Saskatchewan User Guide for Completion and Submission of Adverse Events Following Immunization (AEFI) Reports

May 2021

Saskatchewan

Table of Contents

The Saskatchewan Ministry of Health thanks the BCCDC for permission granted to adapt its *User Guide for Completion and Submission of Adverse Events Following Immunization (AEFI) Reports* (2019).

Purpose and Introduction

This user guide is a guidance document for 811, and community and public health healthcare workers to report an Adverse Event Following Immunization (AEFI) in Saskatchewan using the national AEFI case report form. An AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the administration of the vaccines. The AEFI may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. As per *The Communicable Disease Regulations*, an immunizer/healthcare professional informed of an AEFI must report it to local public health for review by a medical health officer (MHO). For additional information on AEFI reporting criteria, clinical management, interpretation and reporting of AEFIs, refer to the *Saskatchewan Immunization Manual* chapter 11: https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter11.pdf.

AEFI associated with non-vaccine pharmaceuticals

The national AEFI case report form is specifically for recording and reporting adverse events following receipt of vaccines (active immunizing agents). Adverse events related to passive immunizing agents (immunoglobulins) and TB skin tests (Tuberculin Purified Protein Derivative – Mantoux - Tubersol™) are reported directly to Health Canada.

If an AEFI occurs in an individual who received both a vaccine and a passive immunizing agent or TB skin test at the same day, and the health care provider is uncertain about which product was causally associated with the event, the event should be reported as a vaccine-related AEFI. When reporting the AEFI, include details of the concomitant TB skin test or immunoglobulins as concomitant medication(s) in the medical history section of the national AEFI form.

Should all AEFIs be reported?

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

Which AEFIs should be reported?

AEFIs that must be reported include the following:

- serious events: life threatening or resulting in death; requiring hospitalization; resulting in a residual disability; associated with congenital malformation;
- event requiring urgent medical attention;
- unusual or unexpected events:
  - The event that has either not been identified previously [e.g., Oculo-Respiratory Syndrome (ORS) was first identified during the 2000/2001 influenza season], or
  - The event has been identified but is occurring with greater frequency in the population (e.g., extensive local reactions).
- events which the client's health care provider considers to confer precautions, contraindications or a reason to postpone a future immunization;
- all events managed as anaphylaxis;
- all neurological events including febrile and afebrile convulsions;
- other allergic events;
- clusters of events: known or new events that occur in a geographic or temporal cluster (e.g., six in a week, or six in a regional area) that require further assessment, even if the total number of AEFIs may not be higher than expected;

- **Note:** A causal relationship between receipt of a vaccine(s) and an AEFI does not need to be proven. **Refer to Appendix 1: Summary of Reporting Criteria for more information.**

Events that should not be reported:

- Any event:
  - which follows immunization that is a common side effect (i.e. listed on the vaccine fact sheet);
  - has been clearly attributed to other causes (e.g. related to a concurrent illness); **or**
  - does not meet reporting criteria (e.g., not serious such as mild vomiting or diarrhea, temporal relationship incompatible with association with vaccine receipt, death attributed to another cause post-autopsy) should not be reported as an AEFI.
- Expected local injection site reactions and non-specific systemic reactions (e.g., headache, myalgia, lethargy) **should not be** reported as AEFIs **unless** these are more frequent or severe than expected based on clinical trial findings (rates and severity are typically found in the product monographs), or based on the judgement of the health care professional familiar with the side effect profile of the particular vaccine. **Reactions such as 'COVID arm', (a delayed local reaction (4-8 days post-immunization with swelling, pain, erythema and tenderness that resolves on its own within a week), has become a known AEFI that affects about 1% of the population and does not need to be reported.**
- If a client or healthcare provider notifies 811 or public health of an event that does not meet AEFI reporting criteria, **DO NOT REPORT it to the Ministry of Health.** Such events may be documented in Panorama client notes, etc., and the client should be counselled about expected reactions following immunization and how to manage these reactions.

National AEFI form completion instructions

1. Identifying information

1a. Unique Episode # and Region #
A unique episode number and region number is assigned to each AEFI report upon submission to Public Health as per Chapter 11 in the Saskatchewan Immunization Manual: https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter11.pdf.

1b. Region #

2. IMPACT Local Inventory Number (LIN) – For AEFI received from IMPACT only

Unique identifier assigned to a client identified as an AEFI through the Jim Pattison Children's Hospital IMPACT site. Provide this number if the report was received from IMPACT; otherwise leave blank. The number is used by the Public Health Agency of Canada to reconcile reports received both from the province and from IMPACT directly.

Initial or follow up report
It is important to indicate whether this report is an initial report for this unique identifier or a follow-up report for this unique identifier.

3. Patient identification information

Enter the client's complete legal name, health card number, address including community of residence, and telephone number. Address of residence determine the public health unit responsible for management, follow-up, and reporting of the AEFI.

Information Source
Source of information can be the client, the immunizer (Public Health Nurse [PHN], physician, pharmacist), or a secondary source such as parent of a child recipient. If source of information is different from the reporter or client, provide their name, relation to the patient and contact information.

4. Information at time of immunization and AEFI onset

4a. Identify the province or territory where the immunization was administered; the date the vaccine(s) was administered at a single visit, the client's date of birth, their age and their sex. If a woman is pregnant at the time of immunization, the gestational age is noted as weeks and days (as applicable).

4b. Medical history (up to time of AEFI onset)
Indicate the client's medical history prior to the time of AEFI onset by choosing all of options that apply in the list below and provide details in the comment box.

- **'Concomitant medication(s)':** Provide name of all medications, including prescription, over the counter and herbal supplements, which the client had been taking immediately prior to the time of AEFI onset. When available, provide the dose, frequency, route of administration and reason for taking each concomitant medication. If a passive immunizing agent or TB skin test was administered at the same visit as the vaccine(s) provide the details of the passive immunizing agent or TB skin test, including lot number when available.
- **'Known medical conditions/allergies':** Indicate all known medical conditions and/or allergies, including pregnancy, that the client experienced prior to the time of immunization with a corresponding date/month/or year of onset. Include any conditions

for which the client is taking a concomitant medication including chronic conditions with intermittent symptoms such as migraine headaches.

- **'Acute illness/injury':** Indicate if client had an acute illness and/or injury immediately prior to the time of immunization and specify a corresponding date/month/or year of onset.

4c.Immunizing agent

Provide all information pertaining to the vaccine(s) administered prior to the onset of the reported AEFI. Any concomitant passive immunizing and/or diagnostic agent(s) should be reported in medical history, **not** the immunization data section.

When completing this section, provide all information as outlined below for one immunization event:

- **'Immunizing agent(s)':** Please record the proper name or abbreviation as outlined in chapter 11 of the SIM https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter11.pdf.
- **'Trade name':** Indicate the trade name of all vaccine(s) received.
- **'Manufacturer':** Specify the name of the manufacturer as indicated on the product label.
- **'Lot number':** Legibly document the complete lot number including all letters and numbers. This information is essential for conducting future risk assessments or vaccine safety signal tracking.
- **'Dose number':** Provide the number in series (1, 2, 3, 4, or 5), if known. For the Influenza vaccine, the Dose Number should ordinarily be recorded as one, unless the client receives more than one dose in one season, which is then recorded accordingly.
- **'Dosage/unit':** Indicate the dose volume administered for each vaccine in units of volume (e.g., 0.5 millilitre or 0.5/ml).
- **'Route':** Specify the route of administration for each vaccine received (e.g., IM, SC, ID, IN, PO).
- **'Site':** Indicate the injection site for each vaccine administered (e.g., LA, RA, Nose, Mouth).

All of the immunizations given at the same appointment may be associated with the reported event(s). If it was a local reaction at an injection site, it is still important to indicate all vaccines received that visit. If the client had a systemic reaction(s), all vaccines administered at that appointment should be selected (even if client also had a local reaction associated with only one of the vaccines).

If multiple episodes of an adverse event are reported by a client during one communication with a reporter (i.e., that occurred following multiple prior immunization appointments (e.g., after two, four, and six month vaccines), separate AEFI reports should be created for each episode, indicating follow up reports with the same unique identifier as appropriate.

5. Immunization errors: Did this AEFI follow an incorrect immunization?

Indicate whether the AEFI followed an incorrect immunization by choosing one of '**No', 'Unknown', or 'Yes'. If yes, choose all of the following options that apply and provide details 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.
- **'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 a route not recommended for its administration (e.g., subcutaneous vs. intramuscular).
- **'Wrong vaccine given':** An unintended vaccine was administered.
- **'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.

- **'Other':** An error has occurred that is not accurately reflected in the list of provided errors. Provide all details in the corresponding comment box.

4. **6. Previous AEFI: Did an AEFI follow a previous dose of any of the immunizing agents associated with this AEFI report?**

   Indicate whether the client had ever experienced an AEFI following a previous dose of any of the vaccines associated with this AEFI report. Choose <u>one</u> of the values listed below.

   - **'No':** Previously immunized with one or more of the vaccines associated with this report and had not experienced a subsequent AEFI.
   - **'Not applicable (No prior dose)':** Never previously immunized with any of the vaccines associated with this report.
   - **'Unknown':** It is unknown if the client previously received any of the associated vaccines and/or if an AEFI followed.
   - **'Yes':** Previously immunized with one or more of vaccines associated with this report and experienced a subsequent AEFI. If the answer is yes, provide as much detail of the prior AEFI in section 10 including onset and duration, AEFI details, severity of AEFI, whether event was less or more severe than the event following the current dose, dose number, and date of vaccination.

7. Impact of AEFI, outcome, and level of care obtained

7a.Highest impact of AEFI

Indicate the highest impact of the AEFI to the client's daily activities, definitions of daily activities differ between adult (work, exercise, social commitment, etc.) and child (eating, sleeping, playing, etc.).

Choose from: **'Did not interfere with daily activities'**, **'Interfered with but did not prevent daily activities'**, or **'Prevented daily activities'.**

7b.Outcome at time of report

Indicate the outcome of the AEFI at the time of completion of the report**. It is important to complete this section just before submitting to Public Health as the client's status may have changed.**

- **'Fatal'**: Client died. Record the date of death (if known) or date at which found out about fatal outcome (if date of death unknown) in the respective date field.
- **'Permanent disability/incapacity'**: An injury that 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.
- **'Fully recovered'**: All signs and symptoms have resolved. Duration fields for the appropriate section(s) should be complete for this outcome.
- **'Not yet recovered'**: Residual signs and/or symptoms remain at the time of completion of the report. Select this if at least one of the reported AEFIs is unresolved.
- '**Unknown'**: The outcome of the AEFI is unknown (e.g., client lost to follow-up) or unclear.

7c.Highest level of care required

Indicate the highest level of care obtained for the reported AEFI by selecting one of the provided response options:

- **'Admitted to hospital':** Must have been admitted to hospital, not seen on an outpatient basis or only visited ER. If hospitalized, enter admission and discharge dates for analysis of length of stay, which is used as a seriousness criterion.
- '**Emergency visit':** The client was seen by a health care professional for an emergency visit for the assessment and/or treatment of the reported AEFI. Emergency visits are not considered admission to hospital and therefore, admission and discharge dates are not required.

- **'Non urgent visit'**: 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.
- **'Resulted in prolongation of existing hospitalization'**: Patient was already in hospital at the time of immunization and the AEFI resulted in a longer hospital stay. Indicate the number of additional days stayed in hospital as a result of the AEFI.
- **'Telephone advice from a health professional**': The client received telephone advice from a health care professional (e.g., nurse, nurse practitioner, physician, etc.) regarding the reported AEFI.
- **'None'**: No care was received for the reported AEFI.
- **'Unknown'**: It is unknown if the patient received care for the reported AEFI. None: Telephone advice from a health professional.

Provide any additional pertinent details in the section 10.

7d.Treatment received

Indicate whether the patient received any treatment, including self-treatment, for the reported AEFI by choosing **'No'**, **'Unknown'** or **'Yes'**. Provide details of all treatments received following the onset of the AEFI in section 10.

8. AEFI Reporter Information

Reporter refers to the immunizer/health care provider who received and reported the AEFI information to the public health unit.

Date Reported

Date on which the adverse event was reported from the client to the immunizer/healthcare professional.

Setting

Setting in which the reporter is employed (i.e., '**Physician Office'**, **'Public Health'**, **'Hospital'**, **'Pharmacy'**, **'Workplace Health'**, **'Other'**).

Reporter

Name and title of the immunizer/healthcare professional reporter. Reporter refers to the health care provider who received and reported the AEFI information to the public health unit. Reporter does not refer to other identifiers such as pharmacy or clinic name.

9. AEFI Details

Indicate the details of the AEFI by checking all that apply. Include pertinent details (results of medical investigations, laboratory test results, etc.) in the section 10.

Events with an asterisk (*) must be diagnosed by a physician, or where appropriate and based on current scope of practice by a Nurse Practitioner. If not diagnosed by a physician or nurse practitioner, provide sufficient information to support the selected event(s).

The timeline between vaccination and occurrence of an AEFI is very important as it aids in the assessment of the temporal association. AEFIs which occur outside of these timelines can still be submitted at the reporter's clinical discretion as this may indicate a possible safety signal. 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.

For all AEFIs, indicate the time to onset (time from immunization to onset of first symptom/sign) and the duration (time from onset of first symptom/sign to resolution of all signs and symptoms). If the AEFI is not yet resolved at the time of the report, do not document any duration, and check **'Unresolved'**.

Onset
Interval of time between administration of the vaccine(s) associated with the event and the onset of the first symptoms or signs of the event.

Record minute or hour or day parameter. It is not necessary to record more than one time parameter. Record minutes if event onset < 1 hour post-vaccination, hours if event onset < 24 hours post- vaccination, and days if event onset one or more days post-vaccination. If hours or days are recorded, record the number of **complete** hours or days between vaccine administration and onset of event.

Duration
Interval of time from the onset of the first symptom until all the symptoms resolved. Record minute or hour or day parameter. Leave blank of AEFI is unresolved at time of report submission.

9a. Local reaction at or near vaccination site - For non-allergic local reactions only

Time to **onset** and, unless a not yet recovered or unknown checkbox is selected**, duration** of signs and symptoms are mandatory. The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit (day, hour, or minute).

Indicate the local reactions by choosing all that apply.

- **'Infected abscess*'**: Must be diagnosed by a physician.
- **'Sterile abscess*'**: Must be diagnosed by a physician. **'Cellulitis*':** Must be diagnosed by a physician.
- **'Nodule'**
- **'Reaction crosses joint** - pain or redness or swelling extends past the nearest joint'.
- **'Lymphadenitis*':** Must be diagnosed by a physician.
- **'Other':** Examples of "other" local reactions that may be reported here include necrosis, adenopathy, papule, or pain, erythema or swelling persisting for 10 days or more' etc., **with the exception of COVID arm (see page 3)**. Specify details of the 'other' local reaction being reported in section 10.

For all local reactions at or near the vaccination site, describe the signs and symptoms by selecting all that apply from the list below. At least one local reaction must be selected before selecting any corresponding signs or symptoms.

- **'Swelling'**
- **'Pain' 'Tenderness' 'Erythema' 'Warmth' 'Induration'**
- **'Rash'**
- **'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 if known.
- **'Palpable fluctuance'**: Wavelike motion on palpation due to presence of liquid content.
- **'Fluid collection shown by imaging technique' 'Spontaneous/surgical drainage'**
- **'Microbial results'**: Select "Microbial results" only if the result is positive. Record the laboratory result in the comments field associated with this section (e.g., positive for *S. aureus*).
- **'Lymphangitic streaking'**: Red streaks below the skin's surface that 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, including from COVID-19 vaccines.

- **Provide any additional pertinent details in section 10.**

9b. Allergic and Allergic-like events

The clinical signs and symptoms to be recorded in this section are closely aligned to the Brighton Criteria for anaphylaxis: https://brightoncollaboration.us.

Time to **onset** and, unless a not yet recovered or unknown checkbox is selected, **duration time** of signs and symptoms are mandatory. The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit (minutes, hour or day).

Choose one of the following events in this section:

- **'Anaphylaxis':** Any event **managed** as anaphylaxis following immunization, regardless of how or whether it meets the Brighton Criteria should be reported as anaphylaxis.
- **'Ocular-Respiratory Syndrome (ORS)':** Bilateral red eyes AND respiratory symptoms following **influenza** vaccine.
- **'Other allergic events':** Encompasses all allergic reactions that are neither anaphylaxis nor ocular-respiratory syndrome.

For the allergic event reported, describe the signs and symptoms by selecting all that apply from the list below.

- **'Skin/Mucosal'**
  - **'Generalized'**: A reaction involving in two or more body locations (e.g., both arms) and cannot only affect the injection site. User must select **'Non-injection site'** alone or **'At injection site'** AND **'Non-injection site',** but not **'At injection site'** only. If the event occurred only at the injection site, it should be reported as **'Localized'**.
  - **'Localized'**: An event occurring in only one body location. User must select **'Non-injection site'** only or **'At injection site'** only**,** but not both**.**

    If client has both '**Generalized'** and **'Localized'** skin/mucosal symptoms, use **'Generalized'.**

    Users should select at least one of the following signs and symptoms:
    - **'Urticaria' (hives)**: Localized swelling of superficial layers of skin that is itchy, raised, sharply demarcated, and transient (usually <12 hours).
    - **'Erythema'**: Abnormal redness of the skin without any raised skin lesions.
    - **'Pruritus' (itching)**: An unpleasant skin sensation that provokes the desire to rub and/or scratch to obtain relief.
    - **'Prickly sensation'**: Tingling or smarting (stinging) sensation.
    - '**Flushing'**
    - '**Other Rash**'
- **'Eyes'**: Select **'Red bilateral'**, **'Red unilateral'**, or **'Itchy'** if applicable.
- **'Angioedema'**: Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites which may not be well circumscribed and is usually not itchy. Typical sites in anaphylaxis include tongue, lips, around the eyes (periorbital), eyelids. Do not include hereditary angioedema.

  Angioedema should not be reported **unless** this was a visible objective sign, i.e., provider-observed skin or mucosal swelling. If these are experienced as symptoms (subjective descriptions by the client such as "my tongue feels thick") but not observable as signs, **do not report** 'angioedema'.

Check all the locations where angioedema is seen '**Tongue'**, **'Throat'**, **'Uvula'**, **'Larynx'**, **'Lip'**, **'Eyelids'**, **'Face'**, **'Limbs'**, '**Other'**, if applicable. If **'Other'** is checked, provide details.

- '**Cardiovascular'**
  - **'Measured hypotension':** An abnormally low blood pressure documented by appropriate measurement.
    - Infants and children - low systolic blood pressure (age specific) or >30% decrease in BP.
    - Adults – systolic blood pressure of less than 90mm Hg or >30% decrease from that persons' normal BP.
  - **'Decreased central pulse volume':** Absent or decreased pulse in one of the following vessels – carotid, brachial or femoral arteries.
  - **'Capillary refill time > 3 sec':** The 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 or less.
  - **'Tachycardia':** A heart rate that is abnormally high for age and circumstance.
    - Infants and children- A heart rate that is above the upper limit expected for age:
      - <1 year: 160
      - 1 to 2 years: 150
      - 2 to 5 years: 140
      - 5 to 12 years: 120
      - >12 yrs: 100
    - Adults and adolescents - The term is usually applied to a heart rate >100 beats/min.
  - **'Decreased or loss of consciousness':** Partial suspension of conscious relationship with the outside world as demonstrated by a decreased ability to perceive and respond to verbal, visual or painful stimulus.
- '**Respiratory'**
  - **'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 harsh cry in an infant or vocalisation in a child or adult.
  - **'Sensation of throat closure'**: Feeling or perception of throat closing with a sensation of difficulty breathing.
  - **'Stridor'**: A harsh vibrating sound heard during respiration in cases of obstruction of the air passage.
  - **'Dry cough'**: Rapid expulsion of air from the lungs and not accompanied by expectoration (a non- productive cough) that will not abate during the period of observation including through measures such as taking a sip of water. Can be persistent.
  - **'Tachypnea':** Abnormally rapid breathing which is high for age and level of physical activity
    - Infants and children - A respiratory rate that is above the upper limit expected for age
    - Adults – A respiratory rate in excess of 25 breaths per minute
  - **'Wheezing':** A whistling, squeaking, musical, or puffing sound on expiration (bilateral – both lungs).
  - **'Indrawing/retractions':** Inward movement of the intercostal area upon inspiration.
  - **'Increased use of accessory muscles':**
  - **'Grunting'**: A sudden and short noise with each breath when breathing out.
  - **'Cyanosis'**: A dark bluish or purplish discolouration most easily seen in the facial or perioral area or tongue.

- **'Sore throat':** Discomfort or pain in the throat.
- **'Difficulty swallowing'**: Sensation or feeling of difficulty in the passage of solids and liquids down to the stomach.
- **'Difficulty breathing'**: A sensation of difficulty breathing.
  Note: increased use of accessory muscles should be identified here. Vigorous movement of the muscles of breathing, generally best seen in the lower part of the neck (supra-clavicular or tracheal tug) or below the chest (sub-costal). The movements are usually a sign of difficulty with breathing.
- **'Chest tightness'**: Inability or perception of not being able to move air in or out of the lungs.

- '**Gastrointestinal'**
  Only report GI signs/symptoms associated with an allergic event here. Report isolated GI signs/symptoms in the **'Other Defined Events of Interest'** section.
  - **'Diarrhea'**: Loose or watery stool.
  - **'Abdominal pain'**: Sensation of discomfort or pain in the abdominal region.
  - **'Nausea'**: An unpleasant sensation vaguely referred to the upper abdominal 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.

9c. Neurologic events

Time to **onset** and, unless a not yet recovered or unknown checkbox is selected, **duration time** of signs and symptoms are mandatory. The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit (minutes, hour or day).

Indicate the neurologic event by choosing all that apply.
NOTE: Events with an asterisk (*) must be diagnosed by a physician, or where appropriate and based on current scope of practice, the diagnosis may be made by a Nurse Practitioner.

- **'Meningitis*'** Must be diagnosed by a physician.
- **'Encephalopathy/Encephalitis*'** Must be diagnosed by a physician.
- **'Guillain-Barre Syndrome (GBS)*'** Must be diagnosed by a physician.
- **'Bell's Palsy*'** Must be diagnosed by a physician.
- **'Other Paralysis*'.** Must be diagnosed by a physician. Includes vaccine-associated paralytic poliomyelitis.
- **'Seizure(s)'**. Sudden loss of consciousness in conjunction with involuntary generalized motor manifestations. If seizure is selected, users must provide additional details:
  Select in the sub-box either:
  - **'Focal/Partial'**: Seizure that originates from a localized area of the cerebral cortex and involves neurologic symptoms specific to the affected area of the brain (also called partial seizures, which can be divided into simple and complex partial seizures).
  - **'Generalized'**: Bilateral, with more than minimal muscle involvement. For generalized seizures users must specify one of the following:
    - **'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 two to three 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 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.

Provide the following details:

- **'Witnessed by healthcare professional'** ('**Yes'**, **'No'**, **'Unknown'**)
- **'Sudden loss of consciousness'** (**'Yes'**, **'No'**, **'Unknown**')
- **'Previous history of seizures'** (**'Febrile'**, **'Afebrile'**, **'Unknown type'**)

- **'Anaesthesia'** or **'Paresthesia*'.** Indicate whether the '**Anaesthesia/Paresthesia'** was '**Generalized'** or '**Localized'** and choose the appropriate signs/symptoms in the sub-box:
  - '**Numbness'**
  - **'Tingling'**
  - **'Burning'**
  - **'Formication'**
  - **'Other'**
- **'Other neurologic diagnosis*'.** Must be diagnosed by a physician Includes myelitis/transverse myelitis, Acute Disseminated Encephalomyelitis (ADEM), and Sub-acute sclerosing panencephalitis (SSPE). Specify details in comments.

  For neurologic events describe the signs, symptoms, and test results from the following list in the sub-box:
  - '**Depressed/altered level of consciousness,**
  - **'Lethargy'**
  - **'Personality change lasting >=24hrs'**
  - **'Focal or multifocal neurologic sign(s)'**
  - **'Fever (>=38.0 C)'**
  - **'CSF abnormality'**
  - **'EEG abnormality'**
  - **'EMG abnormality'**
  - **'Neuroimaging abnormality'**
  - **'Brain/spinal cord histopathologic abnormality'**

  Provide any additional pertinent details in section 10.

9d. Other defined events of interest

Time to **onset** and, unless a not yet recovered or unknown checkbox is selected**, duration** of signs and symptoms are mandatory. The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit (day, hour, or minute).

Indicate the event by choosing the events that apply. For a selected event, describe the signs and symptoms by checking all the sub-level items that apply. Events with an asterisk (*) must be diagnosed by a physician, or where appropriate and based on current scope of practice, the diagnosis may be made by a Nurse Practitioner.

- **'Hypotonic-Hyporesponsive Episode (age <2 years)*':** Must be diagnosed by physician. Select all sign/symptoms that apply:
  - **'Limpness'**
  - **'Pallor/cyanosis'**
  - **'Reduced responsiveness/unresponsiveness'**

- **'Persistent crying (crying which is continuous and unaltered for >= 3hrs)'**
- **'Intussusception*':** Must be diagnosed by physician. Rotavirus vaccines only.
- **Arthritis*' (rubella vaccine):** Must be diagnosed by physician. **This is not to be confused with arthralgia.**
  Select at least one of the following sub-items:
  - **'Joint redness'**
  - **'Joint warm to touch'**
  - **'Joint swelling'**
  - **'Inflammatory changes in synovial fluid'**
- **'Parotitis*':** Parotid gland swelling with pain and/or tenderness after mumps-containing vaccine. Must be diagnosed by physician.
- **'Rash':** Only report rash here if both not localized at injection site and non-allergic. Otherwise report the rash in the appropriate earlier section as above. Check whether the rash is **'Generalized'** or **'Localized at non-injection site'**, and when possible provide a written description of the rash primary lesion(s) (bulla, cyst, macule, nodule, papule, plaque, pustule, vesicle, wheal), and/or secondary skin change(s) (scaling, atrophy, excoriation, fissure ulcer). If localized at non-injection site is selected, specify the location of the site in 'Comments'.
- **'Thrombocytopenia*':** Must be diagnosed by physician. Select at least one of the following sub- items:
  - '**Platelet count <150x109/L'**
  - **'Petechial rash'**
  - **'Other clinical evidence of bleeding'**
- **'Severe vomiting'**
- **'Severe diarrhea'**
- **'Fever ≥ 38°C':** For fever occurring with non-neurologic conditions. **Only reportable in conjunction with another reportable event.**
- **'Other serious or unexpected event(s) not listed above'**: Choose this category ONLY if the event cannot be reported using a more appropriate existing category. Examples include:
  - **Orchitis** (must be diagnosed by a physician),
  - **Hematochezia** (must be diagnosed by a physician)
  - **Syncope with injury**.
  - **Laboratory - Mast cell tryptase elevation':** Mast cell tryptase levels above upper normal limit.
- If selected, must provide a description and any other pertinent additional details in section 10 that could guide possible classification of the event. Provide any additional pertinent details.

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. **Do not document any identifying client information such as their name**. 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.

11. Recommendations for Future Immunization(s)

In Saskatchewan, this section is only to be completed by a MHO, medical doctor, or nurse practitioner.

Provide name and professional title of individual making immunization recommendation.

Select the recommendation(s) given by the **regional MHO/designate** for this AEFI report that apply, and specify additional information when requested:

- **'No change to immunization schedule'**
- **'Expert referral'**: Specify details in the corresponding comment box.
- **'Determine protective antibody level'**
- **'Controlled setting for next immunization'**
- **'No further immunizations'**: Specify agent(s) in corresponding comment box
- **'Active follow-up for AEFI recurrence after next vaccine'**
- **'Other'**: Specify details in corresponding comment box.

Comments box
Provide any additional pertinent details in the comment box for this section.

5. **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 (vaccines given in series).

   Indicate <u>one</u> of the following:

   - **'Vaccine administered without AEFI'**
   - **'Vaccine administered with recurrence of AEFI'**
   - **'Vaccine administered, other AEFI observed'**
   - **'Vaccine administered without information of AEFI'**
   - **'Vaccine not administered'**

Appendix 1: Summary of AEFI Reporting Criteria

For events with reporting criteria for a physician diagnosis, where appropriate and based on current scope of practice, the diagnosis may be made by a nurse practitioner.

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	Live Attenuated Vaccines
Local Reaction at Injection Site			

Abscess, Infected	• Material from abscess known to be purulent (positive gram stain or culture)
	• OR
	• There are one or more signs of localized inflammation (erythema, pain to light touch, warmth) AND
	  ○ Evidence of improvement on antimicrobial therapy OR
	  ○ Physician-diagnosed
		0-7 days	BCG: Any
			Other: 0-7 days

Abscess, Sterile	• Physician-diagnosed AND any of the following:
	  ○ Material from mass is known to be non-purulent
	  ○ Absence of localized inflammation
	  ○ Failure to improve on antimicrobial therapy
		0-7 days	

Cellulitis	• Physician-diagnosed AND characterized by at least 3 of the following: pain or tenderness to touch, erythema, induration, swelling, warmth	0-7 days	BCG: Any Other: 0-7 days
Lymphadenopathy/Adenopathy	• Physician-diagnosed	0-7 days mRNA COVID-19 5-30 days	BCG: Any Other: 0-42 days
Nodule	• Is more than 2.5 cm in diameter at injection site AND • Persists form more than 1 month	0-7 days	
Pain and/or swelling	• Swelling extends past the nearest joint OR • Severe pain that interferes with the normal use of the limb lasts > 4 days OR • Reaction requires hospitalization	0-2 days	0-7 days
Allergic-type Reactions			
Anaphylaxis	• Sudden onset* AND rapid progression of signs and symptoms AND • Symptoms include one or more of the following: • progressive painless swelling around face or mouth, new onset of wheezing, shortness of breath, and/or stridor, hypotension/collapse OR • Event managed as anaphylaxis at the time of occurrence	0-24 hours	

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	Live Attenuated Vaccines
Oculo-respiratory syndrome (ORS)	• Onset of bilateral red eyes AND • One or more of the following respiratory symptoms: Cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness, sore throat WITH or WITHOUT facial edema.	Influenza vaccine: 0-24 hours	
Other Allergic Reactions	• Skin AND/OR • Respiratory AND/OR • Gastrointestinal manifestations	0-48 hours	
Rash	• Rashes or eruptions on the skin that are not expected, with an onset within 7 days of immunization and lasts ≥ 4 days AND either • Generalized rash: systemic eruption in two or more parts of the body OR • Localized at non-injection site; eruption localized at another part of the body, away from the injection site OR • Requires hospitalization	0-7 days	0-42 days
Neurological Events			
Acute Disseminated Encephalomyelitis (ADEM)	• Physician-diagnosed encephalomyelitis AND • One or more focal or multifocal findings referable to the central nervous system	0-42 days	
Anaesthesia/Paraesthesia (tingling/numbness)	• Physician-diagnosed anaesthesia or paraesthesia lasting 24 hours or more	0-42 days	
Bell's palsy	• Physician-diagnosed Bell's palsy	0-3 months	
Brachial neuritis		0-90 days	0-90 days
Convulsion/ Seizures (febrile or afebrile)	• Seizures (febrile or afebrile) with generalized, tonic, clonic, tonic-clonic, or atonic motor manifestations, occurring within AND • History or report of loss of consciousness.	0-72 hours	5-42 days
Encephalopathy or Encephalitis	• Physician diagnosed encephalitis AND • At least one listed indicator of central nervous system inflammation AND • > 24 hours of depressed or altered consciousness with one or more signs of • reduced responsiveness OR • One or more signs of focal or multi-focal central nervous system abnormality	0-42 days	
Gillian-Barre syndrome (GBS)	• Physician-diagnosed GBS	0-56 days	
Meningitis	• Physician-diagnosed meningitis for which no other cause has been identified	0-15 days	5-42 days
Myelitis	• Physician-diagnosed myelitis AND • Two or more indicators suggestive of spinal cord inflammation.	0-42 days	5-42 days
Paralysis	• Physician-diagnosed paralysis with no other cause identified AND • Lasting more than 24 hours	0-15 days	0-42 days

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	Live Attenuated Vaccines
Other paralytic syndrome	• Peripheral neuropathy and acute flaccid paralysis	0-42 days	
Sub-acute sclerosing panencephalitis (SSPE)	• Physician-diagnosed SSPE	N/A	Measles: Any
Vaccine-Associated Paralytic Poliomyelitis (VAPP)	• Physician-diagnosed paralysis	N/A	OPV: 5-30 days
Other Event of interest			
Arthritis or Arthralgia	• Physician-diagnosed arthritis AND • Lasting 24 hours or more	0-30 days	5-42 days
Death within 30 days of immunization	• Any death of a vaccine recipient temporally linked to immunization where no other clear cause of death can be established.	0-30 days	
Disseminated vaccine strain infection following vaccination	• Varicella-like rash with ≥ 50 lesions OR • Requiring hospitalization	N/A	Varicella: 0-42 days
Erythema Multiforme	• Rash specific to Erythema Multiforme • Must be diagnosed by a physician	5 or more days	
Fever >38°C	**Must be reported with other AEFI symptoms**	0-3 days	0-42 days
Hemorrhagic disease or bleeding disorders	• Ex. abnormal uterine bleeding warranting urgent care	**COVID-19 vaccines:** 0-28 days	N/A
Henoch-Schonlein Purpura	• Must be physician-diagnosed	0-42 days	
Hypotonic-hyporesponsive episode	• Hypotonia (muscle limpness) AND • Either hyporesponsiveness or unresponsiveness AND • Either pallor or cyanosis	0-72 h	
Intussusception or hematochezia	• Physician-diagnosed intussusception following rotavirus vaccine receipt AND • Evidence of intestinal obstruction and/or invagination and/or vascular compromise	N/A	Rotavirus vaccine only 0-42 days
Kawasaki syndrome	• Must be physician-diagnosed	0-42 days	
Narcolepsy	• Narcolepsy is characterized by excessive daytime sleepiness and episodes of muscle weakness brought on by emotions	0-4 weeks	
Orchitis	• Physician-diagnosed orchitis	N/A	Mumps 5-30 days
Other severe or unusual events[2]	• Not clearly covered by other reporting categories and fits description above or • requires emergency room visit within 72 hours of immunization	0-4 weeks	
Parotitis	• Physician-diagnosed parotitis	N/A	Mumps 5-30 days
Persistent crying/screaming episode	• Presence of screaming or crying > 3 hours	0-3 days	
Severe diarrhea and/or vomiting	• Three or more episodes of vomiting or diarrhea within a 24-hour period AND • Vomiting and/or diarrhea is severe	0-72 h	

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	**Live Attenuated Vaccines**
Shoulder injury related to vaccine administration (SIRVA)	• Includes both pain and reduced range of motion AND these are limited to the shoulder in which the intramuscular vaccine was administered; and • No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; including no other condition or abnormality is present that would explain the patient's symptoms. • Lasting longer than 4 days	0-7 days	
Syncope with injury	**Syncope otherwise not reportable**	0-30 minutes	
Thrombocytopenia	• Physician-diagnosed platelet count of less than 150 X 109/L	0-42 days **COVID-19 vaccines**: 0-28 days	
Thrombolytic events	1. Pulmonary embolism 2. Venous thromboembolism (VT) e.g., deep ve thrombosis (DVT), phlebitis, thrombophlebit 3. Ischemic stroke (if it is possible to confirm if the stroke was embolic or hemorrhagic, please specify) 4. Limb ischemia 5. Intra-abdominal thrombosis (such as adrena vein thrombosis, portal/mesenteric vein thrombosis) 6. Cerebral venous sinus thrombosis 7. Myocardial infarction	**COVID-19 vaccines**: 0-28 days	N/A
Other coagulation or blood disorders	a. Disseminated intravascular coagulation (DIC) b. Hemolytic uremic syndrome (HUS) c. Complement disorders	**COVID-19 vaccines**: 0-28 days	N/A

[A] The length of time between vaccine administration and onset of event is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

[B] Other serious, unexpected or unusual events may include AEFIs that:

- are life threatening or result in death
- require hospitalization or prolong hospitalization
- result in a residual disability
- are associated with a congenital malformation
- require urgent medical attention
- have not been previously identified (e.g., Oculo-Respiratory Syndrome (ORS) was first identified during the 2000 / 2001 influenza season)
- have been identified before but is occurring with greater frequency in the population (e.g., extensive or delayed local reactions such as 'COVID arm')
- are clusters of AEFIs, either known or new events that occur in a geographic or temporal cluster that require further assessment, even if the total number of AEFIs may not be higher than expected.

.