Government of Canada / Gouvernement du Canada

Reported side effects following COVID-19 vaccination in Canada

This page will be updated next on October 3, 2022 at noon EST.

This page was last updated on September 2, 2022 with data up to and including August 19, 2022.

On this page

No new safety signals have been identified in Canada

88,237,534
Total doses administered

50,545
Total adverse event following immunization reports

(0.057% of all doses administered)

40,351
Total adverse event following immunization reports that were non-serious

(0.046% of all doses administered)

10,194
Total adverse event following immunization reports that were serious

(0.012% of all doses administered)

279
New adverse event following immunization reports received and processed between July 23 and August 19, 2022.

(163 new non-serious and 116 new serious)

- No new safety signals have been identified during this reporting period.
- Evidence indicates that the benefits of COVID-19 vaccines continue to

issues right away and will inform Canadians about any risks that arise in Canada.

- Of the **50,545** individual reports (**0.057% of all doses administered**), **10,194** were considered serious (**0.012% of all doses administered**).

How to report an adverse event

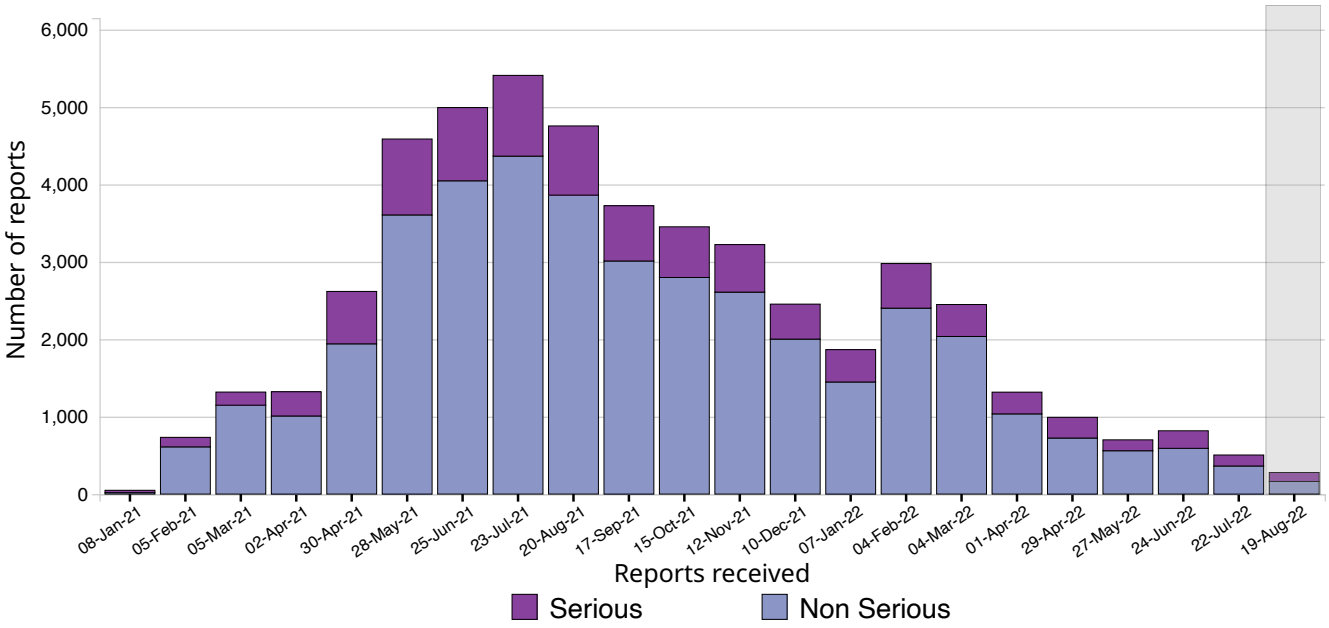
If you experience an adverse event following immunization with a COVID-19 vaccine in Canada, please contact your healthcare provider. Learn more about reporting adverse events.

Summary of adverse event following immunization reports

The information on this page reflects detailed case information data from the Public Health Agency of Canada's Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) and Health Canada's Canada Vigilance program. Doses administered used for reporting rate calculations have been adjusted to account for the delay between vaccination and reporting. The data on this page may undergo changes as more information about cases becomes available.

There have been a total of **50,545** reports (**58.0 reports per 100,000 doses administered**) up to and including **August 19, 2022**. Of the **50,545** reports, **10,194** were considered serious (**11.7 reports per 100,000 doses administered**). Overall, the rate of serious reports has remained low.

Figure 1. Number of COVID-19 vaccine adverse event reports received for all people and total doses administered in a 4-week reporting period, up to and including August 19, 2022 (n=50,545)



Data notes: The shaded area represents a period of time (lag time) where there may be delays in receiving and processing reporting forms. There may also be delays in receiving data on doses administered.

Please note that as of June 27, 2022, this figure reflects counts and rates over a 4 week period. This is due to changes in reporting schedules.

Information on doses administered by age group was only available starting April 23, 2021 for those aged 12 and older, and starting November 27, 2021 for those under the age of 12. Rates of adverse event reports and doses administered by age group are not reported before these dates.

Reports of 11-year-olds who received the Pfizer-BioNTech Comirnaty COVID-19 vaccine dose for individuals 12 years of age and older before the pediatric dose was authorized are included in the 5 to 11 age group. The 5 to 11 year age group also includes reports of individuals born in 2017 who had not yet turned 5 years old at the time of vaccination.

▶ Figure 1: Text Description

Figure 2 shows the breakdown of reports by vaccine name. For doses administered by vaccine type, please visit the vaccination coverage report.

Health Canada authorized booster doses of the Pfizer-BioNTech Comirnaty COVID-19 vaccine on November 9, 2021, the Moderna Spikevax COVID-19 vaccine on November 12, 2021 and Janssen JCOVDEN COVID-19 (formerly known as Janssen COVID-19 vaccine) vaccine on May 11, 2022. Booster doses are administered into the muscle (intramuscularly) to adults at least 6 months after they complete their primary series with an mRNA vaccine, or at least 2 months after primary vaccination with the Janssen JCOVDEN COVID-19 vaccine.

On November 19, 2021, Health Canada authorized the pediatric formulation of the Pfizer-BioNTech Comirnaty COVID-19 vaccine for children 5 to 11 years of age (10 mcg). On March 17, 2022, the pediatric formulation of the Moderna Spikevax COVID-19 vaccine was authorized for children 6 to 11 years of age (50 mcg). On July 14, 2022, the authorization of the Moderna Spikevax COVID-19 vaccine was further extended to children 6 months to 5 years of age (25 mcg).

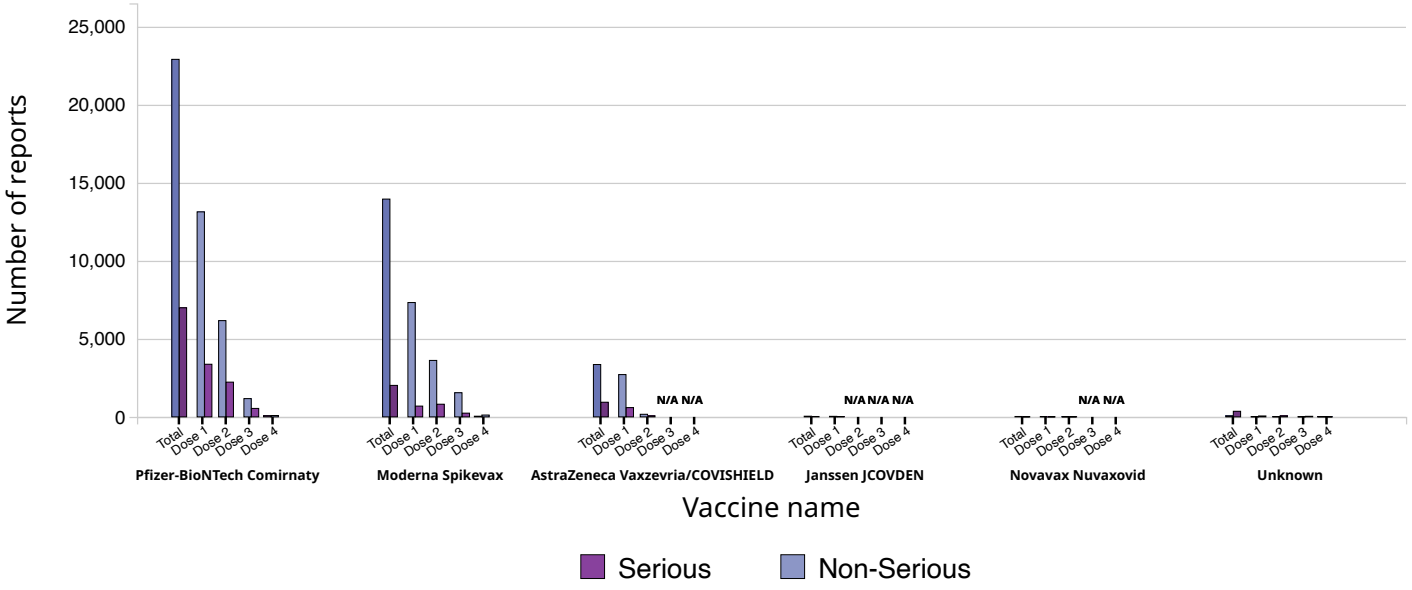
Health Canada authorized the AstraZeneca Vaxzevria COVID-19 vaccine on November 19, 2021, the Janssen JCOVDEN COVID-19 vaccine on November 23, 2021, and Novavax Nuvaxovid COVID-19 vaccine on February 17, 2022. While the Medicago Covifenz COVID-19 vaccine was approved for use in Canada on February 24, 2022, it has not yet been distributed.

For all COVID-19 vaccines being used in Canada, the rate of serious adverse event reports remains lower than that of non-serious adverse event

and fourth doses do not take into account which vaccine an individual received for previous doses. Generally, non-serious adverse event reports are consistent with information provided in the vaccine product pages.

Note: 79 of the 50,545 COVID-19 adverse event reports (0.16%), involved people who received an influenza vaccine and a COVID-19 vaccine on the same day.

Figure 2. Number of adverse event reports received for all people by vaccine name and dose number up to and including August 19, 2022 (n=50,696)

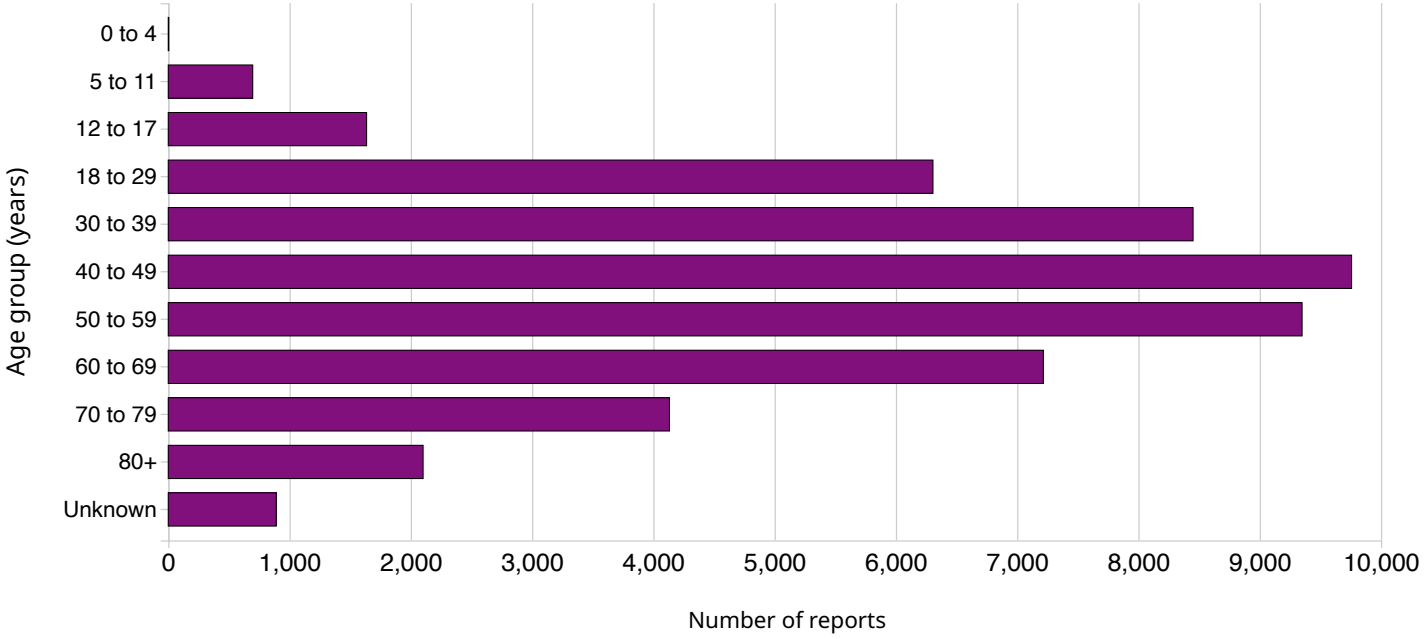


Data notes: Reports of 11-year-olds who received the Pfizer-BioNTech Comirnaty COVID-19 vaccine dose for individuals 12 years of age and older before the pediatric dose was authorized are included in the 5 to 11 age group. The 5 to 11 year age group also includes reports of individuals born in 2017 who had not yet turned 5 years old at the time of vaccination.

Total includes reports that did not specify dose number.

▶ Figure 2: Text Description

- The rate of adverse event reports was highest among the **40 to 49 year age group** (84.5 reports per 100,000 doses administered), followed by those in the 50 to 59 year age group (71.7 reports per 100,000 doses administered).
- The rate of adverse event reports was lowest in the **5 to 11 year age group.**
- There are 24 adverse event reports in 11 year olds who likely received the Pfizer-BioNtech Comirnaty COVID-19 vaccine dose for individuals 12 years of age and older. These reports are included in the 5 to 11 year age group.
- Overall, most adverse event reports were from females (72.7%). The reporting rate for **females** was **78.1 reports per 100,000 doses administered**, compared to **31.3 per 100,000 doses administered** for **males**. However, within the 12 to 17 age group, the proportion and reporting rate in males was slightly higher.
    - It is unclear if this is due in part to health care seeking behaviour (for example, reporting adverse events) or biological differences between females and males.
- The higher proportion and rate of adverse event reports for females has been observed in the United States, the United Kingdom, and other countries.
    - Health Canada, PHAC, and provincial and territorial public health authorities will continue to monitor but have not identified this as a safety issue.



Data notes: Reports of 11-year-olds who received the Pfizer-BioNtech Comirnaty COVID-19 vaccine dose for individuals 12 years of age and older before the pediatric dose was authorized were previously included in the 12 to 17 year age group. As of December 17, 2021, they are included in the 5 to 11 age group, regardless of dosage amount. Reports of 4-year-olds who received the Pfizer-BioNtech Cominarty COVID-19 vaccine dose for individuals 5 to 11 years of age are included in the 0 to 4 age group.

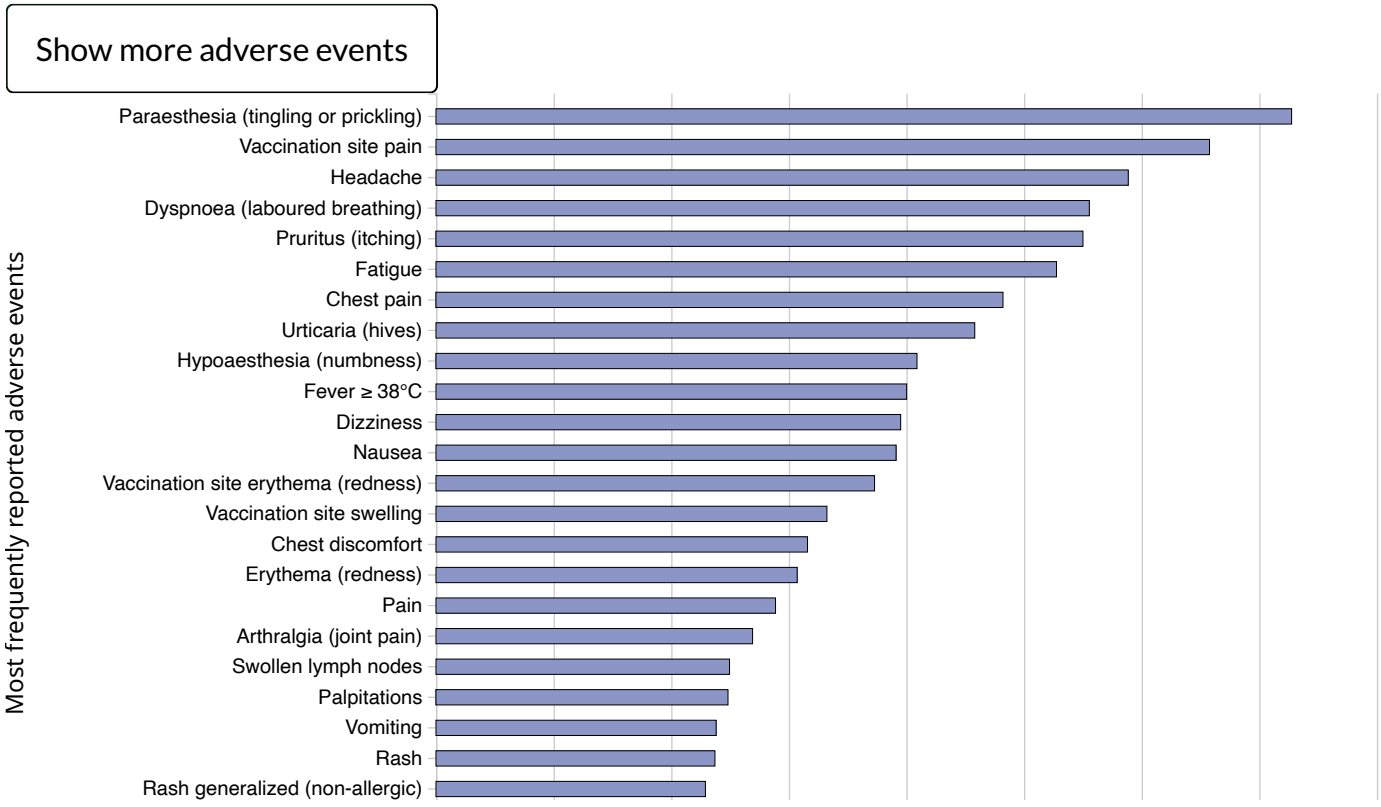
▶ Figure 3: Text Description

Serious and non-serious adverse events reported

- All reports of adverse events following immunization received by Health Canada and PHAC are included in this report, regardless of whether they have been linked to the vaccines. This is because we need to look at all the data available to us so we can detect any early signals of an issue.

- If a new safety issue is found to be related to immunization, Health Canada will take appropriate action. This could include updating the product information, communicating new risks to healthcare providers and the general population or changing the recommended use of the product.
- The **50,545** individual reports represent **50,545** people who reported 1 or more adverse events. Among the **50,545** reports, the most frequently reported adverse events are presented in Figure 4. Most of these adverse events are non-serious.

Figure 4. Number of the most frequently reported adverse events by vaccine type (Total) up to and including August 19, 2022 (n=127,676)



▶ Figure 4: Text Description

Adverse events of special interest

Adverse events of special interest (AESI) are pre-specified medically significant events that have the potential to be causally associated with a vaccine product. They must be carefully monitored and confirmed by further special studies. AESI (Adverse events of special interest) can be serious or non-serious and can include:

- events of interest due to their association with COVID-19 infection.
- events of interest for vaccines in general (e.g. to the specific vaccine type or adjuvants).

The list of AESI (Adverse events of special interest)s below takes into consideration the lists of AESI (Adverse events of special interest)s from these expert groups, manufacturers and regulatory authorities:

- Brighton Collaboration
- Vaccine COVID-19 Monitoring Readiness protocol

The AESI (Adverse events of special interest) list changes based on the evolving safety profile of vaccines. Although adverse events may occur after being vaccinated with a COVID-19 vaccine, they are not necessarily related to the vaccine. Health Canada and PHAC review the reports to determine whether the vaccine may have played a role.

Up to and including August 19, 2022, the most commonly reported AESI (Adverse events of special interest)s were myocarditis/pericarditis and

To align with standard reporting practices, for AESIs with a BCD, only those meeting the BCD level of certainty 1 to 3 are reported. BCD level 4 AESIs (indicating not enough information to confirm the diagnosis) are not included in the case counts and rate calculations for the table below.

Table 1. Count of reported adverse events of special interest by vaccine type (Total) up to and including August 19, 2022 (n=5,393).

AESI (Adverse events of special interest) Category	AESI (Adverse events of special interest)	Total number of events
Auto-immune diseases	Guillain-Barré Syndrome[1]	22
	Thrombocytopenia (low blood platelets)[1]	186
	Subtotal	208
Cardiovascular system	Cardiac arrest	50
	Cardiac failure	57
	Myocardial infarction (heart attack)	133
	Myocarditis/Pericarditis[1] (inflammation of the heart muscle and lining around the heart)	1,114
	Subtotal	1,354

AESI (Adverse events of special interest) Category	AESI (Adverse events of special interest)	Total number of events
	Deep vein thrombosis	347
	Embolism	19
	Haemorrhage (bleeding)	74
	Pulmonary embolism	526
	Thrombosis (blood clot)	321
	Thrombosis with thrombocytopenia syndrome (blood clot with low platelets)[1]	105
	Subtotal	1,479
Hepato-gastrointestinal and renal system	Acute kidney injury	74
	Glomerulonephritis (kidney inflammation) and nephrotic syndrome (kidney disorder)	23
	Liver injury	38
	Subtotal	135
Nerves and central nervous system	Bell's Palsy[1]/facial paralysis	171
	Cerebrovascular accident (stroke)	252

AESI (Adverse events of special interest) Category	AESI (Adverse events of special interest)	Total number of events
Other system	Anaphylaxis[1]	870
	COVID-19[2]	705
	Multisystem inflammatory syndrome[1]	19
	Subtotal	1,594
Pregnancy outcomes[3]	Fetal growth restriction	5
	Spontaneous abortion	86
	Subtotal	91
Respiratory system	Acute respiratory distress syndrome	10
	Subtotal	10
Skin and mucous membrane, bone and joints system	Chilblains	29
	Erythema multiforme (immune skin reaction)	54
	Subtotal	83
All AESI categories	**Total**	**5,393**

[1] Includes adverse events meeting levels 1-3 of the Brighton Collaboration level of diagnostic certainty.

is 100% effective, and some COVID-19 cases will still occur. For vaccines that have a two-dose regimen, protection begins 14 days after the first dose, and 7 to 14 days after the second dose.

[3] WHO guidance on pregnancy related AESIs.

Please note that 1 report represents 1 person and may contain information on more than 1 adverse event of special interest.

Detailed information on safety signals, other safety updates and deaths

These reports do not imply a causal relationship between the vaccine and the adverse event. Some unrelated medical events do occur by chance after immunization, especially when millions of people are being vaccinated.

- ▶ Thrombosis with thrombocytopenia syndrome
- ▶ Guillain-Barré Syndrome
- ▶ Myocarditis/pericarditis
- ▶ Deaths

Acknowledgements

This monthly report would not be possible without the collaboration of federal, provincial and territorial public health partners as well as everyone

Suggested citation

Public Health Agency of Canada. Canadian COVID-19 vaccination safety report. Ottawa: Public Health Agency of Canada; September 2, 2022. https://health-infobase.canada.ca/covid-19/vaccine-safety/

Related links

- Canadian Adverse Events Following Immunization and Surveillance System (CAEFISS)
- Immunization Monitoring Program ACTive (IMPACT)
- Canadian National Vaccine Safety Network (CANVAS)
- Canada Vigilance Program
- Drug Product Database
- Approved COVID-19 Vaccine list
- COVID-19 vaccines and treatments portal
- COVID-19 vaccination in Canada

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