Public Health Ontario | Santé publique Ontario

PARTNERS FOR HEALTH | PARTENAIRES POUR LA SANTÉ

Ontario Adverse Event Following Immunization (AEFI) Reporting Form

Provider Questions & Answers

1. What is an AEFI?

The World Health Organization (WHO) defines an AEFI as "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease."(2)

2. Why is reporting an AEFI important?

Provincial reporting of an AEFI is an important component of the overall safety assessment of any vaccine. This type of surveillance, commonly called post-marketing or post-licensure surveillance allows for monitoring of the vaccines throughout implementation in the context of delivering the vaccine to the general population.

Individual case reports of AEFIs represent an important source of data as they have the potential to generate signals of adverse reactions not previously recognized in clinical studies which can be further evaluated.(1) This is particularly important for rare adverse events which may not have been evident in clinical trials due to limited sample size.

3. Am I required to report AEFI?

Physicians, members of the College of Nurses of Ontario or the Ontario College of Pharmacists are required to report AEFI to their local Medical Officer of Health under Section 38 (3) of the *Health Protection and Promotion Act* (HPPA) and its accompanying regulation, O.Reg 569 s.7(1), prescribes the personal health information that is required to be reported.(1,2)

4. What types of AEFI should be reported?

Under the HPPA, Section 38(1) the following events are considered reportable.(1)

> (a) persistent crying or screaming, anaphylaxis or anaphylactic shock occurring within forty-eight hours after the administration of an immunizing agent,
> (b) shock-like collapse, high fever or convulsions occurring within three days after the administration of an immunizing agent,
> (c) arthritis occurring within forty-two days after the administration of an immunizing agent,
> (d) generalized urticaria, residual seizure disorder, encephalopathy, encephalitis or any other significant occurrence occurring within fifteen days after the administration of an immunizing agent, or
> (e) death occurring at any time and following upon a symptom described in clause (a), (b), (c) or (d).

In general, any adverse event following immunization may be reported to your local health unit for further follow-up and investigation if:

- It has a temporal association with immunization (i.e. the event follows immunization); and
- Has no other clear cause at the time of reporting.(4,5)

A causal relationship does not need to be proven, and submitting a report does not imply causality.

Of particular interest are those AEFIs which:

- Are life threatening; result in death or residual disability; require hospitalization or prolongation of an existing hospitalization; or cause congenital malformation; or
- Are unexpected regardless of seriousness (i.e. an event that has either not been identified previously or one that has been identified previously but reporting frequency seems to have increased.(6)

If there is any doubt as to whether or not an event should be reported, a conservative approach should be taken and the event should be reported.

5. What is the Ontario AEFI Reporting Form?

The Ontario AEFI Reporting Form is a newly available tool to assist health professionals to report adverse events following immunization to their local public health unit. It **replaces** the Public Health Agency of Canada (PHAC) Reporting Form previously in use.

6. Why is there a new AEFI reporting form in Ontario?

The Ontario AEFI Reporting Form has been designed to improve support for the AEFI reporting process within the Ontario context.

It has been simplified to increase usability, reduce the time it takes to complete, and better align with the AEFI investigation and surveillance processes at the local public health unit level.

7. Am I required to use the Ontario AEFI Reporting Form when reporting an AEFI?

Health professionals reporting an AEFI are not required to use the Ontario AEFI Reporting Form however, its use is strongly encouraged to ensure that the type of information required for AEFI follow-up and surveillance is captured and to minimize subsequent follow-up from the local public health unit to obtain missing/incomplete information.

8. What happens to the information provided on the ON AEFI Reporting Form?

Once a reported AEFI is received by the local health unit, it is reviewed and investigated. The local Medical Officer of Health (MOH) may make recommendations to the vaccine recipient/caregiver with respect to additional follow-up and receipt of further doses of vaccine. All 36 public health units in Ontario enter AEFI reports into the integrated Public Health Information System (iPHIS), the electronic reporting system for reportable diseases and AEFI in Ontario.

Public Health Ontario (PHO) continuously monitors all AEFI reported via iPHIS, investigates any identified vaccine safety signals and produces periodic surveillance reports to inform immunization program planning and evaluation.

All AEFI reported in Ontario are also transmitted to PHAC for inclusion in the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), a national database containing AEFIs reported from all provinces and territories in Canada.

9. Where can I access the form?

The form is available on the PHO website: http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/Pages/Immunization-Resources.aspx

It is in PDF format which can be completed electronically and printed or printed and completed by hand. If you choose to complete the form in electronic format, it is important to ensure that you do not leave the computer unattended while you are completing the form. Before leaving the computer, it is also important that you fully exit the application, clear your browser's cache, and close down your browser. This will ensure that no one else can access any personal health information you may have entered.

10. What do I need to know about completing the form?

Please complete the form with as much detail as possible.

In addition to client demographic and immunization information, a detailed description of the event including the following information is essential to be able to provide appropriate advice to vaccine recipients regarding further immunization and contribute towards timely and effective vaccine safety monitoring.

- Time between receipt of vaccine and onset of event
- Vaccine(s) administered
- Duration of the event

- All signs and symptoms associated with the event
- Medical history (e.g., immunocompromised, underlying conditions)
- Concomitant medications
- Investigation, treatment, hospitalization details; as well as a
- Description of any previous history of AEFI or if the AEFI resulted from an immunization error.

For a complete list of the information that is mandated to be reported under the HPPA please refer to the O.Reg. 569 s.7(1) available from: http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_900569_e.htm (2)

Once reported, you may be contacted by your local public health unit to request additional information or clarification as part of the investigation and follow-up process.

11. Once completed, where do I send the Ontario AEFI Reporting Form?

Completed AEFI reporting forms should be sent by secure means to the local public health unit in which professional services are provided by the reporting health care professional. Contact information for all 36 public health units in Ontario can be accessed at: www.health.gov.on.ca/en/common/system/services/phu/locations.aspx

12. Who do I contact if I have questions about reporting an AEFI?

Contact your local public health unit for all AEFI inquiries, including questions about the form or determining if an AEFI should be reported. Contact information for all 36 public health units in Ontario can be accessed at: www.health.gov.on.ca/en/common/system/services/phu/locations.aspx

References

(1) Ministry of Health and Long-Term Care (MOHLTC). Health Protection and Promotion Act (HPPA). R.S.O. 1990, c. H.7, s. 38. 2011; Available at: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90h07_e.htm. Accessed 12/12, 2012.

(2) Ministry of Health and Long-Term Care (MOHLTC). Health Protection and Promotion Act (HPPA). R.R.O. 1990, Regulation 569, s.7. 2011; Available at: http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_900569_e.htm. Accessed 12/12, 2012.

(3) World Health Organization (WHO). Definition and Application of Terms for Vaccine Pharmacovigilance. Report of CIOMS/WHO
Working Group on Vaccine Pharmacovigilance. 2011.

(4) Ministry of Health and Long-Term Care (MOHLTC). Infectious Diseases Protocol, 2013. Appendix B: Provincial Case Definitions for Reportable Diseases. Disease: Adverse events Following Immunization (AEFI). 2013; Available at: http://www.health.gov.on.ca/english/providers/program/pubhealth/oph_standards/ophs/infdispro.html. Accessed 01/01, 2012.

(5) Public Health Agency of Canada (PHAC). Report of adverse events following immunization (AEFI). Reporting form. 2011; Available at: http://www.phac-aspc.gc.ca/im/pdf/raefi-dmcisi-eng.pdf. Accessed 06/26, 2012.

(6) Public Health Agency of Canada (PHAC). Reporting adverse events following immunization (AEFI) in Canada. User guide to completion and submission of AEFI reports. 2011; Available at: http://www.phac-aspc.gc.ca/im/pdf/AEFI-ug-gu-eng.pdf. Accessed 2012, 03/07.