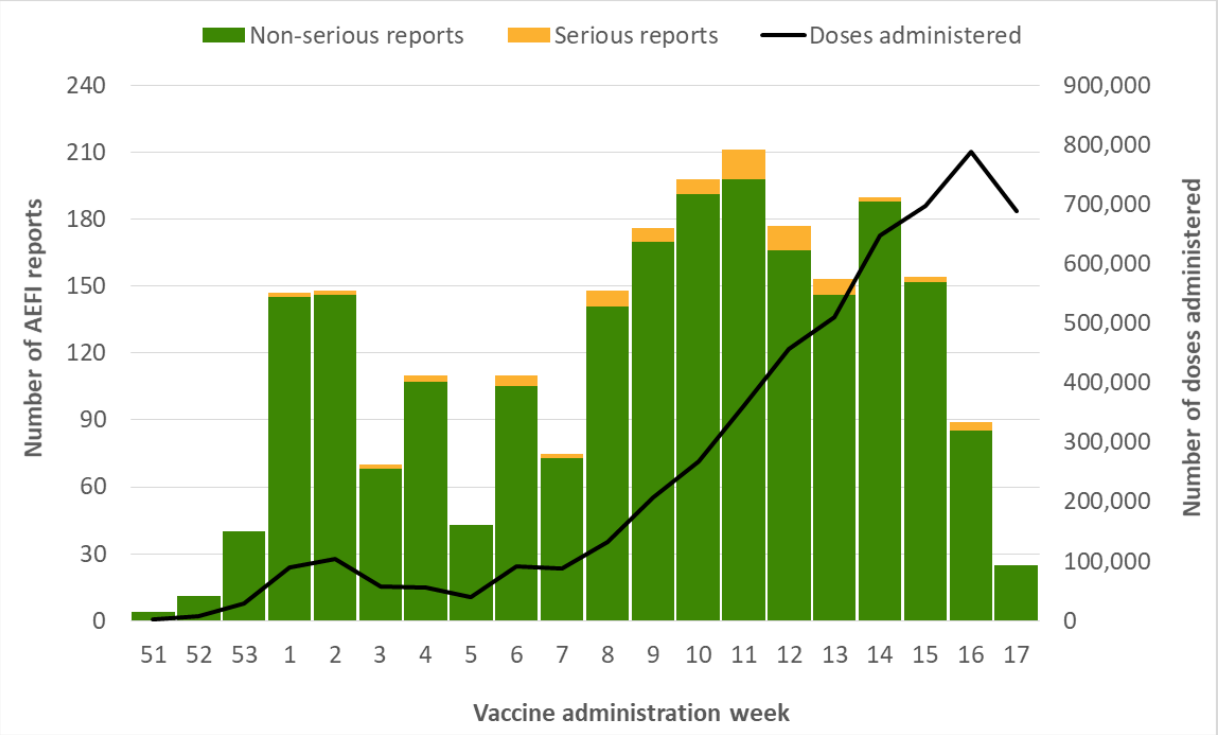
Table 2. Summary of all AEFI reports received to date by age group and gender in Ontario, December 13, 2020 to May 1, 2021

	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Gender: Female	1,893	62.9
Gender: Male	317	13.8
Ages: 18-49 years	857	63.2
Ages: 50-64 years	731	43.5
Ages: 65 years and over	684	30.1

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 May 1, 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 17 (April 25 to May 1, 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.
Data Source: CCM, $COVax_{ON}$ (see technical notes for details on data sources)

Adverse Event Descriptions

For all COVID-19 vaccine products combined, the most commonly reported adverse events are allergic skin reactions and pain/redness/swelling at the injection site, reported in 27.3% and 25.5% of the total AEFI reports respectively. Allergic skin reaction was the most frequently reported adverse event for the Pfizer-BioNTech vaccine (12.1 per 100,000 doses administered) and the AstraZeneca vaccine (5.6 per 100,000 doses administered) while pain/redness/swelling at the injection site was the most frequently reported adverse event for the Moderna vaccine (35.0 per 100,000 doses administered). The 'other severe or unusual events' category was the most frequently reported adverse event for the COVISHIELD vaccine (19.7 per 100,000 doses administered). The number of AEFI reports and reporting rate for each adverse event are presented in Appendix A.

The 'other severe or unusual events' category includes reports of adverse events that do not meet any other pre-defined events outlined in the Infectious Diseases Protocol: Appendix B.[1] These events do not necessarily meet the serious AEFI definition.

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 105 AEFIs reported that were classified as medically important events, representing 4.6% of all reports. The 105 reports of medically important events include:

- Nine reports of thrombocytopenia: three following the COVISHIELD vaccine, three following the Moderna vaccine, two following the Pfizer-BioNTech vaccine and one following the AstraZeneca vaccine
- Four reports of Guillain-Barré syndrome (GBS): two following the COVISHIELD vaccine and two following the Pfizer-BioNTech vaccine
- One report of myelitis/transverse myelitis following the Pfizer-BioNTech vaccine

Of the 14 reports listed above, 12 met the definition of a serious AEFI.

Events Managed As Anaphylaxis

The remaining 91 medically important events were reports of events managed as anaphylaxis, in which nine met the definition of a serious AEFI. Of all 91 reports of events managed as anaphylaxis: 77 received epinephrine, 80 were seen in the emergency department and 66 were fully recovered at the time of reporting. All reports of events managed as anaphylaxis undergo an assessment using the Brighton Collaboration standard definition of anaphylaxis.[6] The most recent breakdown of reports by Brighton level of diagnostic certainty is available in the enhanced epidemiological summary on reports of events managed as anaphylaxis which is updated periodically.

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 47 reports with COVID-19 vaccine-specific AESIs, representing 2.1% of all reports. Of the 47 reports, 20 met the definition of a serious AEFI. The 47 reports of AESIs were:

- 28 reports of "coagulation disorder", including four with thrombocytopenia (referenced in the medically important events section)
- Ten reports of "acute cardiovascular injury"
- Three reports of "anosmia and/or ageusia"
- Two reports of "acute kidney injury"
- Two reports of "erythema multiforme"
- Two reports of "chilblain-like lesions"
- One report of "acute respiratory distress syndrome"
- One report of "single organ cutaneous vasculitis"

Some reports contained more than one AESI. Thus the sum of reports listed above will not equal the total number of reports with COVID-19 vaccine-specific AESIs. The number of AEFI reports and reporting rate for each AESI by vaccine product are presented in Appendix A.

Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) and Thrombosis with Thrombocytopenia Syndrome (TTS)

Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) refers to a rare condition characterized by blood clots associated with low levels of platelets (thrombocytopenia) that has been reported following immunization with adenoviral vector vaccines, including COVISHIELD/AstraZeneca vaccine. The rate of VITT is currently estimated to be approximately 1 per 100,000 persons vaccinated with COVISHIELD/AstraZeneca vaccine, although information in this area is rapidly evolving.[7] Canada's National Advisory Committee on Immunization (NACI) has recently released a detailed benefit-risk analysis concerning the use of the vaccine in different epidemiologic contexts in Canada.[7] A case finding definition proposed by the Brighton Collaboration is being used to support case finding of this new clinical syndrome by identifying individuals who present with thrombosis with thrombocytopenia syndrome (TTS) following COVID-19 vaccination.[8]

To date, there have been three reports of TTS following receipt of COVISHIELD/AstraZeneca vaccine in Ontario. All three events occurred in males, two in the 65+ age group and one in the 50-64 year age group. All followed receipt of COVISHIELD vaccine received between March 16 and March 27. The time to onset of thrombocytopenia for these cases ranged from 11 to 20 days after vaccination and all cases required hospitalization. There are other reports of TTS that are currently under investigation.

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 75 AEFI reports classified as serious, representing 3.3% of all AEFI reports and a serious AEFI reporting rate of 1.4 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.[9] The serious reporting rate was 1.2 and 1.7 per 100,000 doses administered for the Pfizer-BioNTech vaccine and the Moderna vaccine, respectively. The serious reporting rates for the COVISHIELD and AstraZeneca vaccines were 5.9 and 0.7 per 100,000 doses administered, respectively.

AEFI Reports Requiring Hospitalization

Seventy-two clients of the 75 serious reports had a hospital admission related to the reported events. Of the 72 clients, 28 had recovered at the time of reporting, 32 were not yet recovered when the investigation was completed, but likely to recover, and seven had an unknown outcome at the time of reporting. Five reports had an outcome reported as “residual effects”, which is defined as residual disability or sequelae related to the reported event. Due to the relatively short follow-up time for AEFIs reported in CCM, it is uncertain whether these residual effects will resolve, but had not yet resolved at the time of reporting.

When a serious report contained multiple adverse events, one event that was the prominent reason for reporting was chosen to describe the serious report. Of the 72 reports of hospitalizations, 17 reported an AESI, 18 reported a medically important event, and three reported both a medically important event and an AESI (described in the AESI section and the medically important events section). The remaining 34 reports were:

- 22 reports of other severe or unusual events
- four reports of severe vomiting/diarrhea
- three reports of convulsion/seizure
- two reports of anaesthesia/paraesthesia
- one report of syncope (fainting) with injury
- one report of arthritis/arthralgia
- one report of paralysis

AEFI Reports with Fatal Outcome

The remaining three serious AEFIs were reports of death following receipt of COVID-19 vaccine that met the provincial surveillance definition (i.e., other severe/unusual event). One report of death occurred in a resident of a health-care institution with significant co-morbidities. The cause of death was not attributed to the vaccine. The second report of death occurred in a community dwelling senior with complex cardiovascular and renal conditions, wherein the AEFI may have contributed to but was not the underlying cause of death. The third report of death occurred in a community dwelling senior with multiple comorbidities including heart disease and an autoimmune disorder. 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 May 1, 2021, there are ten 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. Four of the ten 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".[10] 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.[11] 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 May 1, 2021

Public Health Unit Name	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Northwestern Health Unit	65	220.3
Thunder Bay District Health Unit	21	31.3
TOTAL NORTH WEST	86	89.1
Algoma Public Health	20	51.9
North Bay Parry Sound District Health Unit	38	79.9
Porcupine Health Unit	48	160.1
Public Health Sudbury & Districts	78	110.9
Timiskaming Health Unit	33	222.7
TOTAL NORTH EAST	217	107.8
Eastern Ontario Health Unit	30	43.0
Hastings Prince Edward Public Health	23	42.4
Kingston, Frontenac and Lennox & Addington Public Health	58	71.4
Leeds, Grenville & Lanark District Health Unit	66	95.4
Ottawa Public Health	14	3.9
Renfrew County and District Health Unit	36	97.7
TOTAL EASTERN	227	34.0
Durham Region Health Department	149	59.0
Haliburton, Kawartha, Pine Ridge District Health Unit	66	83.8

Public Health Unit Name	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Peel Public Health	164	32.4
Peterborough Public Health	62	106.7
Simcoe Muskoka District Health Unit	96	44.1
York Region Public Health	153	34.1
TOTAL CENTRAL EAST	690	44.2
Toronto Public Health	380	35.8
TOTAL TORONTO	380	35.8
Chatham-Kent Public Health	12	32.1
Grey Bruce Health Unit	34	52.4
Huron Perth Public Health	31	58.7
Lambton Public Health	82	163.7
Middlesex-London Health Unit	37	22.8
Southwestern Public Health	56	78.9
Windsor-Essex County Health Unit	59	34.9
TOTAL SOUTH WEST	311	51.2
Brant County Health Unit	28	51.3
City of Hamilton Public Health Services	92	47.1
Haldimand-Norfolk Health Unit	6	14.5
Halton Region Public Health	59	27.3
Niagara Region Public Health	37	20.2
Region of Waterloo Public Health and Emergency Services	103	52.6
Wellington-Dufferin-Guelph Public Health	44	40.6

Public Health Unit Name	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
TOTAL CENTRAL WEST	369	37.1
TOTAL ONTARIO	2,280	42.8

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

Technical Notes

Data Sources

- The data for this report were based on:
    - AEFI information from the Public Health Case and Contact Management Solution (CCM) extracted on **May 3, 2021 at approximately 9:00 a.m.**
    - Doses administered data from the $COVax_{ON}$ application extracted on **May 3 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.[12]

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:[13] 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.[14] 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. 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 Apr 26]. 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

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

9. 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

10. 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

11. 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

12. 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

13. 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

14. 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 May 1, 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	439	119	28	33	622
Pain/redness/swelling at the injection site	209	315	27	29	581
Other severe or unusual events	263	74	40	30	407
Rash	176	115	15	15	322
Fever in conjunction with another reportable event	80	39	11	21	152
Severe vomiting/diarrhea	86	31	15	16	149
Anaesthesia/paraesthesia	102	22	16	7	147
Adenopathy/lymphadenopathy	84	24	4	5	117
Arthritis/arthralgia	71	11	6	12	100
Event managed as anaphylaxis	65	20	1	5	91
Cellulitis	14	60	0	0	74
Bell's Palsy	20	12	1	0	33
AESI – Coagulation disorder	12	7	6	3	28
Convulsions/seizure	11	6	1	1	19
Nodule	1	12	0	1	14
Syncope (fainting) with injury	10	0	1	1	12
AESI – Acute cardiovascular injury	7	1	2	0	10

Adverse event	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine	COVISHIELD COVID-19 vaccine	Astra-Zeneca COVID-19 vaccine	All vaccine products combined
Thrombocytopenia	2	3	3	1	9
Oculorespiratory syndrome (ORS)	4	2	0	0	6
Guillian-Barré syndrome (GBS)	2	0	2	0	4
AESI – Anosmia, ageusia	2	0	1	0	3
Paralysis	2	0	1	0	3
AESI – Acute kidney injury	1	0	1	0	2
AESI – Chilblain-like lesions	2	0	0	0	2
AESI – Erythema multiforme	0	2	0	0	2
Parotitis	1	0	0	1	2
AESI – Acute respiratory distress syndrome	1	0	0	0	1
AESI – Single organ cutaneous vasculitis	1	0	0	0	1
Hypotonic-hyporesponsive episode (HHE)	1	0	0	0	1
Infected abscess	0	1	0	0	1
Myelitis/transverse myelitis	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 May 1, 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	12.1	13.2	13.8	5.6	11.7
Pain/redness/swelling at the injection site	5.8	35.0	13.3	4.9	10.9
Other severe or unusual events	7.2	8.2	19.7	5.1	7.6
Rash	4.8	12.8	7.4	2.5	6.0
Fever in conjunction with another reportable event	2.2	4.3	5.4	3.5	2.9
Anaesthesia/paraesthesia	2.8	2.4	7.9	1.2	2.8
Severe vomiting/diarrhea	2.4	3.4	7.4	2.7	2.8
Adenopathy/lymphadenopathy	2.3	2.7	2.0	0.8	2.2
Arthritis/arthralgia	2.0	1.2	3.0	2.0	1.9
Event managed as anaphylaxis	1.8	2.2	0.5	0.8	1.7
Cellulitis	0.4	6.7	0.0	0.0	1.4
Bell's Palsy	0.6	1.3	0.5	0.0	0.6
AESI – Coagulation disorder	0.3	0.8	3.0	0.5	0.5
Convulsions/seizure	0.3	0.7	0.5	0.2	0.4
Nodule	0.0	1.3	0.0	0.2	0.3
AESI – Acute cardiovascular injury	0.2	0.1	1.0	0.0	0.2
Syncope (fainting) with injury	0.3	0.0	0.5	0.2	0.2
Thrombocytopenia	0.1	0.3	1.5	0.2	0.2
AESI – Anosmia, ageusia	0.1	0.0	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
Guillian-Barré syndrome (GBS)	0.1	0.0	1.0	0.0	0.1
Oculorespiratory syndrome (ORS)	0.1	0.2	0.0	0.0	0.1
Paralysis	0.1	0.0	0.5	0.0	0.1
AESI – Acute kidney injury	0.0	0.0	0.5	0.0	0.0
AESI – Acute respiratory distress syndrome	0.0	0.0	0.0	0.0	0.0
AESI – Chilblain-like lesions	0.1	0.0	0.0	0.0	0.0
AESI – Erythema multiforme	0.0	0.2	0.0	0.0	0.0
AESI – single organ cutaneous vasculitis	0.0	0.0	0.0	0.0	0.0
Hypotonic-hyporesponsive episode (HHE)	0.0	0.0	0.0	0.0	0.0
Infected abscess	0.0	0.1	0.0	0.0	0.0
Myelitis/transverse myelitis	0.0	0.0	0.0	0.0	0.0
Parotitis	0.0	0.0	0.0	0.2	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 May 1, 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