

**User Guide:
Report of Adverse Events Following Immunization (AEFI)**

User Guide: AEFI Report Form

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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 Division of Surveillance and Outbreak Response 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 injection 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 following criteria:

- **Is of a serious nature:** A serious adverse event is one that is life threatening or results in death, requires hospitalization or prolongation of an existing hospitalization, results in residual disability or causes congenital malformation.
- **Requires urgent medical attention.**
- **Is unusual or unexpected:** 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 unusual or unexpected

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events, please refer to the Canadian Immunization Guide which can be accessed on-line at <http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php>.

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 personal identifying information has been removed. On occasion, reports may be submitted directly to PHAC by vaccine manufacturers, 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 systems. 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 (VSWG) 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 will be introduced early in 2009 in most but not all provinces and territories. The form itself, along with information regarding its implementation in Canada, will be published on the Web at http://www.phac-aspc.gc.ca/im/ae-fi-form_e.html. 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.

B. General Overview:

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.

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).

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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).

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

Incorrect route: The vaccine was administered via an incorrect route of administration (e.g., subcutaneous vs. intramuscular).

Wrong vaccine given: An unintended vaccine was administered.

Other: If an error has occurred that is not accurately reflected in the list of provided errors, please choose “other” and provide all details in section 10.

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 all details of 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 reported AEFI by checking all that apply. All additional pertinent details (e.g., associated fever, medical investigation, 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 **must be diagnosed by a physician** and thus a corresponding definition has not been provided within the body of this document. Refer to Appendix III for national case definitions of AEFIs of special interest.

For all AEFIs, indicate the time to onset and the duration of signs and symptoms.

Time to onset and duration of signs and symptoms: The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented according to the following guidelines for all AEFIs:

- If the time to onset or the time to resolution is less than one (1) hour, record in minutes.
- If the time to onset or the time to resolution is greater than or equal to one (1) hour, but less than one (1) day, record in hours.
- If the time to onset or the time to resolution is greater than or equal to one (1) day, record in days.

Section 9a: Local reaction at or near injection site

Indicate, by choosing all that apply any local reactions at or near the injection 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

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 injection site with discrete or well demarcated borders in the absence of abscess^a formation, erythema and warmth (based on Brighton Collaboration definition; Vaccine 2004; 22:575-85).

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

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

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 injection 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.

For all local reactions at or near the injection 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 injection of an injected limb that is assessed by any person (based on Brighton Collaboration definition; Vaccine 2007; 25:5858-74).

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 (based on Brighton Collaboration definition; Vaccine 2007; 25:5839-57).

Rash: a temporary eruption on the skin.

Largest diameter of injection site reaction: Indicate the diameter (in centimetres) of the largest injection 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 (excerpted from the Brighton Collaboration definition; Abscess; Vaccine 2007; 25:5821-38).

Fluid collection shown by imaging technique: An imaging device is used in the detection of fluid collection (e.g., ultrasound, MRI and/or x-ray).

^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.

Spontaneous drainage: Draining of fluid from a site without intervention. When available, provide all gram stain/culture results in section 10.

Surgical drainage: Withdrawal of fluids from the site through needle aspiration or incision which could be complete or partial (excerpted from the Brighton Collaboration definition; Abscess; Vaccine 2007; 25:5821-38). When available, provide all gram stain/culture results in section 10.

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 injection site (e.g., inguinal adenopathy when associated with an IM injection in the thigh, axillary adenopathy associated with an IM injection in the deltoid, etc.).

Section 9b and 9c: Anaphylaxis and other allergic events

For all allergic reactions (anaphylaxis or other allergic event), indicate the affected body system and the associated sign(s) and symptom(s), as described below. Provide all additional details in section 10.

“**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. The national case definition for anaphylaxis is available in appendix III. 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.

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

Skin/mucosal: choose all that apply from the list provided.

Note: Generalized means involving skin/mucosal areas separate from the injection site. The whole body does not have to be involved.

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 injection 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). Check both “Generalized Urticaria” and “Injection Site Urticaria” if applicable.

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.

Red AND itchy eyes: Eyes showing dilatation of conjunctival, episcleral or ciliary blood vessels with a sensation that provokes the desire to rub and/or scratch to obtain relief.

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 tongue, uvula, throat or larynx. It is important that the swelling is confirmed by visual

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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 in section 10.

Cardio-vascular:

Choose all that apply from the list provided.

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
>12 y (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.

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

Respiratory:

Indicate all that apply by choosing from the list provided (described in detail 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.

Gastrointestinal:

Choose all that apply from the list provided (described in detail below):

Diarrhea: Abnormally frequent discharge of loose and/or watery fecal matter from the bowel. Please provide details in section 10.

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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. Please provide details in section 10.

Section 9d: Neurologic events

Indicate, by choosing all that apply from the list provided all neurologic events.

***Meningitis**: Must be diagnosed by a physician. Document the results of any cerebrospinal fluid investigations and pertinent details in section 10.

***Encephalopathy/Encephalitis**: Must 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 in section 10.

***Guillain-Barre Syndrome**: Must 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*, in section 10.

***Bell's Palsy**: Must be diagnosed by a physician. Provide any pertinent details in section 10.

***Other Paralysis**: Must be diagnosed by a physician. Provide all pertinent details in section 10.

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 of generalized convulsive seizure based on the Brighton Collaboration definition; Vaccine 2004; 22:557-62).

***Other Neurologic Diagnosis**: Specify and provide all details in section 10.

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, lethargy or personality change lasting > 24hours: Altered sense of awareness of self and of the environment, abnormal drowsiness or 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 ($\geq 38.0^{\circ}\text{C}$ or $\geq 100.4^{\circ}\text{F}$): A temperature of $\geq 38.0^{\circ}\text{C}$ or 100.4°F 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).

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

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 preceded by a myoclonic jerk and precipitated by hyperventilation (in the absence of HHE, syncope, or myoclonic jerks).

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

Febrile: With fever of $\geq 38.0^{\circ}\text{C}$ or 100.4°F .

Afebrile: Without fever.

Unknown type: It is unknown if the seizure was febrile or afebrile. Provide any known details in section 10.

Section 9e: Other defined events of interest

Hypotonic-Hyporesponsive Episode: Sudden onset, in a child aged less than two years, of hypotonia (limpness), reduced responsiveness and either pallor or cyanosis (based on Brighton Collaboration definition; Vaccine 2007; 25:5875-81.). 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 in section 10.

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 (as excerpted from the Brighton Collaboration definition; HHE; Vaccine 2007; 25: 5875-5881).

Persistent crying: Crying which is continuous, unaltered and lasts for 3 or more hours (based on Brighton Collaboration definition; Vaccine 2004; 22:586-91).

Rash: A skin or mucosal change that is either new or an exacerbation of a previous condition (based on Brighton Collaboration definition; Vaccine 2007; 25:5697-5706). Choose the best descriptor from the list provided below that is most representative of the event. For rash localized to the injection site, capture in section 9a. For rash associated with allergic reaction, capture in section 9b/c.

When possible provide a written description of the rash in section 10 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-injection site: Eruption localized at another part of the body, away from the injection site.

* **Intussusception:** the prolapse of one part of the intestine into the lumen of an immediately adjacent part, causing partial or complete intestinal obstruction. Must be diagnosed by a physician. Provide all pertinent details in section 10.

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

* **Thrombocytopenia**: Must be diagnosed by a physician. A platelet count of less than 150×10^9 /liter accompanied by clinical signs and/or symptoms of spontaneous bleeding (based on Brighton Collaboration definition; Vaccine 2007; 25:5717-24). Indicate the lowest platelet count on the AEFI form and provide any additional pertinent details in section 10.

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

Oculo-Respiratory Syndrome (ORS): A set of signs/symptoms of both the eyes and respiratory system following vaccination with influenza vaccine. Choose all that apply to the reported AEFI from the list provided below:

Bilateral red eyes: Both eyes showing dilatation of conjunctival, episcleral or ciliary blood vessels.

Cough: Rapid expulsion of air from the lungs to clear the lung airways.

Wheeze: A whistling, squeaking, musical, or puffing sound made on exhalation by air passing through the fauces, glottis, or narrowed tracheobronchial airways.

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.

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

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Facial swelling: the build-up of fluid in the tissues of the face (forehead, eyes, nose, mouth, cheeks, chin).

Fever ($\geq 38.0^{\circ}\text{C}$ or $\geq 100.4^{\circ}\text{F}$): A temperature of $\geq 38.0^{\circ}\text{C}$ or 100.4°F in conjunction with any other reportable event other than a neurological event.

Other severe or unusual event(s) not listed above:

Provide any pertinent 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 Further Immunization

This section is to be completed by the health professional that is providing the future recommendation(s) for further immunization(s).

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/MHO: Medical Officer of Health/Medical Health Officer; MD: Medical Doctor; RN: Registered Nurse). If your professional status is not listed, describe under other. 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)

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.