

# ADVERSE EVENT FOLLOWING IMMUNIZATION REPORTING FOR HEALTH CARE PROVIDERS IN ONTARIO

DO YOUR PART TO MONITOR ADVERSE EVENTS!



- 1 Advise** patients to contact you or your team if they experience an adverse event after vaccination.



- 2 Report** adverse events to your local public health unit, using Public Health Ontario's [Report of Adverse Event Following Immunization Reporting Form](#).



- 3 Contact** your [local public health unit](#) if you have any questions about AEFI reporting.

## QUESTIONS & ANSWERS

### ● What is an AEFI?

An adverse event following immunization (AEFI) is an unwanted or unexpected health effect that happens after someone receives a vaccine, which may or may not be caused by the vaccine.

### ● Who should report an AEFI?

Health care providers (i.e. physicians, nurses and pharmacists) are required by law to report AEFIs. Reports should be made using the [Ontario AEFI Reporting Form](#) and sent to the [local public health unit](#).

Vaccine recipients or their caregivers may also voluntarily report AEFIs to public health.

### ● Why is it important to report an AEFI?

When you report an AEFI you provide vital information that is needed to monitor vaccine safety. This information is also used to report on vaccine safety to Ontarians, which contributes to the success of immunization programs.

### ● What types of adverse events should be reported?

You should report any event which may be related to receipt of a vaccine, as outlined on the next page. Of particular importance are events which require medical consultation, or unusual or unexpected events. Submitting a report does not mean that the vaccine caused the event.

### ● What does NOT need to be reported?

Some common or mild events do not need to be reported. These include:

- fever that is not accompanied by any other symptoms
- injection site reactions that last less than 4 days
- vasovagal syncope (without injury)
- events that are clearly attributed to other causes.

### ● What do I need to know about reporting AEFIs for COVID-19 vaccine?

Similar to reports for other vaccines, reports of AEFIs for COVID-19 vaccine should be made using the [Ontario AEFI Reporting Form](#) and sent to your local public health unit. The AEFI reporting form has been updated to include adverse events of special interest **for COVID-19 vaccine**, in addition to the list of adverse events on the next page which apply to all vaccines.

IF YOU ARE UNSURE  
WHETHER TO REPORT AN  
AEFI, BE **PROACTIVE** AND  
**REPORT THE EVENT.**

## TYPES OF ADVERSE EVENTS TO REPORT

The table below lists the types of adverse events that you should report to your [local public health unit](#). For each event there are estimated timelines between vaccination and onset of symptoms (i.e., temporal criteria). Other events not listed below can also be reported if they are clinically significant. If you are unsure, be proactive and report.

Adverse event type	TEMPORAL CRITERIA for Non-live vaccines	TEMPORAL CRITERIA for Live vaccines
<b>Injection site reactions</b>	<b>Non-live vaccines</b>	<b>Live vaccines</b>
Pain or redness or swelling lasting 4 days or more OR extending beyond the nearest joint	0 to 2 days	0 to 7 days
Infected abscess	0 to 7 days	0 to 7 days
Sterile abscess	0 to 7 days	0 to 7 days
Nodule	0 to 7 days	0 to 7 days
Cellulitis	0 to 7 days	0 to 7 days
<b>Systemic reactions</b>	<b>Non-live vaccines</b>	<b>Live vaccines</b>
Rash	0 to 7 days	0 to 42 days
Adenopathy/lymphadenopathy	0 to 7 days	0 to 42 days
Severe vomiting/diarrhea	0 to 3 days	0 to 42 days
Parotitis	N/A	0 to 30 days
Hypotonic-hyporesponsive episode (HHE); under 2 years of age only	0 to 2 days	0 to 2 days
Persistent crying/screaming; under 2 years of age only	0 to 3 days	0 to 3 days
<b>Allergic reactions</b>	<b>Non-live vaccines</b>	<b>Live vaccines</b>
Event managed as anaphylaxis (i.e., epinephrine administered)	0 to 24 hours	0 to 24 hours
Oculorespiratory Syndrome (ORS)	0 to 24 hours	0 to 24 hours
Allergic skin reaction (e.g., hives)	0 to 2 days	0 to 2 days
<b>Neurologic events</b>	<b>Non-live vaccines</b>	<b>Live vaccines</b>
Convulsions/seizure	0 to 3 days	0 to 42 days
Encephalopathy/encephalitis	0 to 42 days	0 to 42 days
Meningitis	0 to 15 days	0 to 42 days
Anaesthesia/paraesthesia	0 to 42 days	0 to 42 days
Paralysis	0 to 42 days	0 to 42 days
Myelitis/transverse myelitis	0 to 42 days	0 to 42 days
Acute disseminated encephalomyelitis (ADEM)	0 to 42 days	0 to 42 days
Guillain Barré Syndrome (GBS)	1 to 8 weeks	1 to 8 weeks
Bell's palsy	0 to 3 months	0 to 3 months
<b>Other events of interest*</b>	<b>Non-live vaccines</b>	<b>Live vaccines</b>
Arthritis/arthralgia	0 to 30 days	0 to 42 days
Intussusception	N/A	0 to 42 days
Thrombocytopenia	0 to 42 days	0 to 42 days
Syncope (fainting) with injury	0 to 30 minutes	0 to 30 minutes
Kawasaki disease	0 to 42 days	0 to 42 days
Other severe/unusual events	Reportable regardless of timeline	Reportable regardless of timeline

\*Other adverse events of special interest for COVID-19 vaccine have been added to the [Ontario AEFI Reporting Form](#), please refer to the form for a complete list of types of adverse events to report.

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For questions about AEFI reporting, contact your [local public health unit](#).  
[PublicHealthOntario.ca/VaccineSafety](https://PublicHealthOntario.ca/VaccineSafety)