Standard for Reporting and Follow-Up of Adverse Events Following Immunization

Section 11: Immunization of Special Populations
Standard #: 11.100

Created by: Province-wide Immunization Program Standards and Quality
Approved by: Province-wide Immunization Program Standards and Quality
Approval Date: February 3, 2014
Revised: June 1, 2017

Preamble

Alberta Health Services (AHS) Province-wide Immunization Program Standards and Quality, Population, Public and Indigenous Health Division provides Public Health and other partners who administer provincially funded vaccines with ongoing and timely information relating to province-wide immunization program standards and quality. These standards are based on currently available evidence based information, Alberta Health (AH) policy, and provincial and national guidelines. Immunizers must be knowledgeable about the specific vaccines they administer.

Background

An essential component of an immunization program is vaccine safety and the activities and processes to detect, assess, understand and communicate adverse events following immunization (AEFI) – vaccine pharmacovigilance. Vaccine preventable infections have decreased and because, in general, vaccines are given to healthy individuals (large portions of which are children), tolerance for adverse events following immunization is low. If reactions occur, they are usually mild, fairly predictable and self-limiting. However, more serious or unexpected reactions can occur but are rare. It is therefore important for health care providers to monitor vaccine side effects and to report immediately all serious or unexpected AEFI. This process is critical for vaccine safety and the prevention of untoward effects of immunization, confirms results of pre-licensure clinical trials, and provides a mechanism for identifying previously unknown concerns for each product. Pharmacovigilance supports the goal of minimizing the risk and maximizing the benefit of vaccines and immunization.

Alberta Health (AH) has developed an Adverse Event Following Immunization (AEFI) Policy for Alberta Immunization Providers (December 2016) http://www.health.alberta.ca/professionals/immunization-policy.html to provide guidance for AEFI reporting for surveillance. This provides a process to monitor vaccine safety, and to detect emerging signals or trends within our province and across the country.

- In Alberta, it is the responsibility of all immunizers who provide provincially funded vaccine and AHS Public Health cost recovery vaccines to be aware of possible adverse events following immunization and to follow zone processes for assessing, reporting and monitoring of AEFI.
- AHS reports AEFI nominally to AH for entry into the AH Immunization and Adverse Reaction to Immunization Reporting (Imm/ARI) system; AH then reports non-identifiable AEFI data to the Public Health Agency of Canada (PHAC).
- As part of the immunization program, screening must be in place to assess for previous AEFI. This is a component of determining fit to immunize.
- As well, there should be systems in place to alert immunization providers to previous AEFIs.

Applicability

This standard applies to:

- AHS immunizers providing either provincially funded or AHS Public Health cost recovery immunizations.
Immunization Competency

In November 2008, the Public Health Agency of Canada published the Immunization Competencies for Health Professionals with a goal of promoting safe and competent practices for immunization providers. The following competency outlined in that document is applicable to this standard:

- Vaccine Development and Evaluation: integrates into practice knowledge about the main steps in vaccine development and evaluation
- Adverse Events Following Immunization: anticipates, identifies, and manages adverse events following immunization, as appropriate to the practice setting

Definitions

Adverse Event Following Immunization (AEFI): “any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of a vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.” Canadian Immunization Guide [http://www.phac-aspc.gc.ca/publicat/cig-gci/p02-01-eng.php](http://www.phac-aspc.gc.ca/publicat/cig-gci/p02-01-eng.php).

Adverse Event Reporting Form: this is the form used to report AEFIs to AH (e.g., AH AEFI Reporting Form or zone Immunization system data base form).

Brighton Collaboration: a global research network that collaborates to facilitate the development, evaluation, and dissemination of high-quality information about the safety of human vaccines. The primary aim of the Brighton Collaboration is to develop globally accepted and implemented standardized case definitions of adverse events following immunizations. [https://www.brightoncollaboration.org/public](https://www.brightoncollaboration.org/public)

Canadian Immunization Monitoring Program Active (IMPACT): “a pediatric, hospital-based network funded by PHAC and administered by the Canadian Paediatric Society. IMPACT conducts a national surveillance network for adverse events following immunization, vaccine failures and selected vaccine preventable diseases in children. The 12 IMPACT hospitals encompass approximately 90% of tertiary care pediatric beds in Canada. Nurse monitors actively search for children admitted to IMPACT hospitals with neurologic and other high priority adverse events. The nurse monitors determine whether these events have followed immunization within a timeframe that could implicate vaccine as a possible cause. All such AEFI are reported to PHAC as well as to local public health officials.” Canadian Immunization Guide [http://www.phac-aspc.gc.ca/publicat/cig-gci/p02-01-eng.php](http://www.phac-aspc.gc.ca/publicat/cig-gci/p02-01-eng.php).

Canadian Adverse Event Following Immunization Surveillance System (CAEFISS): a collaborative post-marketing federal/provincial/territorial (F/P/T) surveillance system that continuously monitors the safety of marketed vaccines in Canada, identifies increases in the frequency or severity of previously identified vaccine-related reactions, identifies previously unknown AEFI that could possibly be related to a vaccine, identifies areas that require further investigation and/or research and provides timely information on AEFI reporting profiles for vaccines marketed in Canada that can help inform immunization related decisions. [http://www.phac-aspc.gc.ca/publicat/cig-gci/p02-01-eng.php#activities](http://www.phac-aspc.gc.ca/publicat/cig-gci/p02-01-eng.php#activities)
1.1 How and When to Report an AEFI

There are numerous ways an AEFI can be reported:

- Client reports AEFI to Public Health (e.g., public health centre, communicable disease control) directly
- Client reports AEFI to Health Link who then contacts Public Health
- External provider (e.g., physician, pharmacist) reports AEFI to Public Health
- Internal partner (e.g., AHS WHS) submits AEFI report to Public Health
- IMPACT reports AEFI to Public Health
- AH sends AEFI to AHS (e.g., for AEFI submitted directly to Public Health Agency of Canada or phone calls received from external providers)

External providers may submit completed Health Canada AEFI forms (for non-provincially funded vaccine) to the zone Public Health or CDC contact who acts as a conduit for submission of this report to AH. These AEFIs are not reviewed nor are recommendations made by the Medical Officer of Health (MOH)/MOH designate.

AEFI reports received by Public Health for provincially-funded vaccines or AHS Public Health cost recovery vaccines are reviewed by designated zone staff (i.e., public health nurses, CD nurses) to ensure information is complete and the event meets reporting criteria as outlined in the Adverse Event Following Immunization Policy for Alberta Immunization Providers, December 2016.

Submission of AEFI reports in a timely manner is required to identify any trends that may be presenting.

1.2 AEFI Report Flow and Associated Reporting Processes

1.2.1 Zone Public Health:

- All AEFI must be submitted to AH as per zone processes within 1 month of notification. In order to meet the 1 month reporting requirements, zone public health must submit initial AEFI information to the zone MOH/MOH designate as soon as possible or within 2 weeks of being reported with the following exceptions:
  - Death must be reported to zone MOH/MOH designate following zone processes as soon as Public Health is notified.
  - Anaphylaxis must be reported to zone MOH/MOH designate following zone processes as soon as notified (by email).
  - Other serious events (e.g., thrombocytopenia, Guillain-Barré, Bell’s Palsy, ORS) must be reported to zone MOH/MOH designate within 1 week.
  - Influenza AEFI must be reported to AH on a weekly basis. In order to achieve this, the following process will take place:
    - Zone Public Health must submit influenza AEFIs (preliminary or final information) as soon as possible but no longer than 1 week following notification to the zone MOH/MOH designate.

- Use one AEFI form to report multiple AEFIs associated with one or more vaccines given to a client on the same immunization date.

- Report all vaccines given on the same immunization date regardless of whether the AEFI appears to be related to one vaccine in particular.

1.2.2 Zone MOH/MOH designate:

- Gather supporting documentation (e.g., emergency/urgent care records, physician visit notes, photos taken by parent, specialist consults) as required to provide as complete a picture of the AEFI as possible. When required, following the Health Information Act (HIA) include supporting documentation for those categories...
requiring diagnosis by a physician (e.g., laboratory reports, summary notes) with the AEFI submitted to AH.

- Assess and provide recommendations for further immunization.
- Communicate recommendations to the client verbally or by letter depending on local zone processes.
- Consult and request recommendations from the CMOH/designate at Alberta Health in those rare circumstances when the event is unusual and not included in the *Adverse Event Following Immunization Policy for Alberta Immunization Providers* document. Indicate CMOH advice is requested in the MOH/MOH designate comments field of the AEFI form if a response or reply is required.
- If an allergist referral is required, follow local zone processes as outlined in Process for Referral to an Allergist Following AEFI.
- Submit the AEFI to AH using the following guidelines.
  o Death must be reported to AH immediately (as soon as Public Health is notified). During business hours, an email can be sent to the Immunization Program, AH. After office hours the zone MOH will contact the Chief Medical Officer of Health (CMOH) on call number (780-638-3630) at AH.
  o Anaphylaxis must be reported to AH within 24 hours (by email). During business hours, an email can be sent to the Immunization Program, AH. After office hours the zone MOH will contact the Chief Medical Officer of Health (CMOH) on call at number (780-638-3630).
  o Other serious events (e.g., thrombocytopenia, Guillain-Barré, Bell’s Palsy, ORS) must be reported to AH within 1 week via submission of an AEFI reporting form.
  o Zone MOH/MOH designate will submit a copy of the influenza AEFI information (preliminary or final) as well as summary data to Province-wide Immunization Program on a weekly basis. The Province-wide Immunization Program will submit summary data weekly to AH Immunization Program. Once the AEFI investigation is complete Zone MOH/MOH designate must submit the final AEFI report to AH as per zone processes.

- If investigation of the AEFI will take greater than 2 weeks, a preliminary report should be submitted with the exception of influenza, anaphylaxis, death or other serious events – see timelines outlined above for these reporting requirements. The final AEFI report can be submitted once the investigation is complete.

Some AEFIs that have occurred in the past are not reported to AH; however, this information may be pertinent to further immunizations. Therefore, documentation should be obtained if possible related to the AEFI and MOH consultation made to determine recommendations for immunization. Zone MOH/MOH designate discretion is required to determine if the AEFI is reportable.

When an AEFI is reported for a client who received care in another zone, or the vaccine was given in another zone, collaboration between Public Health in these zones is necessary to complete the investigation, assess and provide recommendations, and then report to AH. When an AEFI is reported and the client received care in another province, or the vaccine was given in another province, collaboration with AH is necessary to gather further information.

**Section 2: Guidelines for Immunization After An AEFI Has Been Reported or Submitted**

These guidelines should be used in conjunction with the AH AEFI Policy. The Zone MOH/MOH designate responsible for AEFI reporting is available for consultation to respond to questions and/or concerns as needed.
2.1 For the adverse events following immunization listed below NO vaccine(s) should be subsequently given to the client until the recommendation section on the report form has been completed by the MOH/MOH designate:

- Encephalitis, Acute Disseminated Encephalomyelitis (ADEM) or Myelitis
- Convulsion/ Seizure - as it relates to an afebrile convulsion/ seizure
- Meningitis
- Paralysis
- Rash – as it relates to petechial type rashes
- Other Severe or Unusual Events
- Bell’s Palsy

2.2 For the adverse events following immunization listed below subsequent immunization of the client may proceed while awaiting the recommendation by the MOH/MOH designate ONLY if the vaccine is not the same antigen and/or does not contain the same components as the vaccine(s) in question.

- Allergic Reaction
- Anaphylaxis
- Erythema Multiforme
- Guillain-Barré Syndrome
- Subacute Sclerosing Panencephalitis
- Oculo-Respiratory Syndrome (ORS) (if lower respiratory tract symptoms)
- Intussusception
- Thrombocytopenia

2.3 For the adverse events following immunization listed below subsequent immunization of the client may proceed while awaiting the recommendation by the MOH/MOH designate provided the client is fit to immunize at the time of the appointment.

- Adenopathy/Lymphadenopathy
- Anesthesia/ Paresthesia
- Arthritis/Arthralgia (transient)
- Convulsion/ Seizure – as it relates to an uncomplicated febrile convulsion/ seizure. (if the febrile convulsions are multiple or complex [status epilepticus], consider as Section A AEFI)
- Hypotonic Hyporesponsive Episode
- Infected Abscess
- Parotitis
- Rash (ensure not allergic or petechial in nature)
- Orchitis
- Screaming Episode/ Persistent Crying
- Severe Diarrhea and/ or Vomiting
- Swelling and/or Pain
- Sterile Abscess
- Nodule
- Cellulitis

Related Resources

Reporting Form for Adverse Events Following Immunization

References