Alberta Health Services	Standard for Reporting and Follow-Up of Adverse Events Following Immunization		
Section 11:	Immunization of Special Populations		**Standard #: 11.100**
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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 & General Information

The Canadian Immunization Guide provides the following guidelines which informs Alberta's policy on the reporting of AEFI as part of comprehensive vaccine safety surveillance:

- Vaccine pharmacovigilance has been defined as the science and activities related to the detection, assessment, understanding and communication of adverse events following immunization and other vaccine-related or immunization-related issues, and to the prevention of untoward effects of the vaccine or immunization.
- Health care providers have essential and pivotal roles to play in gaining and maintaining public confidence in the safety of vaccines. These include providing evidence-based information on the benefits and risks of vaccines; helping clients and patients to interpret media and Internet vaccine safety messages; and identifying and reporting adverse events following immunization.
- Any single occurrence of an unusual event following immunization may be coincidental or caused by the vaccine. An accumulation of reports, sometimes as few as four or five, may signal a risk due to the vaccine. Thus, each and every report submitted by vaccine providers is important.

Alberta Health (AH) developed the *Adverse Events Following Immunization (AEFI) Policy for Alberta Immunization Providers (October 2019)* 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.

- The *Adverse Events Following Immunization Policy for Alberta Immunization Providers* is provided under the authority of the Public Health Act (Act) and Part 2 of the Immunization Regulation which outlines the requirements for the reporting of adverse events following immunization.
- In Alberta, the management of AEFIs includes analysis of the event and interpretation for subsequent immunization. Individuals who have experienced an AEFI may unnecessarily be advised to avoid subsequent immunization, which may have important adverse personal and population health consequences.
- Data from AEFI reports contribute to provincial immunization program evaluation as well as to the national AEFI surveillance. AHS reports AEFI data nominally to Alberta Health (AH)

for entry into the AH Immunization and Adverse Reaction to Immunization Reporting (Imm/ARI) system. AH submits monthly electronic non-identifiable AEFI data to the Public Health Agency of Canada (PHAC), which is compiled nationally to assist in monitoring emerging safety signals that may not be detected at a provincial or local level.

- In Alberta, it is the responsibility of all immunizers who provide provincially and non-provincially-funded vaccines to be aware of possible adverse events following immunization and to follow provincial processes for assessing, reporting and monitoring of AEFI.
- 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.
- There should be systems in place to alert immunization providers to previous AEFIs.
- Reporting an adverse event with a temporal association to a vaccine does not imply causality. Causality assessment involves the consideration of vaccine attributable risk (whether there is a causal association between a vaccine and an adverse event) and determining whether the vaccine(s) caused the adverse event or whether the event would have occurred anyway.
- Health practitioners are encouraged to consult the following as companion references to this document:
  - Alberta Immunization Policy
  - Canadian Immunization Guide
  - Canadian Communicable Disease Report
  - Public Health Agency of Canada User Guide to Completion and Submission of the AEFI Reports

Applicability

This standard applies to:

Health practitioners who provide immunization and all health practitioners who become aware of an AEFI following immunization.

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):
An adverse event following immunization is defined as an unfavourable health occurrence experienced by a patient that:

(a) follows immunization,
(b) cannot be attributed to a pre-existing condition, and
(c) meets one or more of the following criteria, as determined by a health practitioner:
    (i) the health occurrence is life threatening, could result in permanent disability, requires hospitalization or urgent medical attention, or for any other reason is considered to be of a serious nature;
    (ii) the health occurrence is unusual or unexpected, including, without limitation, an occurrence that
        (A) has not previously been identified, or
        (B) has previously been identified but is being reported at increased frequency;
    (iii) the health occurrence cannot be explained by anything in the patient's medical history, including, without limitation, a recent disease or illness, or consumption of medication

Adverse Event Reporting Form: the on-line electronic form used by non-Public Health practitioners to report AEFIs to the AHS Provincial AEFI team.

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/

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 https://www.cps.ca/en/impact

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. https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html

Section 1: Reporting AEFI to Alberta Health Services Provincial AEFI Team

When to Report an AEFI to Alberta Health Services?

All Health practitioners are to report an adverse event following immunization to the AHS Provincial AEFI team within **3 days** of determining or being informed that a patient has experienced an adverse event following immunization unless it has already been reported.

What to Report to Alberta Health Services?

A) Public Health Practitioners report AEFI based on criteria outlined in part 5 (pages 8-43), Reportable Adverse Events Following Immunization in the *Adverse Events Following Immunization Policy for Alberta Immunization Providers.*

B) Non-Public Health Practitioners report based on the following:
Any adverse event following immunization is defined as an unfavourable health occurrence experienced by a patient that:

(a) follows immunization,

(b) cannot be attributed to a pre-existing condition, and

(c) meets one or more of the following criteria, as determined by a health practitioner:

(i) the health occurrence is life threatening, could result in permanent disability, requires hospitalization or urgent medical attention, or for any other reason is considered to be of a serious nature;

(ii) the health occurrence is unusual or unexpected, including, without limitation, an occurrence that

(A) has not previously been identified, or

(B) has previously been identified but is being reported at increased frequency;

(iii) the health occurrence cannot be explained by anything in the patient's medical history, including, without limitation, a recent disease or illness, or consumption of medication.

If unsure or have questions, contact AHS Provincial AEFI team at AEFI@ahs.ca or 1-855-444-2324.

The following data elements must be reported in respect of the adverse event following immunization:

a) patient first name and last name;

b) patient personal health number or unique lifetime identifier;

c) patient date of birth;

d) patient sex at birth;

e) description of the adverse event, including, without limitation, any applicable symptom or diagnosis listed in the Immunization Regulation Schedule as reported by the patient or observed or diagnosed by the health practitioner, as the case may be, and the onset and duration of the adverse event;

f) vaccine code of the vaccine used in the immunization preceding the adverse event following immunization, if available;

g) lot number of the vaccine used in the immunization preceding the adverse event following immunization, if available;

h) manufacturer of the vaccine used in the immunization preceding the adverse event following immunization, if available;

i) date of the immunization preceding the adverse event following immunization;

j) delivery management site code for the immunization preceding the adverse event following immunization, if available;
k) first name, last name and telephone number of the person reporting.

How do Health Practitioners Report AEFI's?

There are numerous ways an AEFI can be reported:

- Client reports AEFI to any health practitioner (e.g., public health, physician, pharmacist, emergency department) directly
- Client reports AEFI to Health Link who then contacts the client's home Public Health Centre or the Provincial AEFI team, dependent on who administered the vaccine
- External provider (e.g., physician, pharmacist) reports AEFI to the Provincial AEFI team
- Internal partner (e.g., AHS WHS) reports AEFI to the Provincial AEFI team
- IMPACT reports AEFI to the Provincial AEFI team
- AH reports AEFI to AHS Provincial AEFI team (e.g., for AEFI submitted directly to Public Health Agency of Canada or phone calls received from external providers)

Reporting AEFIs - Zone AHS Public Health

Vaccine administered by Public Health:

1. Public Health Nurse (PHN) receives report of suspected AEFI from Client, Parent/Guardian, Provincial AEFI Team, Health Link or other Health Practitioner resulting from vaccine administered by Public Health.
2. PHN collects required information (demographics, location of immunization, vaccines administered, symptoms) from Client, Parent/Guardian, Health Link or other Health Practitioner. Gathers supporting documentation as required to provide as complete a picture of the AEFI as possible.
3. Completes appropriate documentation in AHS electronic immunization database (PCS in Meditech).
4. If the vaccine was administered by AHS Public Health, and the PHN determines that symptoms meet Alberta Health reporting criteria for an AEFI, PHN completes "AdvEventtoImm" Immunization module in AHS electronic immunization database (Meditech).
5. PHN sends an email to AEFI@ahs.ca with client demographic information (Name, DOB, ULI) indicating that an AEFI was completed for the Provincial AEFI team to follow-up. Include any supporting documentation not included in Meditech (e.g., emergency/urgent care records, physician visit notes, photos taken by parent, specialist consults).
    - 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).

Vaccine administered by Non-Public Health Practitioner:

1. If PHN determines that the vaccine was administered by a non-public health practitioner:
    - PHN completes report of suspected AEFI on AHS webpage reporting form or by calling the toll-free phone number at 1-855-444-2324.
2. If a PHN receives report of suspected AEFI from a non-public health practitioner (e.g., physician, pharmacist, long term care, WHS, etc.):
    - PHN should refer the health practitioner to the AHS webpage reporting form or the toll-free phone number at 1-855-444-2324.

Reporting AEFIs - All Non-Public Health Practitioners: (including but not limited to: physicians, pharmacists, acute care, occupational health, non-public health nursing, physiotherapists, etc.)

- Complete and submit the AHS Provincial AEFI report form found at Adverse Event Following Immunization (AEFI) Reporting for All Health Care Practitioners in Alberta or call 1-855-444-2324.

Section 2: AHS Provincial AEFI Team Responsibilities

AEFI reports submitted to the AHS Provincial AEFI team by public health or non-public health practitioners are followed up by a team of public health nurses in consultation with zone Medical Officers of Health to provide immunization recommendations and submission of the AEFI report form to AH.

The Provincial AEFI team:

- Gathers supporting documentation (e.g., emergency/urgent care records, physician visit notes, photos taken by parent, specialist consults) as required for non-public health administered vaccine.
    - When required, following the Health Information Act (HIA) includes supporting documentation for those categories requiring diagnosis by a physician (e.g., laboratory reports, summary notes) when the AEFI is submitted to AH.
- Assesses and provides recommendations for further immunization. Consults zone MOH as appropriate.
- Communicates recommendations to the client verbally or by letter depending on zone processes.
- Consults and requests 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, follows zone processes.
- Submits the AEFI to AH.
- If the investigation of the AEFI will take greater than 2 weeks, a preliminary report should be submitted. The final AEFI report can be submitted once the investigation is complete.

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.

What is reported by AHS Provincial AEFI team to Alberta Health (Chief Medical Officer)

- All AEFIs that meet the criteria for the reportable categories outlined in the Adverse Events Following Immunization Policy temporally related (e.g., related in time) to an immunization, with or without clear evidence of causality within **4 days** of making that determination. The **two exceptions** to this:
    - **Anaphylaxis** (including allergic reactions where epinephrine is administered) following a provincially funded vaccine; and
    - **Death** temporally linked to a provincially funded vaccine

  These are to be reported to AHS immediately/as soon as possible. AHS will report to AH within 24 hours.

- Data elements that must be included: patient first and last name identifiers, patient PHN or ULI, DOB, sex at birth, vaccine code lot number, vaccine manufacturer, immunization date, the adverse event, the recommendation provided, if any, and the delivery management site.
- Additional data elements to be included if available; dosage, route, site, number of previous doses of antigen.
- All antigens given on the same immunization date regardless if the AEFI appears to be related to one antigen in particular.
- Multiple AEFIs associated with one or more vaccines given on the same immunization date using one AEFI report. For example, if a client reports a severe local reaction and a convulsion following the administration of vaccine(s) given on the same immunization date, use the same AEFI report.
- Events that do not meet specific case definitions but are felt to be significant (i.e., serious or unusual) under Other Severe or Unusual Events.

Section 3: Non-Reportable Adverse Events Following Immunization

Fever

- Fever, by itself, is no longer reportable. It is an expected reaction following immunization. Fever is also a common occurrence in children with illnesses unrelated to immunization. Do not report the occurrence of fever unless it accompanies one or more reportable AEFI.

Local inflammation, swelling, and/or pain (moderate severity)

- Do not report less severe local reactions. Mild or moderate local reactions are expected reactions to immunization. See Swelling with/without pain to see if reaction meets reporting requirements.

High pitched unusual crying

- This reaction was almost exclusively related to whole cell pertussis vaccine, which is no longer used; this category is no longer reportable. Unusual crying episodes should be considered under Screaming episode/persistent crying.

Screaming episode/persistent crying (less severe)

- Do not report an episode of consolable but persistent screaming or crying with duration between one and three hours. This is likely related to discomfort from the injection. It is considered an expected reaction in children less than two years of age.

Allergic reaction (mild)

- Do not report using this code. Mild and severe allergic reactions have been combined into one category: Report allergic reactions meeting the criteria Allergic reaction.

Excessive somnolence

- Excessive somnolence or prolonged sleeping with difficulty rousing is not considered to be an adverse reaction.

Irritability

- Responses to pain and the assessment of the level of irritability are highly variable. Irritability is considered to be an expected response of infants to fever, discomfort, or disruptions in schedule. It may also be an indication of an intercurrent condition or illness, unrelated to immunization.

Coma

- Do not report coma using this code. Please use code Other Unusual Events (if appropriate).

Apnoea

- Do not report apnoea.

Section 4: Guidelines for Public Health Immunization After an AEFI has been Reported or Submitted

These guidelines should be used in conjunction with the AH AEFI Policy. The Zone MOH/ Provincial AEFI Team responsible for AEFI reporting is available for consultation to respond to questions and/or concerns as needed.

4.1 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/Provincial AEFI Team:

- Anaphylaxis
- Guillian-Barré Syndrome
- Subacute Sclerosing Panencephalitis
- Intussusception
- Thrombocytopenia
- 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

4.2 For the adverse events following immunization listed below subsequent immunization of the client may proceed while awaiting the recommendation by the MOH/Provincial AEFI Team **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
- Erythema Multiforme
- Oculo-Respiratory Syndrome (ORS) (if lower respiratory tract symptoms)
- Bell's Palsy

4.3 For the adverse events following immunization listed below subsequent immunization of the client may proceed while awaiting the recommendation by the MOH/Provincial AEFI Team 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 4.1)
- 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

- AHS Provincial Adverse Events Following Immunization webpage and reporting form
- AH Eligibility Criteria for Reporting AEFI
- Non-Reportable Adverse Events

References

1. Alberta Health, Health and Wellness Promotion Branch, Public Health and Compliance Branch, *Adverse Events Following Immunization (AEFI) Policy for Alberta Immunization Providers (2019, October)*.
2. National Advisory Committee on Immunization. (2016). *Canadian immunization guide (Evergreen Edition).* Ottawa, ON: Public Health Agency of Canada. https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html