

Reporting Adverse Events Following
Immunization (AEFI) in Manitoba

USER GUIDE FOR COMPLETION AND SUBMISSION OF THE **AEFI** REPORTS

Developed by the Public Health Agency of Canada and adapted
with permission by Manitoba Health



Public Health
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NOTE: Pursuant to section 59 of *The Public Health Act*, C.C.S.M c.P10, within 7 days after becoming aware of a reportable event, a health professional must report it in accordance with the regulations made under the Act.

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A } BACKGROUND

When did National Vaccine Post Marketing Surveillance begin in Canada?

National monitoring of adverse events dates back to 1965 and was the responsibility of the Laboratory Centre for Disease Control (LCDC) for vaccines as well as for drugs. LCDC's responsibility was limited to human preventive vaccines in 1987. That same year, a computerized database was created to collate adverse event reports from all sources. The Canadian Adverse Event Following Immunization Surveillance System (CAEFISS) is currently overseen by the Vaccine Safety Section in the Surveillance and Outbreak Response Division within the Centre for Immunization and Respiratory Infectious Diseases (CIRID) of the Public Health Agency of Canada (PHAC).

What is an Adverse Event Following Immunization (AEFI)?

An AEFI is any untoward medical occurrence in a vaccinee which follows immunization and which does not necessarily have a causal relationship with the administration of the vaccine (based on International Conference on Harmonisation (ICH) Topic E6 definition). The adverse event may be any unfavourable and/ or unintended sign, abnormal laboratory finding, symptom or disease.

Should all AEFIs be reported?

No. During their development, vaccines undergo rigorous testing for safety and efficacy. During these "pre-licensure trials" efforts are made to capture every single adverse event that follows immunization. By the time a vaccine is authorized for marketing, the safety profile for common adverse events such as inflammation at the vaccination site or mild fever is well known. It is always important to counsel vaccinees or their guardians regarding the possible occurrence of such reactions, but there is no need to report such expected events unless they are more severe or more frequent than expected.

What type of AEFI should be reported?

AEFIs should be reported when the event:

- **Has a temporal association with a vaccine.**
- **Has no other clear cause at the time of reporting:** A causal relationship between immunization and the event that follows does not need to be proven and submitting a report does not imply or establish causality. Sometimes the vaccinee's medical history, recent disease, concurrent illness/condition and/or concomitant medication(s) can explain the event(s).

Of particular interest are those AEFIs which:

- **Meet one or more of the seriousness criteria:** An adverse event that is life threatening or results in death, requires hospitalization or prolongation of an existing hospitalization, results in residual disability or causes congenital malformation.
- **Are unexpected regardless of seriousness:** An event that has either not been identified previously or one that has been identified previously but is, at current, being reported at an increased frequency. For additional information regarding unexpected events, please refer to the ICH Harmonised Tripartite Guideline (E2D 2003): http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2D/Step4/E2DGuideline.pdf

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.

Of Note: PHAC collects AEFI reports following the administration of active immunizing agents (vaccines). In comparison, Health Canada (HC) collects case reports of adverse events following the administration of therapeutic (passive) and diagnostic agents. When an adverse event follows the administration of an active immunizing agent (e.g., vaccine) that is administered simultaneously with a passive immunizing agent (e.g., immune globulin) and/or a diagnostic agent (e.g., tuberculin skin test), complete the AEFI Report form. Provide the name of the active immunizing agent, in addition to the passive immunizing agent and/or diagnostic agent, in section 4c, and follow the established procedures for reporting an AEFI in your province. This information will subsequently be forwarded to PHAC and to HC. Alternatively, if no active immunizing agent (vaccine) has been administered, an AEFI Report form should not be completed. Instead, please follow the established procedures in your province for reporting an adverse drug reaction to HC (e.g., completion of the Canada Vigilance Reporting Form).

Who reports AEFIs?

AEFI reports originate from multiple sources in Canada. Vaccine manufacturers are required by law (Food and Drugs Act and Regulations) to report to PHAC all serious AEFIs with vaccines for which they are the Market Authorization Holder within 15 days of knowledge of their occurrence. No other legal requirement for reporting AEFIs exists nationally. Several provinces have enacted mandatory AEFI reporting requirements. However, overall, reports are generally submitted on a voluntary basis by vaccine providers and other health care professionals.

The usual and preferred reporting flow is from local or regional health units to central provincial/territorial immunization programs. Reports are forwarded to PHAC electronically, or in hard copy by the provinces and territories after all personal identifying information has been removed. On occasion, reports may be submitted directly to PHAC by travel health clinics, pharmacists, physicians or the general public.

To enhance timely detection and assessment of serious adverse events involving children, PHAC funds an active pediatric hospital based surveillance system known as the Immunization Monitoring Program ACTive (IMPACT). AEFI reports completed by the IMPACT nurse monitors are sent to the appropriate provincial/territorial jurisdiction as well as to PHAC directly. Special numbering of the reports is done to avoid duplication.

What is done with AEFI reports at the provincial/territorial level?

AEFI reports are received at the local/regional level from multiple sources: physicians, nurses, pharmacists, public health, IMPACT, and the public. Recommendations for future immunizations are usually made at the local/regional level. In provinces and territories with electronic systems, the data are entered at the local health unit or regional health authority level and are then shared with the province/territory. The AEFI data are analyzed and disseminated at the provincial/territorial level to provincial/territorial stakeholders. Data are then sent electronically to PHAC. Those provinces and territories with paper based systems either fax this information directly to PHAC and/or enter the information in a provincial database.

What is done with AEFI reports at the national level?

Personnel in the Vaccine Safety Section screen all submitted reports, ensure they are entered into the CAEFI database and coded using standard international coding terminology. Reports are monitored with special attention to serious or unusual events that could signal a concern regarding vaccine safety. Canadian data are periodically forwarded on to the World Health Organization (WHO) International Drug Monitoring Program in Uppsala, Sweden, where global data are analyzed for any evidence of safety concerns.

When, why and how was a national AEFI report form first developed?

Critical groundwork for the current CAEFISS system was done at the Post Marketing Surveillance of Vaccine Associated Adverse Events workshop in 1990, sponsored by Health Canada's Bureau of Communicable Disease (CDWR 1991; Vol. 17-19:97-98) and attended by Federal, Provincial and Territorial stakeholders as well as vaccine manufacturers, key non-governmental organizations and expert scientific advisors. The purpose of the workshop was to develop a framework for a coordinated approach to optimize vaccine post marketing surveillance in Canada. At the workshop, post marketing surveillance for vaccines was defined as the coordinated, structured, systematic, ongoing collection of data and their subsequent epidemiologic analysis and dissemination. It was recommended that passive surveillance be centrally aggregated with input by public health and physicians and supplemented by active surveillance activities.

The first national vaccine adverse event report form was developed through a federal/provincial/territorial collaborative process during the year following the 1990 workshop. It was agreed that the form would list several adverse events considered to be of public health importance. Reporters could check off the specific event and add written detail. There was also an "other" box so that any adverse event of concern to a reporter could be reported. It was agreed that all Provincial/Territorial AEFI forms would be based on the national form with nothing deleted but items could be added if they were of specific interest to a region. Case definitions were also developed, although many simply specified that a physician diagnosis would be required. In 1996, the AEFI report form was revised and it is that version which has been in use until now. A series of federal / provincial / territorial workshops held from 2000-2002, led to the development of published functional standards, a minimum core data set and updated data definitions for AEFI reporting (CCDR 2002; 28).

Why has the form been revised?

Priorities to improve vaccine safety surveillance in Canada were established during the development of the National Immunization Strategy (NIS). As a part of the efforts to improve voluntary AEFI reporting, it was decided to revise the AEFI report form. This has been done over the last two years by members of the Vaccine Vigilance Working Group (VWVG) which is a federal/provincial/territorial group that reports to the Canadian Immunization Committee (CIC). Another reason to revise the form was to facilitate application of standardized AEFI case definitions developed by the Brighton Collaboration which is an international voluntary group whose goal is to facilitate the development, evaluation, and dissemination of high quality information about the safety of human vaccines.

How is Privacy and Confidentiality of information ensured?

Personal health information is confidential. All provinces, territories and PHAC take great care to protect personal health information. Health care workers are encouraged to discuss with clients, or the clients' caregiver, the reason for reporting the AEFI and the confidentiality of all collected information. For further information regarding the protection of personal health information you may contact the privacy representatives at your local public health office. Alternatively, the Privacy Act can be accessed online at the following address: <http://laws.justice.gc.ca/en/P-21/index.html>

Where and when can copies of the AEFI report form be obtained?

The new form was first introduced in 2009 in Manitoba and other provinces and territories. The form itself, along with information regarding its implementation in Canada, is posted on the Web at www.phac-aspc.gc.ca/im/aefi-form-eng.php. In addition, the form can be viewed in the Compendium of Pharmaceuticals and Specialties and hard copies can be obtained from local public health units, hospitals, clinics (including travel clinics), etc. Manitoba Health's adapted version of the form and user guide are posted at: www.gov.mb.ca/health/publichealth/sri/index.html

B } GUIDELINES ON HOW TO COMPLETE SECTIONS OF THE AEFI FORM:

This guide is intended to be used when completing the Report of AEFI for submission to provincial and territorial authorities as well as to PHAC. Its purpose is to provide assistance on how to accurately complete the form. It is not intended to guide treatment. Treatment of all AEFIs should proceed, as appropriate, prior to completing the AEFI form. Following the immediate care of the vaccine recipient, the AEFI form can be completed with all available information.

Given the variation in practice between each of the provinces and territories, sections of the form may not be applicable to all settings. If in doubt, please contact your local public health unit.

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Complete each section of the AEFI form as follows:

On the top right hand corner: Indicate whether the AEFI report being submitted is an **INITIAL** or a **FOLLOW UP** report. For all “Follow up” reports, provide the **UNIQUE EPISODE NUMBER** and/or **REGION NUMBER** of the initial report.

SECTION 1.

PROVINCIAL AND REGIONAL IDENTIFYING INFORMATION

SECTION 1A) UNIQUE EPISODE NUMBER

A unique episode number is to be assigned to each AEFI report. In provinces/territories that use electronic reporting systems, this number may be automatically generated by the system. In provinces/territories that do not use electronic reporting systems, this number should only be filled in by those persons who are authorized to assign the number at provincial/territorial health authorities (e.g., provincial/territorial health professionals and/or officials). The unique episode number should be marked on the top of the first three (3) pages of the AEFI form as an identifier to link the pages together. If you are not authorized to assign this number, please leave this field blank.

SECTION 1B) REGION NUMBER

A region number that corresponds to a given health unit should be entered for those regions that have one. The region number (the number that corresponds to a given health unit) should be marked on the top of the first three (3) pages of the AEFI form as an identifier to link the pages together. This number should only be filled in by those persons who are authorized to assign it and should be left blank if it does not apply to your locale.

SECTION 2.

IMPACT LIN

IMPACT is a paediatric, hospital-based, national active surveillance network for adverse events following immunization, vaccine failures and selected infectious diseases in children. IMPACT is administered by the Canadian Paediatric Society with funding from the Public Health Agency of Canada. IMPACT reports the more serious hospitalized cases and selected outpatient visits for adverse events and vaccine-preventable diseases.

An IMPACT Local Inventory Number (LIN) is to be assigned by the IMPACT Nurse monitor when an AEFI report is generated from an IMPACT centre. The IMPACT LIN should be marked on the top of the first three (3) pages of the AEFI form. Please leave this section blank if it does not apply to you (e.g., if you are not an IMPACT hospital/centre).

The IMPACT LIN is used to link the initial provincial/territorial AEFI report to the IMPACT report. Once both reports have been received, the data contained on the AEFI form and the IMPACT forms are merged in the CAEFISS database.

SECTION 3.

PATIENT IDENTIFICATION

This section is intended to capture patient information for use by regional and/or provincial/territorial health officials. This information is kept confidential and should **not** be forwarded to PHAC.

This section should be completed in keeping with provincial/territorial guidelines.

Patient Identification Information: Provide the patient's first and last name, health number (if applicable), address of usual residence including postal code (with the understanding that this address might be in a different province/territory than where the vaccine(s) was administered or where the AEFI is being reported) and a telephone number (either residential or business or both), where the patient can be reached.

Information Source: If the source of the information for the AEFI report is a parent, or another care provider, provide their name, relation to the patient and contact information (including their full mailing address and phone number where they can be reached) if it is different from the patient's.

SECTION 4.

INFORMATION AT TIME OF IMMUNIZATION AND AEFI ONSET

SECTION 4A) AT TIME OF IMMUNIZATION

Provide all information, as described below, in the space provided on the form:

Province/Territory of immunization: Indicate the province or territory where the immunization was received. This may be different from the patient's province or territory of residence and/or where the AEFI is being reported.

If the vaccine was administered outside of Canada, indicate the country in which the vaccine(s) was/were administered in the space to capture province/territory and also comment if it was received at a Canadian operated clinic in that country.

Date and time vaccine administered: Indicate the date and time of vaccine administration remembering to specify if the vaccine was administered in the "am" or "pm" by circling the appropriate descriptor. If complete information is unknown, provide as much detail as is available (e.g. month and/or year).

Date of birth: Indicate the patient's date of birth in the space provided. If the complete date is unknown, please provide as much information as is available (e.g. month and/or year).

Age: Indicate the patient's age at the time of immunization. Use days for infant's aged less than 1 week; weeks for infants aged less than 1 month; months for infants aged less than 1 year; and years thereafter. Fractions should be used as appropriate (e.g., 6 weeks should be captured as 1.5 months; 15 months should be captured as 1.25 years). If the patient's exact age is unknown, please estimate patient's age.

Sex: Indicate the patient's gender (e.g., male or female). If the gender is unknown or ambiguous, please choose "other".

SECTION 4B) MEDICAL HISTORY (UP TO THE TIME OF AEFI ONSET)

Indicate the patient's medical history prior to the time of AEFI onset by choosing all that apply from the list provided below. Provide all additional details, when available, in section 10.

Concomitant medication(s): Provide the name of all medications, including prescription, over the counter and herbal supplements, which the patient had been taking immediately prior to the time of AEFI onset, including those taken only as needed in section 10. When available, provide the dose, frequency, route of administration and reason for taking each concomitant medication.

Known medical conditions/allergies: Indicate all known medical conditions and/or allergies that the patient experienced prior to the time of immunization with a corresponding date of onset in section 10. If an exact date of onset is unknown, please provide the greatest amount of detail that is available (e.g., year of onset). Include any conditions for which the patient is taking a concomitant medication including chronic conditions with intermittent symptoms such as migraine headaches. Also, specify in this section if the subject was pregnant at the time of immunization.

Acute illness/injury: Indicate if the patient had an acute illness and/or injury immediately prior to the time of immunization and specify a corresponding date of onset in section 10 if known. If an exact date of onset is unknown, provide the greatest amount of detail that is available (e.g., month and/or year of onset).

SECTION 4C) IMMUNIZING AGENT

Provide all information pertaining to the immunizing agent(s) administered just prior to the onset of the reported AEFI(s). There is space to record five (5) immunizing agents in section 4c; however, if more than five (5) were administered simultaneously, record the additional vaccines in section 10.

Note that PHAC collects AEFI reports following the administration of active immunizing agents (vaccines). In comparison, Health Canada (HC) collects case reports of adverse events following the administration of therapeutic (passive) and diagnostic agents. When an adverse event follows the administration of an active immunizing agent (e.g., vaccine) that is administered simultaneously with a passive immunizing agent (e.g., immune globulin) and/or a diagnostic agent (e.g., tuberculin skin test), complete the AEFI Report form. Provide the name of the active immunizing agent, in addition to the passive immunizing agent and/or diagnostic agent, in section 4c, and follow the established procedures for reporting an AEFI in your province. This information will subsequently be forwarded to PHAC and to HC. Alternatively, if no active immunizing agent (vaccine) has been administered, an AEFI Report form should not be completed. Instead, please follow the established procedures in your province for reporting an adverse drug reaction to HC (e.g., completion of the Canada Vigilance Reporting Form).

When completing section 4c, provide all information as outlined below:

Immunizing agent(s): Please record the proper name or accepted abbreviation as outlined in Appendix II for all immunizing agent(s).

Trade name: Indicate the trade name of all vaccine(s) received.

Manufacturer: Specify the name of the manufacturer as indicated on the product label and as referenced in Appendix II.

Lot number: Document the complete lot number including all letters and numbers. This information is essential for conducting future risk assessments.

Dose number: Provide the number in series (1, 2, 3, 4, or 5) or indicate if known. For the Influenza vaccine, unless a patient receives two doses in one season, the “dose #” should be recorded as one.

Dosage/unit: Indicate the dose (e.g., 0.5) and unit (e.g., ml) for each vaccine.

Route: Specify the route of administration for each vaccine received. Abbreviations (as described below) are acceptable:

- **Intradermal:** ID
- **Intramuscular:** IM
- **Subcutaneous:** SC
- **Intranasal:** IN
- **Oral:** PO
- **Other:** please specify (no abbreviations)

Site: Indicate the site of injection for each vaccine administered. Abbreviations (as described below) are acceptable:

- **Left arm:** LA
- **Right arm:** RA
- **Arm:** Arm
- **Left leg:** LL
- **Right leg:** RL
- **Leg:** Leg
- **Left gluteal:** LG
- **Right gluteal:** RG
- **Gluteal:** Glut
- **Mouth:** Mo
- **Nose:** Nose
- **Multiple sites:** MS
- **Other:** please specify (no abbreviations)

SECTION 5. **IMMUNIZATION ERRORS**

Indicate whether the AEFI has followed an incorrect immunization (an immunization error, program error, etc.) by choosing “no,” “unknown” or “yes.” If “yes,” please indicate all that apply in section 5 by checking the box next to the situation that most closely reflects the error (as described below) and provide all known details in section 10.

Given outside the recommended age limits: The vaccine was administered to an individual who was not within the recommended age limits for a specific vaccine.

Product expired: The vaccine was administered after the expiry date as indicated on the vaccine label by the manufacturer and/or after the recommended amount of time elapsed between the first use of a multi-dose vial and the last use (e.g., as indicated in the product monograph for Fluviral, once entered, the multi-dose vial should be discarded after 28 days).

Incorrect route: The vaccine was administered via a route not recommended for its administration (e.g., subcutaneous vs. intramuscular).

Wrong vaccine given: An unintended vaccine was administered.

Dose exceeded that recommended for age: A larger dose of vaccine was administered than is recommended for the patient’s age group.

Other: If an error has occurred that is not accurately reflected in the list of provided errors, please choose “other” and provide all details.

SECTION 6. PREVIOUS AEFI

Indicate whether the patient had ever experienced an AEFI following a previous dose of any of the immunizing agents as listed in response to question 4c. Choose only one of the answers provided in section 6, as described below:

No: The patient had previously received immunization with one or more of the immunizing agents listed in section 4c and had not experienced a subsequent AEFI.

Yes: The patient had previously received immunization with at least one of the immunizing agents listed in section 4c and had subsequently experienced an AEFI.

Unknown: It is unknown if the patient had previously received immunization with any of the immunizing agents listed in section 4c and/or, if an AEFI followed.

Not applicable: The patient had never previously received immunization with any of the immunizing agents listed section 4c.

If the answer is “yes,” the patient had previously experienced an AEFI following a previous dose of one or more of the immunizing agent(s) listed in section 4c, provide all details of the previous AEFI in section 10, including the corresponding time to onset and duration, when known. Also, when possible, provide information regarding the severity of the AEFI and if the previous AEFI was less or more severe than the currently reported AEFI.

If there is uncertainty regarding which option to choose, or if there is additional information to provide (e.g., multiple vaccines were administered and not all of the information regarding the patient’s past AEFI experience can be captured in section 6), please provide additional details in section 10.

SECTION 7. IMPACT OF AEFI, OUTCOME, AND LEVEL OF CARE OBTAINED

SECTION 7A) HIGHEST IMPACT OF AEFI

Indicate the highest perceived impact of the AEFI by choosing one of the provided responses in section 7a based on the patient’s assessment of the impact on their daily activities:

Did not interfere with daily activities: No change, or only minimal change is reported by the patient in relation to their daily activities (e.g., work, exercise, social commitments, etc.).

Interfered with but did not prevent daily activities: Moderate change is reported by the patient in relation to their daily activities (e.g., interfered with work, exercise and/or social commitments).

Prevented daily activities: Significant change is reported by the patient in relation to their daily activities (e.g., prevented work, exercise and/or social commitments).

For young children (e.g., infants and toddlers), indicate the highest perceived impact of the AEFI on their daily activities as assessed by the child's parent/caregiver according to the following:

Did not interfere with daily activities: No change or only minimal change, is observed in the child's daily patterns and/or habits (e.g., eating, sleeping, playing, etc.).

Interfered with but did not prevent daily activities: Moderate change is observed in the child's daily patterns and/or habits (e.g., reduced appetite, disrupted sleep, disrupted play, etc.).

Prevented daily activities: Significant change is observed in the child's daily patterns and/or habits (e.g., not eating, not sleeping, not playing, etc.).

SECTION 7B) OUTCOME AT TIME OF REPORT

Indicate the outcome of the AEFI at the time of completion of the report by choosing one of the provided responses in section 7b. If the patient is not yet recovered, provide all available details in section 10 and provide updates as they become available. Similarly, should the event result in permanent disability and/or incapacity or death, provide all available details in section 10.

When completing section 7b, provide the information as outlined below:

Death: Patient died (record the corresponding date of death in the space provided).

Permanent disability/incapacity: An injury which impairs the physical and/or mental ability of a person to perform his/her normal work or non-occupational activities supposedly for the remainder of his/her life.

Not yet recovered: Residual signs and/or symptoms remain (at the time of the report).

Fully recovered: All signs and symptoms have resolved.

Unknown: The outcome of the AEFI is unknown or unclear.

SECTION 7C) HIGHEST LEVEL OF CARE OBTAINED

Indicate the highest level of care obtained for the reported AEFI by choosing one of the provided options in section 7c, described in detail below.

Unknown: It is unknown if the patient received care for the reported AEFI.

None: No care was received for the reported AEFI.

Telephone advice from a health professional: The patient received telephone advice from a health care professional (e.g., nurse, nurse practitioner, physician, etc.) regarding the reported AEFI.

Non-urgent visit: The patient was seen by a health care professional (e.g., at a physician's office or walk in clinic) for the assessment and/or treatment of the reported AEFI. Document all investigations conducted in section 10.

Emergency visit: The patient was seen by a health care professional for an emergency visit for the assessment and/or treatment of the reported AEFI. Please note that emergency visits are not considered admission to hospital and therefore, admission and discharge dates are not required. Document all investigations conducted in section 10.

Required hospitalization: The patient was hospitalized for the assessment and/or treatment of the reported AEFI. Indicate the number of days the patient was hospitalized, the date of admission and the date of discharge. Document all investigations conducted in section 10.

Resulted in prolongation of existing hospitalization: If a patient was already in hospital at the time of immunization and the AEFI resulted in a longer hospital stay, please check: "Resulted in prolongation of existing hospitalization" and indicate the number of additional days stayed in hospital as a result of the AEFI. Also indicate the date of hospital admission and discharge for the entire period of hospitalization (if known). Document all investigations conducted in section 10.

SECTION 7D) TREATMENT RECEIVED

Indicate whether the patient received any treatment, including self treatment, for the reported AEFI by choosing yes, no or unknown. Provide details of all treatments received, following the onset of the AEFI in section 10 when applicable.

SECTION 8.

REPORTER INFORMATION

Complete the reporter information section in full including the reporter's first and last names, a phone and fax contact number (including extensions when applicable) and the full mailing address of the institution/setting/centre. Indicate the setting in which the reporter is located (e.g., physician office, public health clinic, hospital) or specify if other. Sign and date the AEFI form in the space provided and specify your professional status (e.g., MD: Medical Doctor; RN: Registered Nurse) or your affiliation (e.g., IMPACT) by choosing one of the options provided. If your professional status or affiliation is not listed, specify beside other.

SECTION 9. AEFI DETAILS

Indicate the details of the AEFI being reported by checking all that apply. All additional pertinent details (e.g., results of medical investigations, laboratory test, treatment, etc.) should be provided in section 10. For convenience and consistency, high level definitions have been provided for most events listed in section 9. However, if an asterisk (*) is present beside an AEFI term, this specific event **should be diagnosed by a physician**. If not, sufficient information should be provided (in section 10) to support the selection(s). For all AEFIs, indicate the time to onset or interval (time from immunization to onset of first symptom/sign), and the duration (time from onset of first symptom/sign to resolution of all of signs and symptoms). Refer to Appendix III for national case definitions of AEFIs of special interest.

Time to onset/interval and duration of signs and symptoms: The time to onset/interval and the duration of the signs and symptoms of the specified AEFI should be documented using appropriate the most appropriate time unit day, hour, minute.

SECTION 9A) LOCAL REACTION AT OR NEAR VACCINATION SITE

Indicate, by choosing all that apply any local reactions at or near the vaccination site, as described below:

Infected abscess: A localized collection of pus in a cavity formed by the disintegration of tissue, usually caused by microorganisms that invade the tissues.

Sterile abscess: An abscess whose contents are not caused by pyogenic bacteria. (Refer to Appendix III for the national case definition of Abscess).

Cellulitis: A diffuse inflammatory process within solid tissues, characterized by edema, redness, pain, and interference with function, usually caused by infection with *streptococci*, *staphylococci*, or similar organisms.

Nodule: A firm, small mass of tissue at the vaccination site with discrete or well demarcated borders in the absence of abscess^a formation, erythema and warmth. (Refer to Appendix III for the national case definition).

Reaction crosses joint: Reaction extending past at least one joint adjacent to the site of vaccine administration.

Lymphadenitis: Inflammation of one or more lymph nodes, usually caused by a primary focus of infection elsewhere in the body.

Other: Specify all details of the vaccination site reaction in section 10 that are not already captured in section 9a above. Examples of “other” local reactions that may be reported here include necrosis, papule etc.

^a The national case definition of abscess can be found in Appendix III.

For all local reactions at or near the vaccination site, describe the signs and symptoms by checking all that apply from the list below. Provide any additional details in section 10:

Swelling: Visible enlargement of the site of vaccination of an vaccinated limb that is assessed by any person. (Refer to Appendix III for the national case definition).

Pain: An unpleasant sensation occurring in varying degrees of severity that could be described as discomfort, distress or agony.

Tenderness: Abnormal sensitivity to touch or release of pressure.

Erythema: Abnormal redness of the skin.

Warmth: A sensation/perception of an increase in temperature.

Induration: Palpable thickening, firmness or hardening of soft tissue that is assessed^b by a health care provider. (Refer to Appendix III for the national case definition).

Rash: A temporary eruption on the skin.

Largest diameter of vaccination site reaction: Indicate the diameter (in centimetres) of the largest vaccination site reaction that is present.

Site(s) of reaction: Site(s) of the local reaction being reported if known. (See abbreviations in section 4c).

Palpable fluctuance: Wavelike motion on palpation due to presence of liquid content. (Refer to Appendix III for the national case definition of Abscess).

Fluid collection shown by imaging technique: An imaging device is used in the detection of fluid collection (e.g., MRI, CT scan and ultrasound).

Spontaneous drainage: Draining of fluid from a site without intervention. When available, provide all gram stain/culture results.

Surgical drainage: Withdrawal of fluids from the site through needle aspiration or incision which could be complete or partial (Refer to Appendix III for the national case definition Abscess). When available, provide all Gram stain/culture results.

Microbial results: Tests that are carried out to identify organisms that can cause disease or infection.

Lymphangitic streaking: Painful and inflamed red streaks below the skin's surface (follows the path of lymph draining from the site of infection via lymphatic vessels to regional lymph nodes).

Regional lymphadenopathy: Abnormal enlargement of the lymph nodes closest to the vaccination site (e.g., inguinal adenopathy when associated with an IM vaccination in the thigh, axillary adenopathy associated with an IM vaccination in the deltoid, etc.).

^b Assessed by a health care provider means that a qualified health care professional has either examined the individual or has judged that the term is appropriate based on a verbal description of the reaction.

SECTION 9B) ALLERGIC AND ALLERGIC-LIKE EVENTS

Choose one of the following events below:

“Anaphylaxis” is a clinical syndrome, characterized by the sudden onset and rapid progression of signs and symptoms which affect more than one body system (e.g., skin/mucosal and/or cardio-vascular and/or respiratory and/or gastrointestinal). The form has been designed to capture the major and minor manifestations of anaphylaxis, each of which are defined below. Accurate documentation of signs and symptoms contributes to the diagnostic certainty that an evolving event is indeed anaphylaxis. (Refer to Appendix III for the national case definition). It is not necessary to know the definition prior to completing the AEFI report form nor should there be, a delay in instituting appropriate management.

“Oculo-Respiratory Syndrome (ORS)” is a set of signs/symptoms of both the eyes and respiratory system following vaccination with influenza vaccine. (Refer to Appendix III for the national case definition).

“Other allergic event” encompasses all non-anaphylactic allergic reactions.

For a chosen event, describe the signs and symptoms by checking all that apply from the list below. Provide all additional details in section 10.

SKIN/MUCOSAL

Choose all that apply from the list provided below, and indicate the site of reaction:

Urticaria (‘hives’): Circumscribed, intensely itchy weals with erythematous, raised edges and pale, blanched centres (from the Australian immunisation handbook, 9th edition). Urticaria may be present at the vaccination site (e.g., within a few centimetres of where immunization was given) and/or may be generalized (involving body sites other than where the vaccine was injected).

Erythema: Abnormal redness of the skin.

Pruritus: An unpleasant cutaneous sensation that provokes a desire to rub and/or scratch to obtain relief.

Prickle sensation: Tingling or smarting (stinging) sensation.

Rash: A skin or mucosal change (temporary eruption). (Refer to Appendix III for the national case definition). Use this check box when reporting rash which is allergic in nature. For rash localized to the vaccination site, capture in section 9a and, for rash related to Varicella, Measles, or other not allergic in nature, capture in section 9d.

Angioedema: Localized edema of the deeper layers of the skin, subcutaneous tissues or mucosa lining the throat, airways and gut. This most often affects the face, near the eyes and mouth or hands and feet, but may also involve the lip, tongue, uvula, throat or larynx. It is important that the swelling is confirmed by visual inspection by a qualified health care professional rather than rely on patient description alone (“my tongue feels swollen”). Check all of the locations where angioedema is seen on the AEFI report form and if “other” is checked, provide details.

Red eyes (bilateral or unilateral): Eye(s) showing dilatation of conjunctival, episcleral or ciliary blood vessels.

Itchy eyes: A sensation that provokes the desire to rub and/or scratch to obtain relief.

CARDIO-VASCULAR

Choose all that apply from the list provided below:

Measured hypotension: An abnormally low blood pressure (systolic pressure <100mm hg) documented by appropriate measurement.

Decreased central pulse volume: Decreased pulse strength as a result of the decrease in volume of blood in the blood vessels.

Capillary refill time >3 sec: Capillary refill time is the time required for the normal skin colour to reappear after a blanching pressure is applied. It is usually performed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue, indicated by a pink colour returning to the nail. Normally it is <3 seconds.

Tachycardia: An extremely rapid heart rate above an established norm that varies by age. The term is usually applied to a heart rate above 100 beats per minute for adults.

TABLE OF PULSE AND RESPIRATORY RATES		
Age	Heart (pulse) rate per minute, Upper Limit	Respiratory rate per minute, Upper Limit
0-1 mo	180	60
2-12 mo	160	50
12-24 mo	140	40
2-6 y	120	30
6-12 y	110	20
>12y (adult)	100	20

From: Emergency Medicine: A comprehensive study guide 6th edition. (2004). McGraw Hill.

Decreased consciousness: Reduced alertness or awareness of the outside world. Indicate duration of the event.

Loss of consciousness: Total unresponsiveness (suspension of conscious relationship with the outside world, inability to perceive and to respond). Indicate duration of the event.

RESPIRATORY

Choose all that apply from the list provided below:

Sneezing: An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose.

Rhinorrhea: Discharge of thin nasal mucus.

Hoarse voice: An unnaturally rough/deep or noisy quality of voice.

Sensation of throat closure: Feeling or perception of throat obstruction or occlusion resulting in difficulty breathing.

Stridor: A harsh, high-pitched breath sound heard on inhalation caused by air passing through a constricted passage.

Dry cough: Rapid expulsion of air from the lungs to clear the lung airways and not accompanied by expectoration (a non-productive cough).

Tachypnea: Abnormally rapid and shallow breathing.

Wheezing: A whistling, squeaking, musical, or puffing sound made on exhalation by air passing through the fauces, glottis, or narrowed tracheobronchial airways (bilateral – both lungs). Wheeze may be audible to the naked ear or may require the use of a stethoscope.

Indrawing/retractions: Inward movement of the muscles between the ribs. The movements are usually a sign of difficulty with breathing.

Grunting: A laboured breathing of expiratory effort due to obstruction of the airway.

Cyanosis: A dark bluish or purplish discoloration of the skin and mucous membrane due to deficient oxygenation of the blood.

Sore throat: Discomfort or pain in the throat.

Difficulty swallowing: Sensation of food stuck in the throat or upper chest.

Difficulty breathing: Sensation of difficult/uncomfortable breathing or a feeling of not getting enough air.

Chest tightness: Chest discomfort or pain anywhere along the front of the body between the neck and upper abdomen.

GASTROINTESTINAL

Choose all that apply from the list provided below:

Diarrhea: Abnormally frequent discharge of loose and/or watery fecal matter from the bowel. Please provide details.

Abdominal pain: Sensation of discomfort, distress or agony in the abdominal region.

Nausea: An unpleasant sensation vaguely referred to the epigastric region (upper region of the abdomen) and the abdomen, with a tendency to vomit.

Vomiting: The reflex act of ejecting the contents of the stomach through the mouth. Provide details.

SECTION 9C) NEUROLOGIC EVENTS

Indicate, by choosing all that apply from the list provided all neurologic events. Provide all additional details in section 10.

Meningitis*: Should be diagnosed by a physician. Document the results of any cerebrospinal fluid investigations and pertinent details.

Encephalopathy/Encephalitis*: Should be diagnosed by a physician. Choose all that apply to the reported AEFI from the list provided on the form and provide all pertinent details.

Guillain-Barre Syndrome (GBS)*: Should be diagnosed by a physician. Indicate if an Electromyograph (EMG) and/or Lumbar Puncture (LP) were conducted and provide a summary of results in addition to any other relevant investigations including tests to look for possible causes, especially Campylobacter.

Bell's Palsy*: Should be diagnosed by a physician. Provide any pertinent details.

Other paralysis*: Should be diagnosed by a physician. Provide all pertinent details.

Seizure(s): Episodes of hyperactivity in the brain resulting in sudden, involuntary muscle contractions and abnormal behaviour, loss or impairment of consciousness (Refer to appendix III for the national case definition).

Other neurologic diagnosis*: Specify and provide all details.

Indicate all signs, symptoms and test results relating to the reported neurologic event by choosing all that apply from the list below and provide a detailed description in section 10.

Depressed/altered level of consciousness: Impairment of the ability to maintain awareness of self and environment combined with markedly reduced responsiveness to environmental stimuli.

Lethargy: A general state of sluggishness, listless, or uninterested, with being tired, and having difficulty concentrating and doing simple tasks.

Personality changes lasting \geq 24 hours: Change in personal behaviour-response patterns.

Focal or multifocal neurologic sign(s): Neurological impairment which is caused by a lesion in one particular focus or many foci of the central nervous system.

Fever (\geq 38.0°C): A temperature of \geq 38.0°C in conjunction with neurologic symptoms.

CSF (Cerebral Spinal Fluid) abnormality: Alteration in the normal CSF values.

EEG (Electroencephalography) abnormality: Abnormal recording of changes in electric potentials in various areas of the brain.

EMG (Electromyography) abnormality: Abnormal test results of the recording and study of the intrinsic electrical properties of skeletal muscle.

Neuroimaging abnormality: Abnormal results in the tests (e.g.: CT scans, MRIs, Pet scans etc) used to detect anomalies or trace pathways of nerve activity in the central nervous system.

Brain/spinal cord histopathologic abnormality: Microscopic changes of the diseased brain/spinal cord tissues.

SEIZURE DETAILS: Check all that apply and record additional details in section 10. Indicate if the event was witnessed by a health care professional by choosing yes or no/unknown.

Witnessed by healthcare professional: A healthcare professional (e.g. doctor, nurse, etc.) observed the seizure.

Sudden loss of consciousness: Sudden total unresponsiveness (suspension of conscious relationship with the outside world, inability to perceive and respond). If Yes, indicate duration of the event.

Generalized: Bilateral, with more than minimal muscle involvement.

Tonic: Sustained increase in muscle contraction lasting a few seconds to minutes.

Clonic: Sudden, brief (<100 milliseconds) involuntary contractions of the same muscle groups, regularly repetitive at a frequency of about 2 to 3 contractions/second.

Tonic-clonic: A sequence consisting of a tonic followed by a clonic phase.

Atonic: Sudden loss of tone in postural muscles often pre-ceded by, a myoclonic jerk and precipitated by hyperventilation (in the absence of Hypotonic-Hyporesponsive Episode, syncope, or myoclonic jerks).

Absence: The occurrence of an abrupt, transient loss of impairment of consciousness (which may not be remembered), sometimes with light twitching, fluttering eyelids, etc.

Myoclonic: Involuntary shock-like contractions, irregular in rhythm and amplitude, followed by relaxation, of a muscle or a group of muscles.

Partial: Seizure that originates from a localized area of the cerebral cortex and involves neurologic symptoms specific to the affected area of the brain.

Previous history of seizures: Individuals who have had seizures at anytime prior to this vaccination.

Febrile: With fever of $\geq 38.0^{\circ}\text{C}$.

Afebrile: Without fever.

Unknown type: It is unknown if the seizure was febrile or afebrile. Provide all known details.

SECTION 9D) OTHER EVENTS

For a selected event, describe the signs and symptoms by checking all that apply. Provide all additional details in section 10.

Hypotonic-Hyporesponsive Episode (age<2 years): Sudden onset, in a child aged less than two years, of hypotonia (limpness), reduced responsiveness and either pallor or cyanosis (Refer to the Appendix III for the national case definition. If the patient is two (2) years of age or older, please check "Other severe or unusual events not listed above" and describe the episode.

Choose all that apply to the reported AEFI from the list provided below:

Limpness: Lacking firmness and strength, no muscle tone.

Pallor: Unnatural lack of colour in the skin (abnormal loss of colour from normal skin).

Cyanosis: A dark bluish or purplish discolouration of the skin and mucous membrane due to deficient oxygenation of the blood.

Decreased responsiveness/unresponsiveness: Change in usual responsiveness to sensory stimuli (Refer to Appendix III for the national case definition on Hypotonic-Hyporesponsive Episode).

Persistent crying: Crying which is continuous unaltered and lasts for 3 or more hours (Refer to Appendix III for the national case definition).

Intussusception*: The prolapse of one part of the intestine into the lumen of an immediately adjacent part, causing partial or complete intestinal obstruction, and should be diagnosed by a physician. Provide all pertinent details.

Arthritis: Inflammation of the joint(s). Choose all that apply to the reported AEFI from the list provided, and described, below:

Joint redness: Redness of the skin at the joint(s).

Joint warm to touch: Sensation of increase in temperature, above body temperature, at the joint(s) to touch.

Joint swelling: An abnormal increase in the size of the joint(s).

Inflammatory changes in synovial fluid: Laboratory synovial or joint fluid analysis indicative of inflammatory response.

Parotitis: Inflammation of the parotid gland(s) with pain and/or tenderness.

Rash: A skin or mucosal change (temporary eruption). (Refer to Appendix III for the national case definition). Choose the best descriptor from the list provided below that is most representative of the event. Use this subsection to capture rash related to Varicella, measles, or other not allergic in nature. For rash localized to the vaccination site, capture in section 9a and, for rash allergic in nature, capture in section 9b.

When possible provide a written description of the rash, using the terminology provided with the case definition of rash in appendix III.

Generalized rash: Systemic eruption in 2 or more parts of the body.

Localized at non-vaccination site: Eruption localized at another part of the body, away from the vaccination site.

Thrombocytopenia*: Should be diagnosed by a physician. Platelets count of less than 150×10^9 /liter; accompanied by petechial rash or other clinical signs and/or symptoms of spontaneous bleeding. (Refer to Appendix III for the national case definition). Indicate the lowest platelet count on the AEFI form and provide any additional pertinent details.

Anaesthesia: The loss of normal feeling or sensation.

Paraesthesia: Abnormal physical sensation such as tingling, burning, prickling, formication, etc.

For Anaesthesia/Paraesthesia, describe the symptoms by checking all that apply, indicate the site of reaction.

Fever ($\geq 38.0^\circ\text{C}$): A temperature of $\geq 38.0^\circ\text{C}$ in conjunction with any other reportable event other than a neurological event.

Other serious or unexpected event(s) not listed in the form: Specify and provide details in section 10.

SECTION 10.

SUPPLEMENTARY INFORMATION

Section 10 should be used to capture information that is pertinent to the AEFI but that has not been fully captured elsewhere or that needs further explanation. Document all known details of any investigations or treatments for the recorded AEFI. Indicate the section of the AEFI report that the information applies to, if applicable, when recording information in section 10.

SECTION 11.

RECOMMENDATIONS FOR FUTURE IMMUNIZATION(S) ACCORDING TO THE PROVINCIAL BEST PRACTICES.

This section is to be completed by the regional Medical Officer of Health (MOH).

Indicate, by choosing all that apply in section 11, your recommendations for the patient with regard to future vaccinations and specify additional information when requested. A comments section has been added for your convenience; however, should you require additional space for your recommendation(s), please capture this information in section 10.

Complete the reporter information section in full providing your full name and professional status (MOH: Medical Officer of Health). In addition, indicate a phone number where you can be reached and sign and date the AEFI form in the space provided.

SECTION 12.

FOLLOW UP INFORMATION FOR A SUBSEQUENT DOSE OF SAME VACCINE(S)

Note: The information in this section is not collected by all provinces/territories.

Complete section 12 when an individual who has previously experienced an AEFI following administration of a vaccine receives a subsequent dose of the same vaccine.

Choose one of the responses as described below to describe the outcome following the administration of the subsequent dose of vaccine and provide all pertinent details in section 10.

Vaccine administered without AEFI: A subsequent dose of vaccine was administered without the occurrence of any AEFI.

Vaccine administered with recurrence of AEFI: A subsequent dose of vaccine was administered and followed by the occurrence of the same adverse event that was previously experienced by the patient. Please fill out a new AEFI form for the subsequent AEFI.

Vaccine administered, other AEFI observed: A subsequent dose of vaccine was administered and followed by the occurrence of a different adverse event than was previously experienced by the patient. Please fill out a new AEFI form for the subsequent AEFI.

Vaccine administered without information on AEFI: A subsequent dose of vaccine was administered and it is unknown if it was followed by the occurrence of any AEFI.

Vaccine not administered: A subsequent dose of the vaccine was not administered.

APPENDIX I

WHERE TO SEND A COMPLETED AEFI REPORT

Upon completion of an AEFI report, please send to your regional Medical Officer of Health.

Nationally, the contact information, listed by federal/provincial/territorial (F/P/T) institution for any AEFI-related questions can be accessed at: **www.phac-aspc.gc.ca/im/ci-rp-eng.php**

APPENDIX II

LIST OF CURRENT VACCINES

VACCINE	ABBREVIATION	TRADE NAME	MARKET AUTHORIZATION HOLDER
Bacillus Calmette Guérin	BCG	BCG	SP
Cholera - <i>E.coli</i> - Oral	Chol-Ecol-O	Dukoral®	CV
Combined Diphtheria and Tetanus Toxoids, acellular Pertussis	DTaP	Infanrix™	GSK
		Tripacel®	SP
		Tripacel® Hybrid	
Combined Diphtheria and Tetanus Toxoids, acellular Pertussis, Hepatitis B (recombinant), Inactivated Poliomyelitis and adsorbed conjugated <i>Haemophilus influenzae</i> type b	DTaP-HB-IPV-Hib	Infanrix hexa™	GSK
Combined Diphtheria and Tetanus Toxoids, acellular Pertussis, Hepatitis B (recombinant), Inactivated Poliomyelitis	DTaP-HB-IPV	Pediarix™	GSK
<i>Haemophilus b</i> conjugate vaccine reconstituted with Diphtheria and Tetanus Toxoids and Acellular Pertussis vaccine adsorbed	DTaP-Hib	Actace ™	SP
		ACTacel®	
		ACTacel® Hybrid	GSK
		Infanrix™ -Hib	
Diphtheria and Tetanus Toxoids, Acellular Pertussis vaccine adsorbed, combined with Inactivated Poliomyelitis	DTaP-IPV	Infanrix™ -IPV	GSK
		Quadracel®	SP
Diphtheria and Tetanus Toxoids and acellular Pertussis vaccine adsorbed combined with Inactivated Poliomyelitis vaccine and <i>Haemophilus influenzae</i> type b	DTaP-IPV-Hib	Infanrix™ -IPV/Hib	GSK
		Pediacel®	SP
Hepatitis A	HA	Avaxim®	SP
		Avaxim® - Pediatric	
		Havrix® 1440	GSK
		Havrix® 720 (Junior)	
Hepatitis A and B	HAHB	Vaqta®	MF
		Twinrix®	GSK
Hepatitis A - Typhoid	HA-Typh-I	Twinrix® Junior	
		ViVAXIM®	
Hepatitis B (Thimerosal free)	HB	Enerix®-B	GSK
		Enerix®-B (Pediatric)	
		Recombivax HB®	MF
<i>Haemophilus influenzae</i> type b	Hib	ACT-HIB®	SP
		Hiberix™	GSK
		Liquid PedvaxHib	MF
Human Papillomavirus (Types 16 and 18) recombinant	HPV-2	Cervarix	GSK
Quadrivalent Human Papillomavirus - (Types 6, 11, 16, 18) recombinant	HPV-4	Gardasil®	MF

LIST OF CURRENT VACCINES (con't)

VACCINE	ABBREVIATION	TRADE NAME	MARKET AUTHORIZATION HOLDER
Influenza (Inactivated)	Inf	Fluviral®	GSK
Influenza (Live, attenuated - Intranasal)		Vaxigrip®	SP
		Flumist®	AZC
Influenza (Thimerosal free)		Agriflu®	NVD
		Fluad®	NP
		®Influvac®	API
		Intanza™	SP
Inactivated Poliomyelitis	IPV	Imovax® Polio	SP
Japanese Encephalitis	JE	IXIARO®	NP
Meningococcal - Conjugate	Men-C-C	Meningitec™	Pfizer
		Menjugate®	NVD
		NeisVac-C®	GSK
	Men-C-ACYW-135	Menactra®	SP
		Menveo™	NP
Meningococcal - Polysaccharide	Men-P-ACYW-135	Menomune® - A/C/Y/W-135	SP
Measles, Mumps and Rubella	MMR	MMR® II	MF
		Priorix®	GSK
Measles, Mumps, Rubella and Varicella	MMRV	Priorix-Tetra®	GSK
Pneumococcal - Conjugate - valent	Pneu-C-7	Pevnar®	Pfizer
	Pneu-C-10	Synflorix™	GSK
	Pneu-C-13	Pevnar® 13	Pfizer
Pneumococcal - Polysaccharide - valent	Pneu-P-23	Pneumovax® 23	MF
		Pneumo 23®	SP
Rabies	Rab	Imovax® Rabies	SP
		RabAvert®	NP
Rotavirus	Rot-1	Rotarix™	GSK
	Rot-5	RotaTeq™	MF
Tick-borne Encephalitis	TBE	FSME-IMMUN	Bax
Tetanus Toxoid, reduced diphtheria toxoid and acellular pertussis	Tdap	Adacel®	SP
		Boostrix™	GSK
Tetanus Toxoid, reduced diphtheria toxoid and acellular pertussis combined with Inactivated poliomyelitis	Tdap-IPV	Adacel® -Polio	SP
		Boostrix®- Polio	GSK
Tetanus and diphtheria toxoids adsorbed and Inactivated Poliomyelitis	Td-IPV	Td Polio Adsorbed	SP
Typhoid - Injection	Typh-I	Typherix™	GSK
		Typhim Vi®	SP
Typhoid - Oral	Typh-O	Vivotif® (capsules)	CV
Varicella	Var	Varilrix™	GSK
		Varivax® III	MF
Yellow Fever	YF	YF-Vax®	SP
Zoster	Zos	Zostavax®	MF

ACRONYMS:

API = Abbott Products Inc.

AZC = AstraZeneca Canada

Bax = Baxter Corporation

CV = Crucell Vaccines Inc

GSK = Glaxo Kline Smith

MF = Merck Frosst

NP = Novartis Pharmaceuticals Canada Inc.

NVD = Novartis Vaccines and Diagnostics

Pfizer = Pfizer Canada Inc.

Solv = Solvay Pharma

SP = Sanofi Pasteur

For additional information on each of the vaccines please refer to the Canadian National Immunization Guide at: www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

APPENDIX III

NATIONAL CASE DEFINITION OF AEFIS OF SPECIAL INTEREST

PREAMBLE: KEY CAVEATS

- The Canadian AEFI case definitions are intended for purposes of AEFI classification and analysis, not to govern management/therapeutic decisions.
- Having standard case definitions for AEFI facilitates vaccine safety monitoring on a global scale from pre-licensure studies to post-marketing surveillance. Canada is a founding member of the WHO Programme for International Drug Monitoring (since 1968) and shares AEFI report data in an effort to identify new adverse reaction signals.
- Where possible, AEFI case definitions have been based on published Brighton Collaboration case definitions (see attached description of Brighton and process to develop case definitions).
- AEFI reporters need not worry about classifying cases according to diagnostic level, nor do they need to know the definition. The 2008 AEFI form revision and accompanying user manual have been designed to incorporate, as much as possible, the case definition requirements.
- Given the need for both clarity and simplicity in spontaneous AEFI reporting each case definition has been based on a single level of diagnostic certainty. Inherent in choosing a single level is a goal for AEFI reports to include enough detail to meet the case definition as often as possible. It is understood, however, that this is a long term goal, and in the meantime AEFI reports will be accepted whether they meet the case definition or not. Annual analyses will include a description of the proportion of reports that meet each level of diagnostic certainty and those that fail to meet any level of diagnostic certainty. These analyses will inform efforts to either improve the quality of AEFI report data and/or to revise national case definitions as appropriate.
- Many of the defined AEFI include those that have previously required a physician diagnosis for reporting purposes (e.g. encephalitis, Guillain-barre syndrome). This concept remains and has been incorporated into the case definition terminology.

Abscess at the injection site (based on Brighton level 2, Vaccine 2007; 25:5821-38)

A confirmed¹ localized collection of material in subcutaneous tissue, fat, fascia or muscle at the site of immunization. Depending on the availability of case details the abscess may be further classified as due to infectious etiology², a sterile abscess³ or indeterminate.

1. The localized collection must be confirmed in one of three ways:
 - Spontaneous or surgical drainage of material from the mass
 - Demonstration of material by an imaging technique (such as ultrasound, CT or MRI)
 - Presence of palpable fluctuance (defined as a wavelike motion on palpation due to liquid content).
2. Material from abscess known to be purulent OR one or more signs of localized inflammation (erythema, pain to light touch, warmth to touch) with evidence of improvement related to antimicrobial therapy.
3. Material from abscess known to be non-purulent OR absence of localized signs of inflammation OR failure to improve on antimicrobial therapy.

Cellulitis at the injection site (based on Brighton level 2, Vaccine 2007; 25:5803-20)

An acute, infectious, expanding inflammatory condition of the skin, located in subcutaneous tissue, fat, fascia or muscle at the vaccine injection site that has been diagnosed as cellulitis by a qualified healthcare provider and which is characterized by at least 3 of the following local signs or symptoms: pain or tenderness to touch, erythema, induration or swelling, warmth to touch.

Anaphylaxis (based on Brighton level 2; Vaccine 2007; 25:5675-84)

A clinical syndrome, characterized by sudden onset and rapid progression of signs and symptoms which include at least one major skin/mucosal¹, respiratory², or cardiovascular³ manifestation and at least one more manifestation from a different organ system. Evidence of involvement of a second organ system can be a major manifestation¹⁻³ OR a minor skin/mucosal⁴, respiratory⁵, cardiovascular⁶ or gastrointestinal⁷ manifestation OR laboratory confirmation of an elevated serum mast cell tryptase.

1. Generalized urticaria OR generalized erythema OR generalized pruritus with rash OR angioedema.
2. Stridor OR bronchospasm OR visible upper airway swelling OR ≥ 2 signs of respiratory distress [tachypnea, chest wall recession, cyanosis, grunting, increased use of respiratory muscles].
3. Measured hypotension OR ≥ 3 signs of uncompensated shock [tachycardia, reduced central pulse volume, capillary refill time > 3 seconds, decreased level of consciousness].
4. Urticaria only at the injection site OR generalized prickle sensation OR generalized pruritus without skin rash OR red and itchy eyes.
5. Persistent dry cough OR hoarse voice OR sensation of throat closure OR sneezing OR rhinorrhea OR difficulty breathing in the absence of wheeze OR stridor OR.
6. ≥ 2 Signs of uncompensated shock [tachycardia, reduced central pulse volume, capillary refill time > 3 seconds, decreased level of consciousness].
7. Diarrhoea OR abdominal pain OR nausea OR vomiting.

Generalized convulsive seizure (based on Brighton level 2; Vaccine 2004; 22:557-62)

An episode of unconsciousness accompanied by generalized motor manifestations that may be tonic, clonic, tonic-clonic or atonic.

Aseptic meningitis (based on Brighton level 2; Vaccine 2007; 25:5793-5802)

An acute illness, diagnosed by a physician as meningitis, with cerebrospinal fluid test results showing pleocytosis, negative gram stain and either no bacterial culture done, or negative bacterial culture in the event that antibiotics were started prior to obtaining the CSF sample. *NOTE:* where available a negative PCR or other validated nucleic acid test may substitute for a negative gram stain.

Guillain-Barré Syndrome (GBS)

(based on Brighton level 1B; Vaccine 2011; 29: 599-612)

An illness, diagnosed by a physician as GBS, that includes acute onset of bilateral flaccid weakness/paralysis of the limbs with decreased or absent deep tendon reflexes and electrophysiologic findings consistent with GBS. CSF test results, if available, must either be normal, or, have <50 wbc/mm³. The evolution of illness is monophasic with a maximum degree of weakness reached from 12 hours to 28 days after onset, followed by a clinical plateau and then either improvement or death.

Encephalitis (based on Brighton level 3; Vaccine 2007; 25:5771-92)

An illness, diagnosed by a physician as encephalitis, in which there is at least one listed indicator of central nervous system inflammation¹ AND either >24 hours depressed or altered consciousness with one or more signs of reduced responsiveness² or one OR more signs of focal or multi-focal central nervous system abnormality³.

1. Indicators of central nervous system inflammation

- Fever $\geq 38.0C$
- CSF pleocytosis (>15 wbc/mm³ if <2 months old; $>5WBC/mm^3$ if ≥ 2 months)
- EEG findings consistent with encephalitis
- Neuroimaging consistent with encephalitis.

2. Signs of reduced responsiveness (global cerebral dysfunction)

- Decreased or absent response to environment as defined by response to loud noise or painful stimuli
- Decreased or absent eye contact
- Inconsistent or absent response to external stimuli
- Decreased arousability
- Seizure associated with loss of consciousness.

3. Signs of focal or multifocal central nervous system abnormality

- Focal cortical signs (e.g. aphasia, alexia, agraphia, cortical blindness)
- Cranial nerve abnormality/abnormalities
- Visual field defect(s)
- Presence of primitive reflexes (e.g. Babinski's sign, sucking reflex)
- Motor weakness (diffuse or focal)
- Sensory abnormalities (positive or negative)
- Altered deep tendon reflexes (asymmetry, hypo/hyperreflexia)
- Cerebellar dysfunction (e.g. ataxia, dysmetria, cerebellar nystagmus).

Myelitis (based on Brighton level 3; Vaccine 2007; 25:5771-92)

An illness, diagnosed by a physician as myelitis, in which there is clinical evidence of myelopathy accompanied by at least one indicator of spinal cord inflammation¹.

1. Indicators of central nervous system inflammation

- Fever $\geq 38.0\text{C}$
- CSF pleocytosis ($>15 \text{ WBC/mm}^3$ if <2 months old; $>5 \text{ WBC/mm}^3$ if ≥ 2 months)
- Neuroimaging demonstrates acute inflammation (\pm meninges), or spinal cord demyelination.

Acute disseminated encephalomyelitis (ADEM) (based on Brighton level 3; Vaccine 2007; 25:5771-92)

An illness, diagnosed by a physician as acute disseminated encephalomyelitis, in which there are one or more focal or multifocal findings referable to the central nervous system¹.

1. Signs of focal or multifocal central nervous system abnormality

- Depressed or altered level of consciousness, lethargy or personality change lasting >24 hours
- Focal cortical signs (e.g. aphasia, alexia, agraphia, cortical blindness)
- Cranial nerve abnormality/abnormalities
- Visual field defect(s)
- Presence of primitive reflexes (e.g. Babinski's sign, sucking reflex)
- Motor weakness (diffuse or focal)
- Sensory abnormalities (positive or negative)
- Altered deep tendon reflexes (asymmetry, hypo/hyperreflexia)
- Cerebellar dysfunction (e.g. ataxia, dysmetria, cerebellar nystagmus).

Hypotonic-Hyporesponsive Episode (HHE) (based on Brighton level 1, Vaccine 2007; 25:5875-81)

The sudden onset, in a child aged less than 2 years, of hypotonia AND either hyporesponsiveness or unresponsiveness AND either pallor or cyanosis.

Persistent crying (based on Brighton level 1, Vaccine 2004; 22:586-91)

Crying of infants and children that is continuous unaltered and lasts for three or more hours.

Intussusception (based on Brighton level 2, Vaccine 2004; 22:569-74)

An acute illness, diagnosed by a physician as intussusception, in which there is evidence of intestinal obstruction¹ and/or invagination² and/or vascular compromise³. If only one of these three is present at least 3 of the following must also be present: <1 year old male; abdominal pain; lethargy, pallor, hypovolemic shock, non bile-stained vomiting, non-specific gas pattern on a plain abdominal radiograph.

1. History of bile-stained vomiting AND either examination findings of acute abdominal distension and abnormal OR absent bowel sounds or plain abdominal radiograph showing fluid levels and dilated bowel loops.
2. Presence of ≥ 1 of: abdominal mass; rectal mass; intestinal prolapse; visible intussusceptum or soft tissue mass shown on plain abdominal radiograph OR abdominal ultrasound OR abdominal C.
3. Presence of ≥ 1 of: passage of blood per rectum; passage of a stool containing "red currant jelly" material; blood detected on rectal examination.

Thrombocytopenia (based on modified Brighton level 1; Vaccine 2007; 25:5717-24)

A platelet count of less than $150 \times 10^9/\text{Liter}$, accompanied by clinical signs and/or symptoms of spontaneous bleeding.

Rash (based on Brighton level 3; Vaccine 2007; 25:5697-5706)

A skin or mucosal change that followed immunization, and that is either new, or an exacerbation of a previous condition. *NOTE:* while a morphologic description of the rash is not required it is preferred when possible, using standard terms.

Mucocutaneous lesions (pictures can be found at www.dermatologylexicon.org)

- **Bulla:** a fluid-filled cavity or elevation ≥ 1 cm in diameter. Fluid can be clear, serous, hemorrhagic, or pus-filled.
- **Cyst:** A closed cavity or sac containing fluid or semisolid material. A cyst may have an epithelial, endothelial or membranous lining.
- **Macule:** A flat, generally < 0.5 Cm area of skin or mucous membranes with different colour or texture from surrounding tissue.
- **Nodule:** A dermal or subcutaneous, firm, well-defined lesion.
- **Papule:** A discrete, solid, elevated body usually < 0.5 Cm in diameter. Papules are further classified by shape, size, color and surface change.
- **Plaque:** A discrete, solid, elevated body usually broader than it is thick measuring > 0.5 Cm in diameter. Plaques may be further classified by shape, size, color, and surface change.
- **Pustule:** A superficial vesicle containing a cloudy or purulent fluid. Pustules are usually < 0.5 Cm in diameter.
- **Vesicle:** Fluid filled cavity or elevation < 1 cm diameter. Fluid may be clear, serous, or hemorrhagic.
- **Wheal (hive):** An edematous transitory papule or plaque.

Secondary mucocutaneous changes

- **Erosion:** A localized loss of the epidermal or mucosal epithelium.
- **Crusting:** Dried exudates of plasma.
- **Scaling:** Whitish scales or flakes are present on the skin.
- **Atrophy:** Thinning or absence of the dermis or subcutaneous fat.
- **Excoriations:** Oval or linear depressions in the skin with complete removal of the epidermis, exposing a broad section of red dermis.
- **Fissures:** Linear, wedge-shaped cracks in the epidermis which may extend down to the dermis.
- **Ulcer:** A circumscribed loss of the epidermis or mucosa extending to dermis.

Arthritis (modified from previous Canadian definition; ccdr 2002; 28 S6, p 22)

Evidence of joint inflammation¹ lasting at least 24 hours and/or requiring hospitalization

1. By joint swelling, pain, redness and/or sensation of warmth.

Parotitis (unchanged from previous Canadian definition – CCDR 1995; 21-13: page f-8)

Swelling with pain and/or tenderness of parotid gland(s).

Oculo-Respiratory Syndrome (ORS) (unchanged from previous Canadian definition; there is no published Brighton Collaboration definition)

Level 1 – *Coding definition as of September 2004 (PHAC case definition);*

The presence of “bilateral red eyes” plus ≥ 1 of the seven respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) that starts within 24 hrs of vaccination, with or without facial oedema (no restriction for duration).

Level 2 – *NACI case definition;*

The onset of bilateral red eyes and/or respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) and/or facial swelling occurring within 24 hours of influenza immunization.