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Adverse Events Following Immunization: Information for Health Care Providers

What is an Adverse Event Following Immunization (AEFI)?

An adverse event following immunization (AEFI) is any event or reaction that occurs after receiving a vaccine and which does not necessarily have a causal relationship with the administration of the vaccine.

What are the common symptoms of adverse reactions to immunizations?

Most symptoms are mild such as local injection site reactions of erythema, swelling, pruritus or pain, a fever, drowsiness or nausea. Life-threatening or severe reactions are rare occurring in 1 in 10,000 to 1 million doses administered.

How long do reactions appear after immunization?

Most reactions occur within minutes to a few days of vaccination. Live vaccines, such as MMR and chickenpox may have reactions 1-4 weeks following immunization. Killed or subunit vaccines such as Pediacel[®] (DTaP-IPV-Hib) can have reactions up to 7 days later. Immune-mediated events may occur up to 8 weeks following vaccination.

Who should report an Adverse Event Following Immunization?

In the Ontario Health Protection and Promotion Act, all health care professionals who administer vaccines and/or care for patients who may have had an adverse event following immunization are required by law to report the event to local public health authorities within 7 days of recognizing the event.

How are Adverse Events Following Immunization reported?

Health care providers who observe adverse events or reactions following immunization must report them to Toronto Public Health. Toronto Public Health sends these reports to the Ministry of Health and Long Term Care. The province forwards the information without personal identifiers to the Public Health Agency of Canada (PHAC) where it is stored in the Canadian Adverse Events Following Immunization (CAEFI) database.

How are Adverse Events Following Immunization monitored?

The data in the Canadian Adverse Events Following Immunization (CAEFI) database is monitored by the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). The surveillance system ensures the safety of vaccines on the Canadian market by monitoring adverse events and responding to unusual occurrences. Adverse events are also compared internationally.

What do I do if I think a patient is having a reaction to a vaccine?

If you have a patient who is experiencing an AEFI, call the Toronto Public Health Immunization Nursing Information Line at 416-338-2030 **OR** complete the AEFI form and fax it to 416-338-2028. You can access the form at <http://www.phac-aspc.gc.ca/im/ae-fi-form-eng.php> or call Toronto Public Health to receive one.

The W5 of Adverse Event Following Immunization Reporting in Canada

WHY report:

- To ensure that the vaccines used in Canada are safe
- To maintain public confidence in Canada's immunization programs
- It is a health care professional responsibility
- It is a legal requirement in many Canadian jurisdictions

WHO should report:

- All vaccine providers
- All health care professionals caring for patients who may have had an AEFI
- All vaccine manufacturers to whom an AEFI report is submitted

WHEN to report:

- When an AEFI is
 - severe (death, hospitalization for > 3 days, congenital abnormality, life threatening)
 - unexpected (in terms of type or frequency)
 - of concern (to the patient, his/her caregiver(s) or AEFI reporter)
- When an AEFI occurs within a timeframe that is generally consistent with one or more of the following:
 - immunizing agent: 30 days after live vaccine/7 days after killed or subunit vaccine
 - plausible biologic mechanism: up to 8 weeks for immune-mediated events
 - reporter suspects the AEFI may be linked to immunization

WHAT to report: details regarding

- Patient – unique identifier, date of birth and sex;
- Immunization event(s) – province/territory where given, date, all vaccines given including name, manufacturer, lot number, administration site and route, as well as the number in series of vaccine doses if relevant;
- Adverse event(s) – description, including time of first onset following immunization, duration, health care utilization, treatment and outcome;
- Relevant medical history – underlying disease, known allergies, prior AEFI;
- Associated event(s) – acute illness, current medication, injury, exposure to environmental toxins.

WHERE to find the AEFI report form:

- Call Toronto Public Health's Immunization Nursing Line at 416-338-2030
- Public Health Agency of Canada (PHAC) AEFI form: <http://www.phac-aspc.gc.ca/im/ae-fi-form-eng.php>
- PHAC AEFI Form User Guide: http://www.phac-aspc.gc.ca/im/ae-fi_guide/index-eng.php