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Your Health Connection



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Reporting of Adverse Events Following Immunization (AEFI)

Attention: Emergency Departments

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According to the Health Protection and Promotion Act (HPPA), all health care providers, "while providing professional services to a person, recognizes the presence of a reportable event and forms the opinion that it may be related to the administration of an immunizing agent shall, within seven days after recognizing the reportable event, report thereon to the medical officer of health of the health unit where the professional services are provided." R.S.O. 1990, c. H.7, s. 38 (3); 1998, c. 18, Sched. G, s. 55 (4); 2017, c. 25, Sched. 3, s. 8 (2).

An Adverse Event Following Immunization (AEFI) is an unwanted or unexpected reaction following immunization that **may or may not** be a result of the immunization. Health units are required to collect information on possible AEFIs, investigate them and provide recommendations on future immunizations for the client. All data is then reported provincially to identify possible safety signals, which is a critical factor in Canada's vaccine safety surveillance system.

It is important to assess patient's immunization history, in particular when the reason for the Emergency Room visit is temporally associated with having received a vaccine. This is especially important for more severe events or reactions, as this will help in ensuring the continuing safety of immunizations.

Attached you will find a HCP Fact Sheet from Public Health Ontario on AEFI reporting along with a list of adverse events and the timeframes in which they need to be reported. If you are unsure whether to report an AEFI, be proactive and report the event so that it can be further investigated.

When you suspect that a patient is experiencing an AEFI, please complete an AEFI Reporting Form and submit it to Public Health for follow up. The provincial AEFI reporting form can be found on the SMDHU Health Professionals portal at www.smdhu.org/hpportal under Immunization and Forms. Completed forms need to be faxed to the health unit at 705-726-3962.

If you have any questions, please contact the Simcoe Muskoka District Health Unit's Immunization Program at 705-721-7520 or toll free at 1-877-721-7520 ext. 8806.



Public Health Ontario



ADVERSE EVENT FOLLOWING IMMUNIZATION REPORTING

FOR HEALTH CARE PROVIDERS IN ONTARIO

DO YOUR PART TO MONITOR ADVERSE EVENTS!



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



Report adverse events to your local public health unit, using Public Health Ontario's Report of Adverse Event Following Immunization. Reporting Form.



Contact your <u>local public</u> <u>health unit</u> 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.

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 <u>local public health unit</u>. 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
Injection site reactions	Non-live vaccines	Live vaccines
Pain, redness or swelling lasting 4 days or more OR extending beyond the nearest joint	0 to 48 hours	0 to 48 hours
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
Systemic reactions	Non-live vaccines	Live vaccines
Rash	0 to 7 days	5 to 42 days
Adenopathy/lymphadenopathy	0 to 7 days	5 to 42 days
Severe vomiting/diarrhea	0 to 72 hours	0 to 42 days
Parotitis	N/A	5 to 30 days
Hypotonic-hyporesponsive episode (HHE); under 2 years of age only	0 to 48 hours	0 to 48 hours
Persistent crying/screaming; under 2 years of age only	0 to 72 hours	0 to 72 hours
Allergic reactions	Non-live vaccines	Live vaccines
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 48 hours	0 to 48 hours
Neurologic events	Non-live vaccines	Live vaccines
Convulsions/seizure	0 to 72 hours	5 to 42 days
Encephalopathy/encephalitis	0 to 15 days	5 to 42 days
Meningitis	0 to 15 days	5 to 42 days
Anaesthesia/paraesthesia	0 to 15 days	0 to 42 days
Paralysis	0 to 15 days	5 to 42 days
Myelitis/acute disseminated encephalomyelitis	0 to 15 days	5 to 42 days
Guillian Barré Syndrome (GBS)	1 to 8 weeks	1 to 8 weeks
Bell's palsy	0 to 3 months	0 to 3 months
Other events of interest	Non-live vaccines	Live vaccines
Arthritis/arthralgia	0 to 15 days	1 to 3 weeks
Intussusception	N/A	0 to 42 days
Thrombocytopenia	0 to 30 days	0 to 30 days
Syncope (fainting) with injury	0 to 30 minutes	0 to 30 minutes
Other severe/unusual events	Reportable regardless of timeline	Reportable regardless of timeline

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For questions about AEFI reporting, contact your local public health unit.

PublicHealthOntario.ca/VaccineSafety

