Government of Canada / Gouvernement du Canada

Reported side effects following COVID-19 vaccination in Canada

Summary | Weekly Report

We update this page every Friday at 12:00 PM Eastern Time. A summary and background information are available.

This report was last updated on May 21, 2021 with data up to and including May 14, 2021.

On this page

What you need to know up to and including May 14, 2021

No new safety signals (potential safety issues) have been identified

(one continues to be monitored)

17,734,322

Total doses administered

5,488

Total adverse event following immunization reports

(0.031% of all doses administered)

4,511

Total adverse event following immunization reports that were non-serious

(0.025% of all doses administered)

977

Total adverse event following immunization reports that were serious

(0.006% of all doses administered)

222

New adverse event following immunization reports since last update

(128 new non-serious and 94 new serious)

- The benefits of vaccines authorized in Canada continue to outweigh the risks

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

- Of the **5,488** individual reports (**0.031% of all doses administered**), **977** were considered serious (**0.006% of all doses administered**).

Definitions

▶ Adverse Event Following Immunization (adverse event)

▶ Adverse event report

▶ Serious adverse event

▶ Medically important event

▶ Adverse Events of Special Interest (AESI)

▶ Safety signal

How to report an adverse event

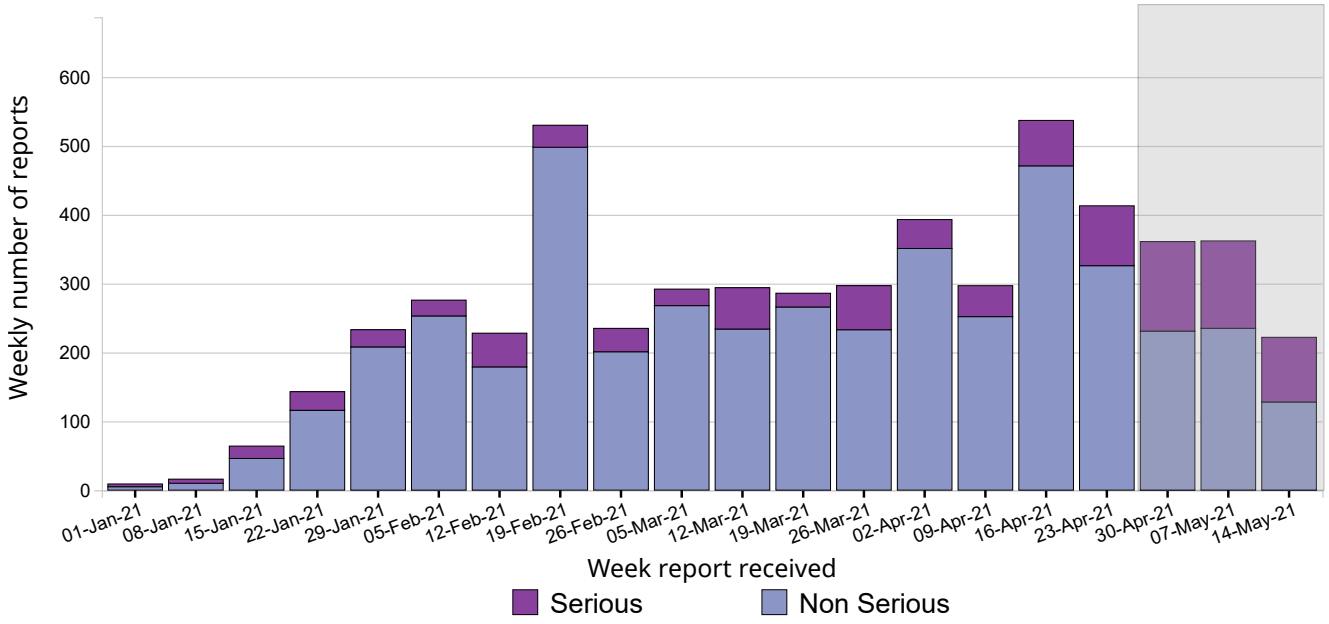
If you experience an adverse event following immunization with a COVID-19 vaccine in Canada, please contact your healthcare provider. Learn more about reporting adverse events.

Summary of adverse event following immunization reports

The information on this page reflects detailed case information data from

There have been a total of **5,488** reports (**31.0 reports per 100,000 doses administered**) up to and including **May 14, 2021**. Of the **5,488** reports, **977** were considered serious (**5.5 reports per 100,000 doses administered**). While the number of doses administered have increased over time, the rate of serious reports has remained low. The cumulative and weekly number of reports, as well as the weekly report rate, are shown in Figure 1.

Figure 1. Weekly number of COVID-19 vaccine adverse event reports and total doses administered per week up to and including May 14, 2021 (n=5,488)



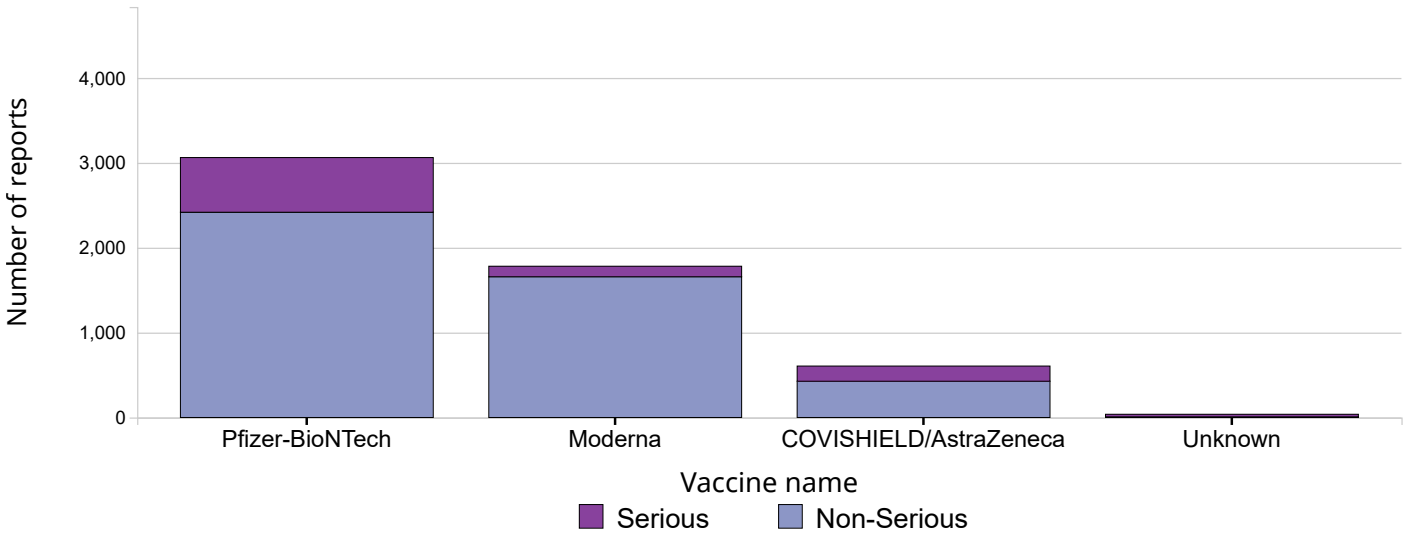
Data note: The shaded area represents a period of time (lag time) where there may be delays in receiving and processing reporting forms.

▶ 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. COVID-19 vaccines approved for use in Canada currently include: Pfizer-BioNTech, Moderna, AstraZeneca, COVISHIELD (a version of the AstraZeneca vaccine manufactured by the Serum Institute of India and sponsored in Canada by Verity Pharmaceuticals Inc.) and Janssen (Johnson and Johnson). While the Janssen vaccine has been approved for use in Canada, it has not yet been distributed during this reporting period.

Higher rates of non-serious adverse event reports are observed for each vaccine, with serious report rates continuing to remain low. Generally, reported non-serious adverse events are consistent with information provided in the vaccine product pages.

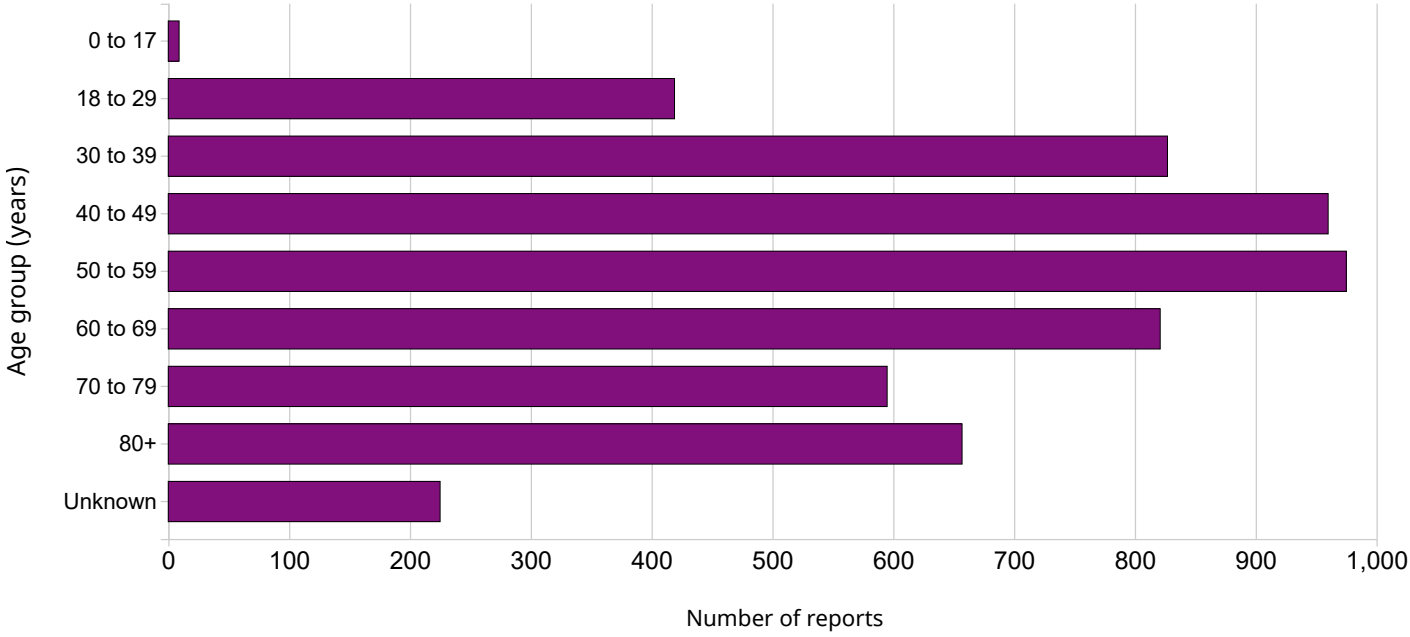
Figure 2. Number of adverse event reports by vaccine name up to and including May 14, 2021 (n=5,488)



Adverse event following immunization reports by age and sex

- The rate (number of adverse events per 100,000 doses) of reported adverse events was highest among the **30-39 year age group**.
- As well, although there are similar number of doses administered to males and females, the majority of adverse event reports were among **females** (82.9%) where sex was known (Figure 3), up to and including May 14, 2021.
- The rate of reports for **females** was **43.3 per 100,000 doses administered**, which was higher than the rate of reports for **males** at **10.9 per 100,000 doses administered**.
    - It is unclear if this is due in part to health care seeking behaviour (e.g. reporting adverse events) or biological differences between females and males.
- The higher proportion and rate of females and younger age groups reporting adverse events has been observed in the United States, the United Kingdom, and other countries.
    - Health Canada, the Public Health Agency of Canada, provincial and territorial public health authorities will continue to monitor but have not identified this as a safety issue.

Figure 3. Number of adverse event reports by age group up to and including May 14, 2021 (n=5,488)



▶ Figure 3: Text Description

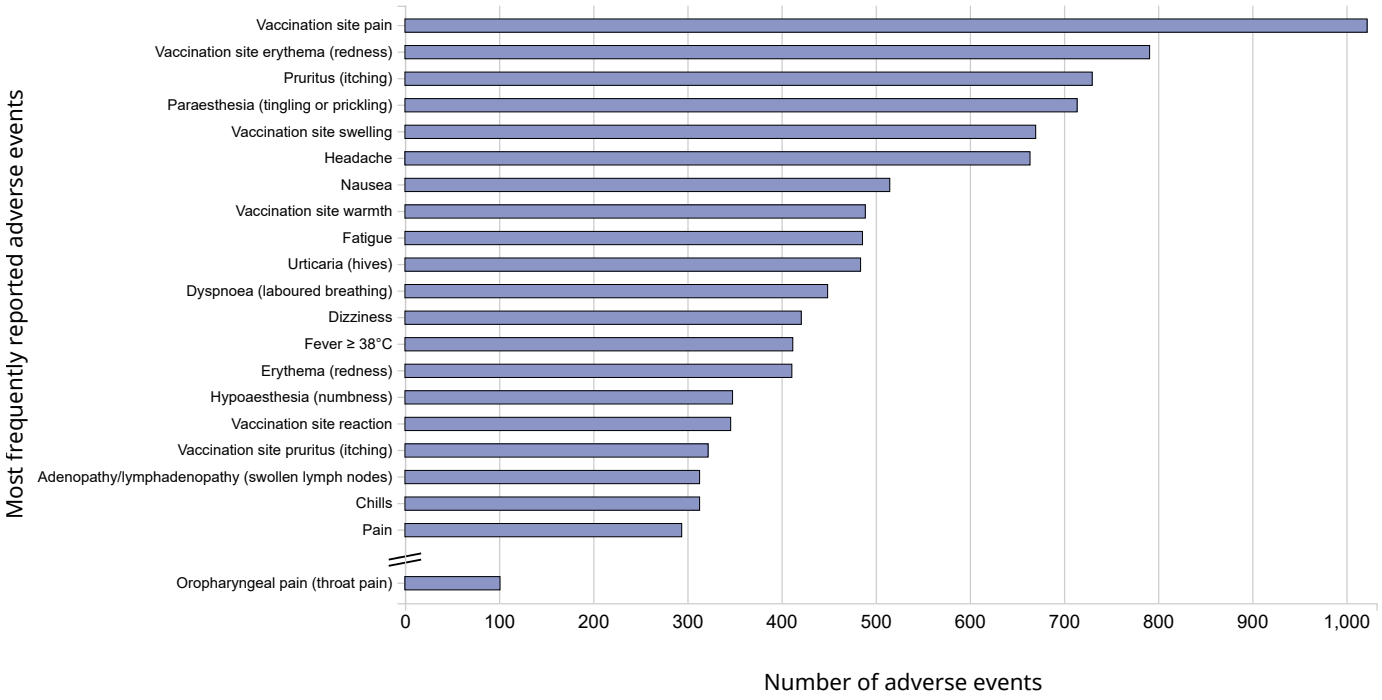
Serious and non-serious adverse events reported

- 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.
- Health Canada, PHAC, the provinces and territories, and manufacturers continue to closely monitor the safety of COVID-19 vaccines. Serious events will be reviewed to determine if there is a new safety signal.
- If a new safety issue is found to be related to immunization, Health

- The **5,488** individual reports represent **5,488** people who reported one or more adverse events. Among the **5,488** reports, the most frequently reported adverse events are presented in Figure 4.
- The majority of these adverse events are non-serious.

Figure 4. Most frequently reported adverse events (serious and non-serious combined) up to and including May 14, 2021 (n=15,145)

Show more adverse events



Please note that one report represents one person and may contain information on more than one adverse event.

▶ Figure 4: Text Description

- Thrombosis with thrombocytopenia syndrome (TTS) is characterized as

vaccine-induced due to the laboratory-confirmed presence of platelet factor (PF) 4 antibodies.

- Up to and including May 14, 2021, there were **22 reports of TTS** in Canada. Of the TTS (Thrombosis with thrombocytopenia syndrome) cases:
  - 22 cases received COVISHEILD/AstraZeneca vaccines
  - Symptom onset ranged from 3 to 24 days after vaccination
  - 12 were males (age range 34 to 73 years old), 9 were females (age range 40 to 72 years old), and the sex of one was not specified
  - 13 had laboratory results showing the presence of platelet factor (PF) 4 antibodies, indicating VITT (also known as VIPIT)
  - Three people died
- Up to and including May 14, 2021, a total of **72 deaths were reported** after the administration of a vaccine. Following medical case review using the WHO-UMC causality assessment categories, it has been determined that:
  - 39 are still under investigation
  - 25 of these deaths are unlikely linked to a COVID-19 vaccine
  - 5 deaths could not be assessed due to insufficient information.
  - 3 deaths were likely linked to the vaccine (refer to the Thrombosis with Thrombocytopenia Syndrome bullet above)

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

- 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. It is important to recall that although these adverse events may occur after being immunized with a COVID-19 vaccine in Canada, they are rare and may not necessarily be related to the vaccine. Health Canada and PHAC review the reports to determine whether the vaccine may have played a role in the occurrence of these events.

Up to and including May 14, 2021, the most commonly reported AESI (Adverse events of special interest)s were Bell's palsy and pulmonary embolism (Table 1).

Table 1. Reported adverse events of special interest by vaccine type (Total) up to and including May 14, 2021 (n=587).

AESI (Adverse events of special interest) Category	AESI (Adverse events of special interest)	Total

AESI (Adverse events of special interest) Category	AESI (Adverse events of special interest)	Total
	Subtotal	**35**
Cardiovascular system	Cardiac arrest	9
	Cardiac failure	1
	Microangiopathy	0
	Myocardial infarction (heart attack)	15
	Myocarditis (heart inflammation)	15
	Stress cardiomyopathy	0
	Subtotal	**40**
Circulatory system	Cerebral venous (sinus) thrombosis	4
	Cerebral thrombosis	3
	Cutaneous vasculitis	1
	Deep vein thrombosis	36
	Embolism	2
	Haemorrhage (bleeding)	6
	Pulmonary embolism	75
	Thrombosis (blood clot)	39

AESI (Adverse events of special interest) Category	AESI (Adverse events of special interest)	Total
Hepato-gastrointestinal and renal system	Acute kidney injury	8
	Liver injury	1
	Subtotal	**9**
Nerves and central nervous system	Bell's Palsy/Facial Paralysis	131
	Cerebrovascular accident (stroke)	46
	Generalized convulsion (seizure)	0
	Transverse myelitis (inflammation of spinal cord)	6
	Subtotal	**183**
Other system	Anaphylaxis	62
	COVID-19*	56
	Subtotal	**118**
Pregnancy outcomes	Fetal growth restriction	3
	Spontaneous abortion	3
	Subtotal	**6**
Respiratory system	Acute respiratory distress syndrome	1
	Subtotal	**1**

AESI (Adverse events of special interest) Category	AESI (Adverse events of special interest)	Total
	Subtotal	**7**
All AESI categories	**Total**	**587**

* COVID-19 vaccines that are currently authorized **cannot cause an infection** because they do **not** contain the **live virus**. While they are all highly effective at preventing severe COVID-19 illness and death, no vaccine 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.

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

Data notes

The data presented in this report are estimates and may not accurately represent national COVID-19 vaccine adverse events for the following reasons:

1. There may be delays in receiving reporting forms and processing reporting forms which may contribute to variations in the amount of reports presented weekly. These delays may be due to jurisdictions investigating and reviewing each adverse event prior to submitting the

2. Information is collected on individuals for whom an report was submitted, not on the total number of individuals who experience an adverse event as not every adverse event is reported.
3. New information contained in this report may not be comprehensive but rather represents preliminary results of data received on a weekly basis.
4. Reporting jurisdictions may refer to gender as opposed to sex.
5. Information on COVID-19 vaccine doses administered are obtained from provincial and territorial partners or their websites. More details on the number of COVID-19 vaccine doses administered are available.
6. The data presented in this report represent combined numbers from both CAEFISS and the Canada Vigilance program. Canada Vigilance receives reports directly from vaccine manufacturers, healthcare professionals and consumers. CAEFISS receives reports from regional public health authorities. Although data from these two surveillance systems are carefully merged together, the individual programs are subject to different reporting requirements and definitions. It is also possible that the weekly report contains duplicate reports.
7. The current adverse event reporting results only reflect the population that is currently prioritized for vaccination. For more information on priority vaccination for COVID-19, please see National Advisory Committee on Immunization statement.
8. Adverse events of special interest are assessed according to the Brighton Collaboration criteria (if available). For example, anaphylaxis reports that meet the Brighton Collaboration criteria Level 1-3 are

Acknowledgements

This weekly report would not be possible without the collaboration of federal, provincial and territorial public health partners as well as everyone taking part in the COVID-19 vaccination rollout in Canada.

We would also like to thank each individual who took the time to submit an adverse event report for their contribution to vaccine safety in Canada.

Suggested citation

Public Health Agency of Canada. Canadian COVID-19 vaccination safety report. Ottawa: Public Health Agency of Canada; May 21, 2021. 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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