ADVERSE EVENT FOLLOWING IMMUNIZATION REPORTING

FOR HEALTH CARE PROVIDERS IN ONTARIO

Public Health Ontario | Santé publique 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 (e.g., 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.

What happens when an AEFI is reported?

When you report an AEFI you provide vital information that is needed to monitor vaccine safety. This information helps evaluate immunization programs and is also used to report on vaccine safety to Ontarians. Submitting a report does not mean that the vaccine caused the event.

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.

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
- injection site reactions that do not extend past the nearest joint
- vasovagal syncope (without injury)
- events that are clearly attributed to other causes.

For adverse events following drug products (e.g., nirsevimab) in the absence of an active immunizing agent, please follow the established procedure for reporting adverse drug reactions to Health Canada using the Side Effect Reporting Form.

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

ADVERSE EVENTS TO **REPORT**

The table below lists the 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 and category	TEMPORAL CRITERIA for non-live vaccines	TEMPORAL CRITERIA for live vaccines
Injection site reactions	**Non-live vaccines**	**Live vaccines**
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**
Adenopathy / lymphadenopathy	**0 to 7 days**	**0 to 42 days**
Systemic reactions	**Non-live vaccines**	**Live vaccines**
Fever in conjunction with another reportable event	**0 to 3 days**	**0 to 42 days**
Rash	**0 to 7 days**	**0 to 42 days**
Hypotonic-hyporesponsive episode (HHE) (under 2 years of age only)	**0 to 2 days**	**0 to 2 days**
Persistent crying / screaming (young children only)	**0 to 3 days**	**0 to 3 days**
Severe vomiting / diarrhea	**0 to 3 days**	**0 to 42 days**
Parotitis	**N/A**	**0 to 30 days**
Allergic reactions	**Non-live vaccines**	**Live vaccines**
Event managed as anaphylaxis (i.e., epinephrine administered)	**0 to 24 hours**	**0 to 24 hours**
Oculo-respiratory Syndrome (ORS)	**0 to 24 hours**	**0 to 24 hours**
Allergic skin reaction - skin/mucosal (e.g., hives)	**0 to 2 days**	**0 to 2 days**
Neurologic events	**Non-live vaccines**	**Live vaccines**
Convulsions / seizure	**0 to 3 days**	**0 to 42 days**
Bell's palsy	**0 to 3 months**	**0 to 3 months**
Anaesthesia / paraesthesia	**0 to 42 days**	**0 to 42 days**
Meningitis	**0 to 15 days**	**0 to 42 days**
Paralysis	**0 to 42 days**	**0 to 42 days**
Guillain Barré Syndrome (GBS)	**1 to 8 weeks**	**1 to 8 weeks**
Encephalopathy / encephalitis	**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**
Other events of interest	**Non-live vaccines**	**Live vaccines**
Thrombocytopenia	**0 to 42 days**	**0 to 42 days**
Arthritis / arthralgia	**0 to 30 days**	**0 to 42 days**
Intussusception	**N/A**	**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**
Myocarditis / pericarditis	**0 to 42 days**	**0 to 42 days**
Coagualtion disorders (including thrombotic events)	**0 to 42 days**	**0 to 42 days**
Thrombosis with thrombocytopenia syndrome (TTS)	**0 to 42 days**	**0 to 42 days**
Single organ cutanrous vasculitis	**0 to 42 days**	**0 to 42 days**
Multisystem inflammatory syndrome in children / adults	**0 to 42 days**	**0 to 42 days**
Erythema multiforme	**0 to 42 days**	**0 to 42 days**
Other severe/unusual events	**Reportable regardless of timeline**	**Reportable regardless of timeline**