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SURVEILLANCE REPORT

Adverse Events Following Immunization (AEFIs) for COVID-19 in Ontario: December 13, 2020 to April 21, 2024

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

This summary includes AEFIs reported in the Public Health Case and Contact Management Solution (CCM) as of **April 21, 2024** and doses administered up to and including **April 21, 2024** in the Ontario Ministry of Health's COVaxON application (see technical notes for details on data sources). Data were extracted on April 22, 2024. This report is updated every 4 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 23,358 AEFI reports received following 40,385,486 doses of COVID-19 vaccines administered in Ontario to date with a reporting rate of 57.8 per 100,000 doses administered (0.06 % of all doses administered). This represents an increase of 26 new AEFI reports compared to the previous report.

Of the total 23,358 AEFI reports received to date:

- 22,076 AEFI reports are non-serious (94.5% of total AEFI reports)
- 1,282 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 28.2% and 22.5% of the total AEFI reports, respectively
- 1,767 reports include a COVID-19 vaccine-specific adverse event of special interest, in which 769 reports also meet the serious definition (see Adverse events of special interest section for more information)

To date, two safety signals have been confirmed for COVID-19 vaccines based on AEFIs reported in Canada during the COVID-19 vaccination program roll-out: Thrombosis with thrombocytopenia syndrome (TTS) and myocarditis/pericarditis. These two signals were also detected internationally. Refer to the Adverse Event section of this report 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). 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] See Table 1 for a summary of all AEFI reports received to date in Ontario.

Table 1. Summary of AEFI reports by COVID-19 vaccine product: Ontario, December 13, 2020 to April 21, 2024

	Pfizer-BioNTech Comirnaty	Pfizer-BioNTech Comirnaty Bivalent BA.4/5	Pfizer-BioNTech Comirnaty XBB.1.5	Moderna Spikevax	Moderna Spikevax Bivalent BA.1	Moderna Spikevax Bivalent BA.4/5	Moderna Spikevax XBB.1.5	AstraZeneca Vaxzevria/ COVISHIELD	Janssen Jcovden (Johnson & Johnson)	Novavax Nuvaxovid	All vaccine products combined
Total number of AEFI reports	13,703	222	89	7,294	194	23	76	1,700	20	36	23,358
Number of non-serious reports	12,998	204	82	6,898	183	22	65	1,567	20	36	22,076
Number of serious reports	705	18	7	396	11	1	11	133	0	0	1,282
Proportion of total AEFI reports that are serious (%)	5.1	8.1	7.9	5.4	5.7	4.3	14.5	7.8	0.0	0.0	5.5
Doses administered	23,619,627	2,317,276	1,630,486	9,634,542	1,256,502	140,945	674,919	1,087,755	4,003	16,677	40,385,486
Total reporting rate per 100,000 doses administered	58.0	9.6	5.5	75.7	15.4	16.3	11.3	156.3	499.6	215.9	57.8
Serious reporting rate per 100,000 doses administered	3.0	0.8	0.4	4.1	0.9	0.7	1.6	12.2	0.0	0.0	3.2

Notes:

- The columns above for Pfizer-BioNTech Comirnaty and Moderna Spikevax COVID-19 vaccines include AEFIs associated with all indicated dosages: 3 mcg, 10 mcg and 30 mcg for Pfizer-BioNTech Comirnaty and 25 mcg, 50 mcg and 100 mcg for Moderna Spikevax. Moderna Spikevax Bivalent BA.1 (50 mcg), Moderna Spikevax Bivalent BA.4/5 (50 mcg) and Pfizer-BioNTech Comirnaty Bivalent BA.4/5 (10 mcg and 30 mcg) COVID-19 vaccines are presented separately and were previously recommended vaccine products before the approval of the XBB.1.5-containing COVID-19 mRNA vaccines. Currently, Pfizer-BioNTech Comirnaty XBB.1.5 and Moderna Spikevax XBB.1.5 COVID-19 vaccines are approved and recommended for vaccinating individuals who were not previously vaccinated and as additional doses for those previously vaccinated in approved age groups.
- Novavax Nuvaxovid includes Novavax Nuvaxovid and Novavax Nuvaxovid XBB.1.5 Omicron subvariant COVID-19 vaccines.
- One AEFI report did not specify a vaccine product received.
- Reporting rate for the Janssen Jcovden (Johnson & Johnson), Novavax Nuvaxovid, and Moderna Spikevax Bivalent BA.4/5 COVID-19 vaccines should be interpreted with caution due to unstable reporting rate arising from the relatively small number of doses administered.

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

Table 2. Number of AEFI reports and reporting rates by age group and sex: Ontario, December 13, 2020 to April 21, 2024

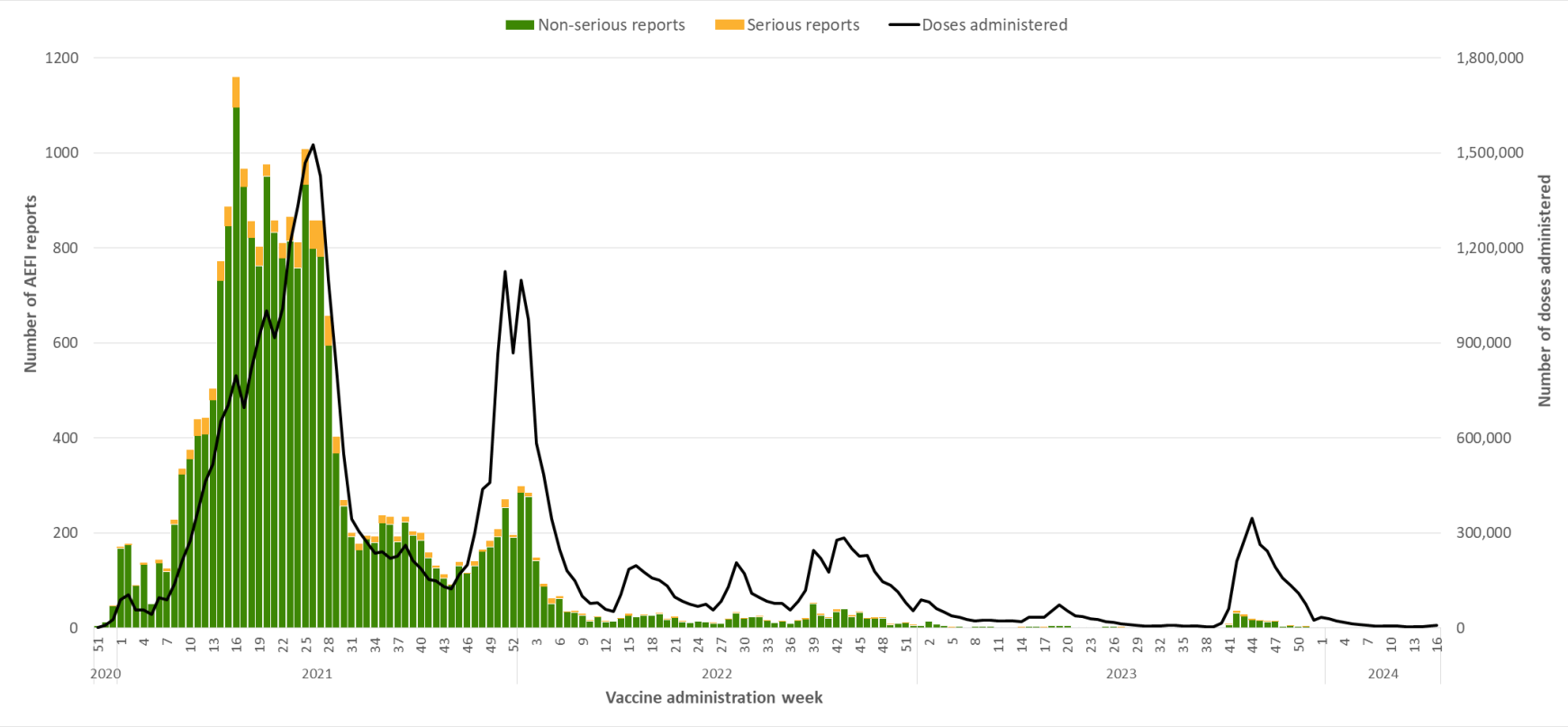
	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Sex: Female	17,123	81.1
Sex: Male	6,036	31.5
Ages: 0-4 years	66	44.1
Ages: 5-11 years	339	25.0
Ages: 12-17 years	823	39.0
Ages: 18-24 years	1,455	46.7
Ages: 25-29 years	1,437	56.9
Ages: 30-39 years	3,756	73.6
Ages: 40-49 years	4,543	92.1
Ages: 50-59 years	4,443	74.2
Ages: 60-69 years	3,536	52.1
Ages: 70-79 years	1,975	37.7
Ages: 80 years and over	985	32.0

Note:

- Age represents age at time of immunization. Gender is used when sex is 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 April 21, 2024



Note:

- AEFI reports are assessed based on date of vaccine administration. The administration week ranges from week 51 (Dec 13 – 19, 2020) to week 16 (April 14 – 20, 2024). April 21, 2024 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).

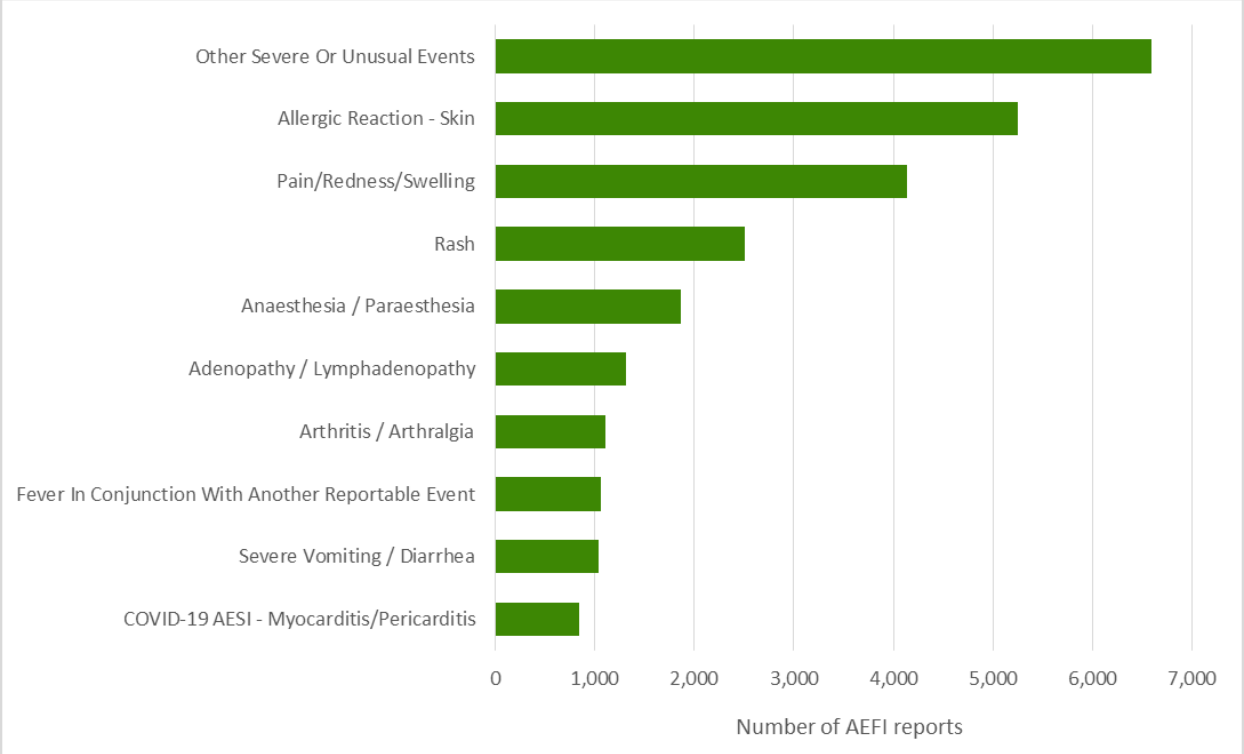
Data Source: CCM, COVaxON (see technical notes for details on data sources)

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 22.5% of the total AEFI reports, respectively. Figure 2 shows the ten most frequently reported adverse events for all COVID-19 vaccines combined.

To date, two safety signals have been confirmed for COVID-19 vaccines based on AEFIs reported in Canada during the COVID-19 vaccination program roll-out: Thrombosis with thrombocytopenia syndrome (TTS) and myocarditis/pericarditis. These two signals were also detected internationally. Ontario is continuing to monitor all AEFIs reported following receipt of COVID-19 immunization in collaboration with its partners.

Figure 2. Ten most frequently reported adverse events for all COVID-19 vaccines: Ontario, December 13, 2020 to April 21, 2024



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 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 702 reports with medically important events, representing 3.0% of all reports. The most frequently reported medically important event was events managed as anaphylaxis (n=520), of which 40 met the definition of a serious AEFI (7.7%). See this resource for more information on management of anaphylaxis following immunization in the community.[7]

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 1,767 reports with COVID-19 vaccine-specific AESIs, representing 7.6% of all reports. Of the 1,767 reports, 769 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.

MYOCARDITIS/PERICARDITIS

Rare myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) events have been reported following vaccination with COVID-19 mRNA vaccines.[9] Information from vaccine safety monitoring systems and evidence from multiple observational studies across many countries support an association between COVID-19 mRNA vaccines and an increased risk of myocarditis/pericarditis.[10-12] 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 12 to 29 years of age, and more often in males than females.[9]

Vaccine safety surveillance data in Canada suggest relatively higher rates of myocarditis/pericarditis reported after the original monovalent Moderna Spikevax COVID-19 vaccine compared to the original monovalent Pfizer-BioNTech Comirnaty COVID-19 vaccine.[13] Similar trends have been observed in Ontario's vaccine safety surveillance data where the reporting rates of myocarditis/pericarditis was observed to be higher following vaccination with the original monovalent Moderna Spikevax COVID-19 vaccine compared to the original monovalent Pfizer-BioNTech Comirnaty COVID-19 vaccine in the 18 to 24 year old age group, particularly among males.[12] There are no available data on the risk of myocarditis/pericarditis following the currently recommended COVID-19 mRNA vaccine formulations (i.e., Moderna Spikevax XBB.1.5, Pfizer-BioNTech Comirnaty XBB.1.5). Ontario's COVID-19 vaccine guidance provides more detailed information on vaccine recommendations and eligibility by age and vaccine product, as well as additional information on myocarditis/pericarditis following vaccination with a COVID-19 mRNA vaccine.[14]

As of April 21, 2024, there have been 840 reports of myocarditis/pericarditis following receipt of COVID-19 vaccines in Ontario, with 829 following mRNA vaccines. All reports of myocarditis/pericarditis are assessed using the Brighton Collaboration case definition for myocarditis and the Brighton Collaboration case definition for pericarditis. 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, see the Canadian Immunization Guide on COVID-19 vaccines.[9]

THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME (TTS)

Thrombosis with thrombocytopenia syndrome (TTS) is a serious health condition characterized by the presence of acute venous or arterial thrombosis (blood clot) with new onset thrombocytopenia (low levels of platelets), and no known recent exposure to heparin. TTS emerged in 2021 as a new adverse event following immunization with COVID-19 adenoviral vector-based vaccines, including AstraZeneca Vaxzevria/COVISHIELD and Janssen Jcovden COVID-19 vaccines.[15] 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). The province announced a pause on the administration of first doses of the AstraZeneca Vaxzevria COVID-19 vaccine on May 11, 2021, due to an observed increase in reports of TTS/VITT in Ontario.

There have been 21 reports of TTS following the AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine in Ontario (including one probable TTS), with the most recent event having a vaccination date of May 6, 2021. All events were following the first dose of AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccine. Based on the total number of AstraZeneca Vaxzevria/COVISHIELD COVID-19 vaccines administered in Ontario to date, the reporting rate of TTS based on 21 reports is 1.9 per 100,000 doses administered (approximately 1 in 51,800). The reporting rate of VITT (as a subtype of TTS) based on 16 reports is 1.5 per 100,000 doses administered (approximately 1 in 68,000). Of the 21 reports, 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). 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). See Appendix A for the number of TTS/VITT reports by vaccine product.

As part of vaccine safety surveillance at the national level, the Advisory Committee on Causality Assessment (ACCA) has conducted a review of reports of TTS following COVID-19 vaccines.[16] ACCA is a committee of experts who review reports of AEFIs to determine whether an event was likely to have been causally related to a given vaccine. ACCA reviewed 103 potential TTS reports following receipt of any COVID-19 vaccine from across Canada. Among these reports, 37 were found to be "consistent with causal association to immunization" using the World Health Organization's (WHO) causality assessment classification, including 16 from Ontario.[17] All 16 events followed administration of a viral vector vaccine and all occurred between March and May 2021. A national summary of the ACCA assessment results is published online.[18]

Serious AEFIs

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

There were 1,282 AEFI reports classified as serious, representing 5.5% of all AEFI reports and a serious AEFI reporting rate of 3.2 per 100,000 doses administered for all COVID-19 vaccine products combined. Of the 1,282 reports meeting the serious definition, 1,237 reports had a hospital admission related to the adverse event and 45 were reports of deaths. See Table 1 for serious AEFI reporting rate by vaccine product. 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.[19]

AEFI REPORTS REQUIRING HOSPITALIZATION

Of the 1,237 reports of hospitalization, 487 were recovered at the time of reporting, 548 were not yet recovered when the investigation was completed but likely to recover, and 105 reported persistent or significant disability/incapacity related to the adverse event. Due to the relatively short follow-up time for AEFIs reported in CCM, it is uncertain whether these disability/incapacity will eventually resolve, but had not yet resolved at the time of reporting. The remaining reports had unknown outcome at the time of reporting.

AEFI REPORTS WITH FATAL OUTCOME

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

As of April 21, 2024, there are 45 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 3. Number of AEFI reports and reporting rates by public health unit and region: Ontario, December 13, 2020 to April 21, 2024

Public Health Unit Name	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Northwestern Health Unit	201	90.2
Thunder Bay District Health Unit	145	32.4
TOTAL NORTH WEST	346	51.6
Algoma Public Health	172	51.4
North Bay Parry Sound District Health Unit	208	57.4
Porcupine Health Unit	149	69.7
Public Health Sudbury & Districts	456	80.7
Timiskaming Health Unit	108	121.1
TOTAL NORTH EAST	1,093	69.8
Eastern Ontario Health Unit	608	103.5
Hastings Prince Edward Public Health	230	48.0
Kingston, Frontenac and Lennox & Addington Public Health	492	74.5
Leeds, Grenville & Lanark District Health Unit	420	72.9
Ottawa Public Health	2,480	77.6
Renfrew County and District Health Unit	292	102.0
TOTAL EASTERN	4,522	78.2
Durham Region Health Department	3,298	172.3
Haliburton, Kawartha, Pine Ridge District Health Unit	570	102.4
Peel Public Health	1,500	40.5
Peterborough Public Health	305	70.9
Simcoe Muskoka District Health Unit	864	53.2
York Region Public Health	1,868	58.5
TOTAL CENTRAL EAST	8,405	73.6

Public Health Unit Name	Number of AEFI reports received to date	Reporting rate per 100,000 doses administered
Toronto Public Health	2,700	33.5
TOTAL TORONTO	2,700	33.5
Chatham-Kent Public Health	82	29.3
Grey Bruce Health Unit	200	42.1
Huron Perth Public Health	426	101.2
Lambton Public Health	609	174.3
Middlesex-London Health Unit	353	24.8
Southwestern Public Health	480	84.2
Windsor-Essex County Health Unit	398	36.7
TOTAL SOUTH WEST	2,548	55.4
Brant County Health Unit	170	43.6
City of Hamilton Public Health Services	665	43.5
Haldimand-Norfolk Health Unit	67	22.1
Halton Region Public Health	956	55.8
Niagara Region Public Health	567	43.1
Region of Waterloo Public Health and Emergency Services	801	50.2
Wellington-Dufferin-Guelph Public Health	518	59.7
TOTAL CENTRAL WEST	3,744	48.5
TOTAL ONTARIO	23,358	57.8

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

Technical Notes

Data Sources

The data for this report were based on:

- AEFI information from the Public Health Case and Contact Management Solution (CCM) extracted on **April 22, 2024 at approximately 8:30 a.m.**
- Doses administered data from the Ontario Ministry of Health's COVaxON application extracted on **April 22, 2024 at approximately 7:00 a.m**.

Data Caveats

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

- 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.

- Serious AEFIs are defined using the World Health Organization (WHO) standard definition:[20] 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, myocarditis, pericarditis and TTS/VITT are further assessed using the internationally recognized case definition from the Brighton Collaboration. 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.[21] These are: vaccine-associated enhanced disease, multisystem inflammatory syndrome in children and adults, acute respiratory distress syndrome, acute cardiovascular injury, myocarditis/pericarditis, coagulation disorder (including thrombotic events), thrombosis with thrombocytopenia syndrome (TTS) and vaccine-induced immune thrombotic thrombocytopenia (VITT), acute kidney injury, acute liver injury, anosmia and/or ageusia, chilblain-like lesions, single organ cutaneous vasculitis, erythema multiforme, acute pancreatitis, rhabdomyolysis, and subacute thyroiditis.

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

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Appendix A

Table A1. Number of AEFI reports by adverse event and COVID-19 vaccine product: Ontario, December 13, 2020 to April 21, 2024

Adverse event	Pfizer-BioNTech Comirnaty	Pfizer-BioNTech Comirnaty Bivalent BA.4/5	Pfizer-BioNTech Comirnaty XBB.1.5	Moderna Spikevax	Moderna Spikevax Bivalent BA.1	Moderna Spikevax Bivalent BA.4/5	Moderna Spikevax XBB.1.5	AstraZeneca Vaxzevria/ COVISHIELD	Janssen Jcovden (Johnson & Johnson)	Novavax Nuvaxovid	All vaccine products combined
Other severe or unusual events*	4,197	63	22	1,754	45	4	17	462	11	16	6,591
Allergic skin reactions	3,383	45	12	1,474	28	5	9	281	4	11	5,252
Pain/redness/ swelling at the injection site	1,580	35	22	2,105	34	9	25	325	3	3	4,141
Rash	1,369	23	12	873	23	3	9	189	3	2	2,507
Anaesthesia/ paraesthesia	1,210	11	5	396	11	1	8	215	6	8	1,871
Adenopathy/ lymphadenopathy	867	14	4	365	9	2	0	50	0	0	1,311
Arthritis/ arthralgia	710	12	6	252	21	0	5	107	0	0	1,113
Fever in conjunction with another reportable event	478	7	1	384	10	1	5	171	1	3	1,062
Severe vomiting/ diarrhea	560	5	3	303	11	1	1	149	1	3	1,037
AESI - Myocarditis/ pericarditis	523	4	2	295	4	0	1	9	0	2	840
Event managed as anaphylaxis†	368	2	1	122	1	0	1	23	1	1	520

Adverse event	Pfizer-BioNTech Comirnaty	Pfizer-BioNTech Comirnaty Bivalent BA.4/5	Pfizer-BioNTech Comirnaty XBB.1.5	Moderna Spikevax	Moderna Spikevax Bivalent BA.1	Moderna Spikevax Bivalent BA.4/5	Moderna Spikevax XBB.1.5	AstraZeneca Vaxzevria/ COVISHIELD	Janssen Jcovden (Johnson & Johnson)	Novavax Nuvaxovid	All vaccine products combined
AESI – Coagulation disorder (including thrombotic events)	254	10	4	103	10	0	4	76	0	0	461
Bell's Palsy	227	9	3	94	5	0	2	15	0	0	355
Syncope (fainting) with injury	256	5	4	72	3	0	0	8	0	0	348
Cellulitis	47	0	1	212	0	1	2	23	0	0	286
AESI – Acute cardiovascular injury	146	2	0	74	5	0	3	19	0	0	249
Convulsions/seizure	113	2	2	41	1	0	0	13	0	1	173
Nodule	32	0	0	40	2	0	1	21	0	0	96
Thrombocytopenia†	55	0	1	15	3	1	0	20	1	0	96
Paralysis	32	1	0	10	2	0	0	9	0	0	54
AESI – Anosmia, ageusia	31	0	0	11	0	1	0	4	0	0	47
Guillain-Barré syndrome (GBS)†	16	1	0	11	0	0	0	17	0	0	45
AESI - Acute liver injury	24	0	1	12	0	0	0	2	0	0	39
AESI - Acute kidney injury	16	0	2	8	1	0	0	3	0	0	30

Adverse event	Pfizer-BioNTech Comirnaty	Pfizer-BioNTech Comirnaty Bivalent BA.4/5	Pfizer-BioNTech Comirnaty XBB.1.5	Moderna Spikevax	Moderna Spikevax Bivalent BA.1	Moderna Spikevax Bivalent BA.4/5	Moderna Spikevax XBB.1.5	AstraZeneca Vaxzevria/ COVISHIELD	Janssen Jcovden (Johnson & Johnson)	Novavax Nuvaxovid	All vaccine products combined
AESI – TTS/VITT	4	0	0	3	0	0	0	21	0	0	28
Oculorespiratory syndrome (ORS)	18	0	0	8	0	0	0	2	0	0	28
Myelitis/transverse myelitis†	15	0	0	6	1	0	0	3	0	0	25
AESI – Single organ cutaneous vasculitis	12	0	0	6	0	0	0	4	0	0	22
AESI - Subacute thyroiditis	14	1	0	5	0	0	0	1	0	0	21
AESI – Chilblain-like lesions	15	0	0	5	0	0	0	1	0	0	21
AESI - Acute pancreatitis	12	0	0	5	0	0	0	1	0	0	18
AESI - Rhabdomyolysis	7	0	0	6	2	0	0	1	0	0	16
AESI – Erythema multiforme	9	0	0	6	0	0	0	1	0	0	16
AESI - Multisystem inflammatory syndrome in children/adults	10	0	0	5	0	0	0	0	0	0	15
Encephalopathy/ encephalitis†	7	1	0	4	0	0	0	1	0	0	13
Abscess at the injection site (infected)	2	0	0	6	0	0	0	0	0	0	8
Parotitis	6	1	0	1	0	0	0	0	0	0	8

Adverse event	Pfizer-BioNTech Comirnaty	Pfizer-BioNTech Comirnaty Bivalent BA.4/5	Pfizer-BioNTech Comirnaty XBB.1.5	Moderna Spikevax	Moderna Spikevax Bivalent BA.1	Moderna Spikevax Bivalent BA.4/5	Moderna Spikevax XBB.1.5	AstraZeneca Vaxzevria/ COVISHIELD	Janssen Jcovden (Johnson & Johnson)	Novavax Nuvaxovid	All vaccine products combined
AESI - Vaccine-associated enhanced disease	6	0	0	0	1	0	0	0	0	0	7
AESI – Acute respiratory distress syndrome	3	0	0	2	0	0	0	0	0	0	5
Abscess at the injection site (sterile)	2	0	0	2	0	0	0	0	0	0	4
Kawasaki Disease	2	0	0	2	0	0	0	0	0	0	4
Meningitis	3	0	0	0	0	0	0	1	0	0	4
Acute disseminated encephalomyelitis (ADEM)†	1	0	0	0	0	0	0	0	0	0	1
Hypotonic-hyporesponsive episode (HHE)	0	0	0	1	0	0	0	0	0	0	1
Persistent crying/screaming	1	0	0	0	0	0	0	0	0	0	1

Notes:

- The columns above for Pfizer-BioNTech Comirnaty and Moderna Spikevax COVID-19 vaccines include AEFIs associated with all indicated dosages: 3 mcg, 10 mcg and 30 mcg for Pfizer-BioNTech Comirnaty and 25 mcg, 50 mcg and 100 mcg for Moderna Spikevax. Moderna Spikevax BA.1 Bivalent (50 mcg), Moderna Spikevax BA.4/5 Bivalent (50 mcg) and Pfizer-BioNTech Comirnaty Bivalent BA.4/5 (10 mcg and 30 mcg) COVID-19 vaccines are presented separately and were previously recommended vaccine products before the approval of the XBB.1.5-containing COVID-19 mRNA vaccines. Currently, Pfizer-BioNTech Comirnaty XBB.1.5 and Moderna Spikevax XBB.1.5 COVID-19 vaccines are approved and recommended for vaccinating individuals who are not previously vaccinated and as additional doses for those previously vaccinated in approved age groups.
- Novavax Nuvaxovid includes Novavax Nuvaxovid and Novavax Nuvaxovid XBB.1.5 Omicron subvariant COVID-19 vaccines.
- An AEFI report may contain multiple adverse events. Thus the sum of all adverse event-specific counts may not equal to the total number of AEFI reports. Some AEFI reports did not specify vaccine product received; these are included in the counts for all vaccine products combined.

* This category includes reports of death that are temporally associated with immunization and where no other clear cause of death was established; these reports should not be interpreted as causally related with vaccine. These reports are described in the Serious AEFI section.

†Represents a medically important event.

Data Source: CCM

Table A2. Reporting rate per 100,000 doses administered by adverse event and COVID-19 vaccine product: Ontario, December 18, 2020 to April 21, 2024

Adverse event	Pfizer-BioNTech Comirnaty	Pfizer-BioNTech Comirnaty Bivalent BA.4/5	Pfizer-BioNTech Comirnaty XBB.1.5	Moderna Spikevax	Moderna Spikevax Bivalent BA.1	Moderna Spikevax Bivalent BA.4/5	Moderna Spikevax XBB.1.5	AstraZeneca Vaxzevria/ COVISHIELD	Janssen Jcovden (Johnson & Johnson)	Novavax Nuvaxovid	All vaccine products combined
Other severe or unusual events*	17.8	2.7	1.3	18.2	3.6	2.8	2.5	42.5	274.8	95.9	16.3
Allergic skin reactions	14.3	1.9	0.7	15.3	2.2	3.5	1.3	25.8	99.9	66.0	13.0
Pain/redness/ swelling at the injection site	6.7	1.5	1.3	21.8	2.7	6.4	3.7	29.9	74.9	18.0	10.3
Rash	5.8	1.0	0.7	9.1	1.8	2.1	1.3	17.4	74.9	12.0	6.2
Anaesthesia/ paraesthesia	5.1	0.5	0.3	4.1	0.9	0.7	1.2	19.8	149.9	48.0	4.6
Adenopathy/ lymphadenopathy	3.7	0.6	0.2	3.8	0.7	1.4	0.0	4.6	0.0	0.0	3.2
Arthritis/arthralgia	3.0	0.5	0.4	2.6	1.7	0.0	0.7	9.8	0.0	0.0	2.8
Fever in conjunction with another reportable event	2.0	0.3	0.1	4.0	0.8	0.7	0.7	15.7	25.0	18.0	2.6
Severe vomiting/ diarrhea	2.4	0.2	0.2	3.1	0.9	0.7	0.1	13.7	25.0	18.0	2.6
AESI - Myocarditis/ pericarditis	2.2	0.2	0.1	3.1	0.3	0.0	0.1	0.8	0.0	12.0	2.1
Event managed as anaphylaxis†	1.6	0.1	0.1	1.3	0.1	0.0	0.1	2.1	25.0	6.0	1.3

Adverse event	Pfizer-BioNTech Comirnaty	Pfizer-BioNTech Comirnaty Bivalent BA.4/5	Pfizer-BioNTech Comirnaty XBB.1.5	Moderna Spikevax	Moderna Spikevax Bivalent BA.1	Moderna Spikevax Bivalent BA.4/5	Moderna Spikevax XBB.1.5	AstraZeneca Vaxzevria/ COVISHIELD	Janssen Jcovden (Johnson & Johnson)	Novavax Nuvaxovid	All vaccine products combined
AESI – Coagulation disorder (including thrombotic events)	1.1	0.4	0.2	1.1	0.8	0.0	0.6	7.0	0.0	0.0	1.1
Bell's Palsy	1.0	0.4	0.2	1.0	0.4	0.0	0.3	1.4	0.0	0.0	0.9
Syncope (fainting) with injury	1.1	0.2	0.2	0.7	0.2	0.0	0.0	0.7	0.0	0.0	0.9
Cellulitis	0.2	0.0	0.1	2.2	0.0	0.7	0.3	2.1	0.0	0.0	0.7
AESI – Acute cardiovascular injury	0.6	0.1	0.0	0.8	0.4	0.0	0.4	1.7	0.0	0.0	0.6
Convulsions/seizure	0.5	0.1	0.1	0.4	0.1	0.0	0.0	1.2	0.0	6.0	0.4
Nodule	0.1	0.0	0.0	0.4	0.2	0.0	0.1	1.9	0.0	0.0	0.2
Thrombocytopenia †	0.2	0.0	0.1	0.2	0.2	0.7	0.0	1.8	25.0	0.0	0.2
AESI - Acute liver injury	0.1	0.0	0.1	0.1	0.0	0.0	0.0	0.2	0.0	0.0	0.1
AESI - Subacute thyroiditis	0.1	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.1
AESI - TTS/VITT	0.0	0.0	0.0	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	0.1	0.1	0.0	0.0	0.3	0.0	0.0	0.1
AESI – Anosmia, ageusia	0.1	0.0	0.0	0.1	0.0	0.7	0.0	0.4	0.0	0.0	0.1

Adverse event	Pfizer-BioNTech Comirnaty	Pfizer-BioNTech Comirnaty Bivalent BA.4/5	Pfizer-BioNTech Comirnaty XBB.1.5	Moderna Spikevax	Moderna Spikevax Bivalent BA.1	Moderna Spikevax Bivalent BA.4/5	Moderna Spikevax XBB.1.5	AstraZeneca Vaxzevria/ COVISHIELD	Janssen Jcovden (Johnson & Johnson)	Novavax Nuvaxovid	All vaccine products combined
AESI – Chilblain-like lesions	0.1	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.1
AESI – Single organ cutaneous vasculitis	0.1	0.0	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.0	0.1
Guillain-Barré syndrome (GBS)†	0.1	0.0	0.0	0.1	0.0	0.0	0.0	1.6	0.0	0.0	0.1
Myelitis/transverse myelitis†	0.1	0.0	0.0	0.1	0.1	0.0	0.0	0.3	0.0	0.0	0.1
Oculorespiratory syndrome (ORS)	0.1	0.0	0.0	0.1	0.0	0.0	0.0	0.2	0.0	0.0	0.1
Paralysis	0.1	0.0	0.0	0.1	0.2	0.0	0.0	0.8	0.0	0.0	0.1
AESI - Acute pancreatitis	0.1	0.0	0.0	0.1	0.0	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	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AESI - Rhabdomyolysis	0.0	0.0	0.0	0.1	0.2	0.0	0.0	0.1	0.0	0.0	0.0
AESI - Vaccine-associated enhanced disease	0.0	0.0	0.0	0.0	0.1	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	0.0	0.0	0.0

Adverse event	Pfizer-BioNTech Comirnaty	Pfizer-BioNTech Comirnaty Bivalent BA.4/5	Pfizer-BioNTech Comirnaty XBB.1.5	Moderna Spikevax	Moderna Spikevax Bivalent BA.1	Moderna Spikevax Bivalent BA.4/5	Moderna Spikevax XBB.1.5	AstraZeneca Vaxzevria/ COVISHIELD	Janssen Jcovden (Johnson & Johnson)	Novavax Nuvaxovid	All vaccine products combined
AESI – Erythema multiforme	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0
Abscess at the injection site (infected)	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Abscess at the injection site (sterile)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Acute disseminated encephalomyelitis (ADEM)†	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Encephalopathy/ encephalitis†	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
Hypotonic-hyporesponsive episode (HHE)	0.0	0.0	0.0	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	0.0	0.0	0.0
Meningitis	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
Parotitis	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Persistent crying/screaming	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Notes:

- The columns above for Pfizer-BioNTech Comirnaty and Moderna Spikevax COVID-19 vaccines include AEFIs associated with all indicated dosages: 3 mcg, 10 mcg and 30 mcg for Pfizer-BioNTech Comirnaty and 25 mcg, 50 mcg and 100 mcg for Moderna Spikevax. Moderna Spikevax BA.1 Bivalent (50 mcg), Moderna Spikevax BA.4/5 Bivalent (50 mcg) and Pfizer-BioNTech Comirnaty Bivalent BA.4/5 (10 mcg and 30 mcg) COVID-19 vaccines are presented separately and were previously recommended vaccine products before the approval of the XBB1.5-containing COVID-19 mRNA vaccines. Currently, Pfizer-BioNTech Comirnaty XBB.1.5 and Moderna Spikevax XBB.1.5 COVID-19 vaccines are approved and recommended for vaccinating individuals who are not previously vaccinated and as additional doses for those previously vaccinated in approved age groups.

- Novavax Nuvaxovid includes Novavax Nuvaxovid and Novavax Nuvaxovid XBB.1.5 Omicron subvariant COVID-19 vaccines.
- 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), Novavax Nuvaxovid and Moderna Spikevax Bivalent BA.4/5 COVID-19 vaccines 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.

†Represents a medically important event.

Data Source: CCM, COVaxON (see technical notes for details on data sources

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