

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

December 2021

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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 (four to eight 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

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. A new AEFI report and unique identifier are assigned to new doses of a vaccine given in a series. A follow-up report follows a previously reported AEFI when section 12 is completed.

1. Identifying information

1a. Unique Episode # and 1b. Region

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

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

Unique identifier assigned by an IMPACT nurse 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 (PHAC) to reconcile reports received both from the province and from IMPACT directly.

3. Patient identification

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, 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 including mailing address.

4. Information at time of immunization and AEFI onset

4a. At time of Immunization: Identify the province or territory where the immunization was administered; the date the vaccine was administered at a single visit, the client's date of birth, their age and their gender. Indicate if a woman is pregnant (document gestational age) or breastfeeding at time of immunization. Racial background and Indigenous status are not collected by the Ministry of Health and are only for the use of the PHAC.

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 condition:** Indicate all known medical conditions that the patient experienced prior to the time of AEFI onset 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 and those with intermittent symptoms such as migraine headaches.
- **Allergies and reactions:** Indicate all allergies and details of previous anaphylactic reactions that the patient was known to have at the time of AEFI onset, including allergies to vaccinations, medications and/or foods in section 10. Please provide the greatest amount of detail that is available (e.g., year of onset) and previous reactions.
- **Acute illness/injury:** Indicate if the patient had an acute illness and/or injury immediately prior to the time of AEFI onset 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).
- **COVID-19 infection history:** Indicate if the patient had a positive COVID-19 test result prior to the time of AEFI onset, including the type of test, date of test and details of infection in section 10.
- **COVID-19 immunization history:** Indicate dates, dose number, vaccine trade names(s) and vaccine manufacturer for any previous COVID-19 immunization (if known).

4c. Immunizing agent(s) and diluent (for COVID-19 vaccines)

Provide all information pertaining to the vaccine(s) administered prior to the onset of the reported AEFI.

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).

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.
- **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 product storage:** Any excursion from conditions recommended during the transport, storage and handling of vaccines may impact their effectiveness. The administration of a vaccine known to have been improperly stored or handled should be reported in section 10 (e.g. the use of a vaccine exposed to light or temperatures outside those recommended for the product; the use of multi-dose vials outside the specified time after initial puncturing or after reconstitution).
- **Wrong vaccine given:** An unintended vaccine was administered.
- **Incorrect route:** The vaccine was administered via a route not recommended for its administration (e.g., subcutaneous vs. intramuscular).
- **Inappropriate dose of vaccine given:** A larger or smaller dose of vaccine was administered than is recommended for the patient's age group.
- **Product preparation error:** Any errors in the preparation of vaccines prior to administration should be included in section 10. This may include inappropriate processes used for mixing or reconstituting vaccines, and/or the use of an incorrect diluent type or volume.
- **Other:** If an error has occurred that is not accurately reflected in the list of provided errors, please choose "Other" and provide all details.

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

NOTE: 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 need to be submitted for each episode, each with a separate unique identifier.

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

- **'No':** Previously immunized with one or more of the vaccines in 4c associated with this report and had not experienced a subsequent AEFI.
- **'Not applicable (No prior dose)':** Never previously immunized with any of the vaccines in 4c associated with this report.
- **'Unknown':** It is unknown if the client previously received any of the associated vaccines in 4c and/or if an AEFI followed.
- **'Yes':** Previously immunized with one or more of vaccines in 4c 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 perceived impact of the AEFI to the client's daily activities, definitions of
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.).

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 within 30 days of vaccine administration (record the corresponding date of death in the space provided). **NOTE: Deaths that are attributed to other known causes are not to be reported as AEFIs.**
- **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.

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:

- **Unknown:** It is unknown if the patient received care for the reported AEFI.
- **None:** No care was received for the reported AEFI.
- **Telephone/virtual advice from a health professional:** The patient received telephone advice from a health care professional (e.g., nurse, nurse practitioner (NP), 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. **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 including days spent in intensive care unit, 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.

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 when applicable.

8. AEFI 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., long-term care home, physician office, nursing station, public health clinic, hospital, workplace clinic, pharmacy) 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, pharmacist) 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”.

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 NP. If not diagnosed by a physician or NP, 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).

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 if 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.

- **Sterile abscess:** An abscess whose contents are not caused by pyogenic bacteria.
- **(Note presence of any of the following by ticking the appropriate box on the form:** erythema, pain, tenderness, warmth, spontaneous/surgical drainage, palpable fluctuance, fluid collection shown by imaging technique, lymphangitic streaking, regional lymphadenopathy and microbial results; if fever present check box in section 9d; use section 10 for additional details. If treated with antibiotics indicate if resolution/ improvement were temporally related to treatment.
- **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. (Note presence of any of the following by ticking the appropriate box on the form: swelling, pain, tenderness, erythema, warmth, induration, lymphangitic streaking, regional lymphadenopathy and microbial results; if fever present check box in section 9d; use section 10 for additional details).
- **Nodule:** Discrete, well demarcated soft tissue mass or lump at the vaccination site that has a firm texture and is not accompanied by erythema, warmth or abscess formation.
- **Reaction crosses joint:** Reaction extending past at least one joint adjacent to the site of vaccine administration. Specify which joint(s) is/are crossed in Section 10.
- **Reaction stretches joint-to-joint:** Reaction extending between two joints by not past either adjacent joint. Specify which joints in Section 10.
- **Lymphadenitis:** Inflammation of one or more lymph nodes, usually caused by a primary focus of infection elsewhere in the body.
- **Other:** Specify all details of the vaccination site reaction in section 10 that are not already captured in section 9a above. Examples of “**Other**” local reactions that may be reported here include necrosis, papule etc.

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

- **Swelling:** Visible enlargement of the vaccinated limb that is assessed by any person, with or without objective measurement.

- **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 tactile sensation/perception of an increase in temperature.
- **Induration:** Palpable thickening, firmness or hardening of soft tissue (subcutaneous tissue, fat, fascia or muscle) that is assessed by a health care provider.
- **Rash:** A morphologically described change in the appearance of the skin or mucosa at or near vaccination site that consists of one or more clearly identified primary lesion(s) (macule, papule, vesicle, nodule, bulla, cyst, plaque, pustule), and/or secondary skin change(s) (scaling, atrophy, ulcer, fissure, excoriation).
- **Largest diameter of vaccination site reaction:** Indicate the diameter (in centimeters) of the largest vaccination site reaction that is present.
- **Site(s) of reaction:** Site(s) of the local reaction being reported if known. (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, if Other: please specify.
- **Palpable fluctuance:** Wavelike motion on palpation due to presence of liquid content.
- **Fluid collection shown by imaging technique:** An imaging device is used in the detection of fluid collection (e.g., ultrasound, Magnetic Resonance Imaging (MRI) and/or X-ray).
- **Spontaneous drainage:** Draining of fluid from a site without intervention. When available, describe drainage material (purulent or non-purulent, bloody, etc.) and provide all Gram stain/culture results.
- **Surgical drainage:** Withdrawal of fluids from the site through needle aspiration or incision, which could be complete or partial. When available, describe drainage material (purulent or non-purulent, bloody, etc.) and provide all Gram stain/culture results. (BCCD: Vaccine 25 (2007) 5821–5838).
- **Microbial results, specify:** Tests that are carried out to identify organisms that can cause disease or infection.
- **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 (e.g., inguinal adenopathy when associated with an IM vaccination in the thigh, axillary adenopathy associated with an IM vaccination in the deltoid, etc.).

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).

One of the following events must be indicated in this section:

- **Anaphylaxis:** An acute hypersensitivity reaction with multi-organ-system involvement that can present as, or rapidly progress to, a severe life-threatening reaction. Check all applicable signs/symptoms referable to skin/mucosal, cardio-vascular, respiratory and/or gastrointestinal systems that were observed during the course of the event and use section 10 for additional details.

Provide specific measurements, where available, for pulse, respiratory rate and blood pressure and indicate for each if before or after treatment with epinephrine if given.

- **Oculo-Respiratory Syndrome (ORS):** The presence of “bilateral red eyes” plus ≥ 1 respiratory symptom (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) that starts within 24 hours of vaccination, with or without facial edema.
- **Other allergic event:** An event considered by reporter to be allergic in nature but not anaphylaxis, ORS or status asthmaticus. Check all symptoms/signs in section 9b that were present and use section 10 for any additional details.
- **Epinephrine administered:** Select if epinephrine was used to treatment the allergic event.
- For a chosen event, describe the signs and symptoms by checking all that apply from the list below. Provide all additional details in section 10.

Skin/Mucosal - Choose all that apply from the list provided below:

- **Urticaria (hives):** Localized redness of superficial layers of skin that is itchy, raised, sharply demarcated and transient (that is skin changes at any location are usually present for less than 12 hours). Specify site of reaction.
- **Erythema:** Abnormal redness of the skin without any raised skin lesions. Specify site of reaction.
- **Pruritus:** An unpleasant skin sensation that provokes a desire to rub and/or scratch to obtain relief. Specify site of reaction.
- **Paraesthesia: (prickling or tingling):** Tingling or smarting (stinging) sensation. Specify site of reaction.
- **Flushing:** A transient erythema due to heat, exertion, stress or disease.
- **Other rash:** A morphologically described change in the appearance of the skin or mucosa that occurs in the context of and in conjunction with an emerging allergic event that consists of one or more clearly identified primary lesion(s) (macule, papule, vesicle, nodule, bulla, cyst, plaque, or pustule) and/or secondary skin change(s) (scaling, atrophy, ulcer, fissure, or excoriation).
- **Generalized:** Involving more than one body site i.e.: each limb is counted separately as is the abdomen, back, head and neck.
- **Localized (site):** Involving one body site only.
- **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 (Reported symptoms of ‘swelling of the lip’ or ‘swelling of the tongue or throat’ should not be documented as angioedema unless there is visible skin or mucosal swelling.) Check all of the locations where angioedema is seen on the AEFI report form (tongue, throat, uvula, larynx, lip, eyelids, face, and limbs) and if “Other” is checked, provide details. Indicate if there was visible swelling, or if it the vaccinee reported a sensation of swelling.
- **Red eyes (bilateral or unilateral):** Redness of the white(s) of the eye (s) (sclera).
- **Itchy eyes:** A sensation that provokes the desire to rub and/or scratch to obtain relief.

Cardiovascular - Choose all that apply from the list provided below:

- **Measured hypotension:** An abnormally low blood pressure (BP) and documented by appropriate measurement. Infants and children: age specific systolic BP of < 3 –5% percentile or greater than a 30% decrease from that person’s baseline; Adults: systolic BP of < 90 mm Hg or greater than 30% decrease from that person’s baseline.
- **Decreased central pulse volume:** Absent or decreased pulse in one of the following vessels: carotid, brachial or femoral arteries.

- **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:** A heart rate that is abnormally high for age and circumstance (In beats per minute: <1year old: >160; 1–2 yrs: >150; 2–5 yrs: >140; 5–12 yrs: >120; >12 yrs: >100).
- **Decreased consciousness:** Reduced alertness or awareness of the outside world. Indicate duration of the event.
- **Loss of consciousness:** Total suspension of conscious relationship with the outside world demonstrated by the inability to perceive and to respond to verbal, visual, and painful stimulus. Indicate duration of the event.

Respiratory - Choose all that apply from the list provided below:

- **Sneezing:** An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose.
- **Rhinorrhea:** Discharge of thin nasal mucus.
- **Hoarse voice:** An unnaturally harsh cry of infant or vocalization in a child or adult.
- **Sensation of throat closure:** Feeling or perception of throat closing with a sensation of difficulty breathing.
- **Stridor:** A harsh and continuous sound made on breathing in.
- **Wheezing:** A whistling, squeaking, musical, or puffing sound made by breathing out.
- **Dry cough:** Rapid expulsion of air from the lungs to clear the lung airways and not accompanied by expectoration (a non-productive cough).
- **Tachypnea:** Rapid breathing which is abnormally high for age and circumstance rapid breathing which is abnormally high for age and circumstance (<1yr: >60; 1–2 yrs: >40; 2–5 yrs: >35; 5–12 yrs: >30; >12 yrs: >16), (same source as tachycardia).
- **Indrawing/retractions:** Inward movement of the muscles between the ribs (inter-costal), 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.
- **Grunting:** A sudden and short noise with each breath when breathing out.
- **Increased use of accessory muscles:** 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.
- **Cyanosis:** A dark bluish or purplish discolouration of the skin and mucous membrane due to lack of oxygen in the blood.
- **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:** Sensation of difficult/uncomfortable breathing or a feeling of not getting enough air.
- **Chest tightness:** Inability or perception of not being able to move air in or out of the lungs.

Gastrointestinal (GI) - Choose all that apply from the list provided below:

Only report GI signs/symptoms associated with an allergic event here. Report isolated GI signs and symptoms in the ‘**Other Defined Events of Interest**’ section.

- **Diarrhea:** Loose or watery stools, which may occur more frequently than usual.
- **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 - Indicate, by choosing all that apply from the list provided of all neurologic events. Provide all additional details in section 10.

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 NP.

- **Meningitis*:** Should be diagnosed by a physician. Check all applicable 9c boxes and use section 10 to record all additional pertinent clinical details and test results.
- **Encephalopathy/Encephalitis*:** Should be diagnosed by a physician. Check all applicable 9c boxes and use section 10 to record all additional pertinent clinical details and test results.
- **Guillain-Barré Syndrome*:** Should be diagnosed by a physician. Check all applicable 9c boxes and use section 10 to record all additional pertinent clinical details and test results especially Electromyography (EMG) and /or Lumbar Puncture (LP).
- **Bell's Palsy*:** Should be diagnosed by a physician. Provide any pertinent details.
- **Other paralysis*:** Should be diagnosed by a physician. Provide all pertinent details.
- **Seizure(s):** Sudden loss of consciousness in conjunction with involuntary generalized motor manifestations.
- **Myelitis/transverse myelitis*:** Should be diagnosed by a physician. Provide all pertinent details.
- **Subacute sclerosing panencephalitis*:** Should be diagnosed by a physician. Provide all pertinent details.
- **Other neurologic diagnosis*:** Specify and provide all details.

For all neurologic events above, describe the SIGNS, SYMPTOMS and TEST RESULTS relating to the reported event(s) by checking all that apply from the list below. Provide any additional details in section 10:

- **Depressed/altered level of consciousness:** Impairment of the ability to maintain awareness of self and environment combined with markedly reduced responsiveness to environmental stimuli.
- **Lethargy:** A general state of sluggishness, listless, or uninterested, with being tired, and having difficulty concentrating and doing simple tasks.
- **Personality changes lasting \geq 24 hours:** Change in personal behaviour-response patterns.
- **Focal or multifocal neurologic sign(s):** Neurological impairment which is caused by a lesion
- **Fever ($\geq 38.0^{\circ}\text{C}$):** Endogenous elevation of at least one body temperature, regardless of measurement device, anatomic site, age or environmental conditions.
- **CSF (Cerebral Spinal Fluid) abnormality:** Alteration in normal CSF visual appearance, measured hydrostatic pressure, chemistry (protein, sugar) and/or cellular content (white blood cells, red blood cells) as well as Gram stain/routine bacterial culture results or other tests for presence of microbes.
- **EEG (Electroencephalography) abnormality:** Abnormal EEG as interpreted by a qualified health professional.
- **EMG (Electromyography) abnormality:** Abnormal skeletal EMG as interpreted by a qualified health professional.

Neuroimaging abnormality: Abnormal results of any test used to detect anomalies or trace pathways of nerve activity in the central nervous system; includes Computed Tomography (CT) scans, MRI, Positron Emission Tomography (PET) scans.

Brain/spinal cord histopathologic abnormality: Microscopic changes of the diseased brain/ spinal cord tissues. Abnormalities seen on routine and/or electron microscopy by qualified health professionals using appropriately prepared (e.g., using special stains) tissue samples from brain and/or spinal cord.

Anaesthesia (numbness): Loss of sensation resulting from pharmacologic depression of nerve function or from neurogenic dysfunction. (Stedman’s Medical Dictionary (2016)). Indicate site of reaction.

Burning: Sensation of stinging or heat not necessarily accompanied by redness, or physical signs of skin irritation. Indicate site of reaction.

Formication: Sensation of insects crawling over or within the skin. Indicate site of reaction.

Paraesthesia: A spontaneous abnormal usually non-painful sensation (e.g., burning, pricking); may be due to lesions of both the central and peripheral nervous systems. **Brief tingling immediately following immunization should be included under 9b. Allergic and Allergic-like events.**

Other, Specify: Specify in section 10.

TYPES OF SEIZURES

- **Partial seizure:** Seizure that originates from a localized area of the cerebral cortex and involves neurologic symptoms specific to the affected area of the brain.
OR
- **Generalized seizure:** 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 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-Hypo-responsive 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.
- **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”, “No” or “Unknown”.
- **Sudden loss of consciousness:** Sudden total unresponsiveness (suspension of conscious relationship with the outside world, inability to perceive and respond). If “Yes”, indicate duration of the event.
- **Witnessed by healthcare professional:** A healthcare professional (e.g.: doctor, nurse, etc.) observed the seizure. If “Yes”, provide details.
 - Febrile: With fever of $\geq 38.0^{\circ}\text{C}$.
 - Afebrile: Without fever.
 - Unknown type: It is unknown if the seizure was febrile or afebrile. Provide all known details.
- **Previous history of seizures:** Individuals who have had seizures at any time prior to this vaccination.
 - Febrile: With fever of $\geq 38.0^{\circ}\text{C}$.
 - Afebrile: Without fever.
 - Unknown type: It is unknown if the seizure was febrile or afebrile. Provide all known details.

9d. Other events

- **Hypotonic-Hyporesponsive Episode (HHE) (age <2 years):** Sudden onset of two to three of: limpness (reduced muscle tone), change in skin colour (pallor or cyanosis) and/or reduced responsiveness (i.e., less responsive than usual to verbal or other sensorial stimuli). Check each appropriate box in section 9d and use section 10 to indicate if muscle tone, responsiveness or skin colour is known to be normal. **Do not use the HHE checkbox if the patient is two (2) years of age or older; instead please check “Other severe or unusual events not listed above” and describe the episode.**

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

- **Limpness:** Lacking firmness and strength, no muscle tone.
- **Pallor:** Unnatural lack of colour in the skin (abnormal loss of colour from normal skin).
- **Cyanosis:** A dark bluish or purplish discolouration of the skin and mucous membrane due to lack of oxygen in the blood.
- **Decreased responsiveness:** Change in usual responsiveness to sensory stimuli.
- **Unresponsiveness:** Lack of responsiveness to sensory stimuli.
- **Persistent crying:** Crying which is continuous unaltered and lasts for three or more hours among young children.
- **Intussusception*:** Should be diagnosed by a physician. The prolapse of one part of the intestine into the lumen of an immediately adjacent part, causing partial or complete intestinal obstruction. Provide all pertinent details.
- **Arthritis:** Inflammation of the joint(s). Choose all that apply to the reported AEFI from the list provided, and described, below:
 - **Joint redness:** Redness of the skin at the joint(s).
 - **Joint warm to touch:** Sensation of increase in temperature, above body temperature, at the joint(s) to touch.
 - **Joint pain:** Discomfort, pain or inflammation arising from any part of the joint.
 - **Joint swelling:** An abnormal increase in the size of the joint(s).
 - **Inflammatory changes in synovial fluid:** Laboratory synovial or joint fluid analysis indicative of inflammatory response.
- **Parotitis:** Swelling with pain and/or tenderness of parotid gland(s).
- **Syncope with injury:** Details of the injury resulting from syncope should be reported in Section 10.
- **Rash:** A skin or mucosal change (either new or an exacerbation of a previous condition) following immunization that consists of clearly identified primary lesion(s) (bulla, cyst, macule, nodule, papule, plaque, pustule, vesicle, wheal), and/or secondary skin change(s) (scaling, atrophy, excoriation, fissure ulcer).
- **Generalized rash:** Systemic eruption in two or more parts of the body.
- **Localized at non-vaccination site:** Eruption localized at another part of the body, away from the vaccination site.
- **Kawasaki Disease*:** Should be diagnosed by a physician. A systemic vasculitis of infancy and childhood affecting medium-sized muscular arteries. Provide all pertinent details.
- **Thrombocytopenia*:** Should be diagnosed by a physician. Platelets count of less than 150 X 10⁹/liter; accompanied by petechial rash or other clinical signs and/or symptoms of spontaneous bleeding (epistaxis, hematoma, hematemesis, hematochezia, hematuria, hemoptysis, petechiae, purpura, and ecchymosis). Indicate the lowest platelet count on the AEFI form and provide any additional pertinent details, including the clinical evidence for spontaneous bleeding.
- **Severe vomiting:** The reflex act of ejecting the contents of the stomach through the mouth. (Severe enough to interfere with daily routine).

- **Severe diarrhea:** An increase by three or more loose or liquid stools (above normal or baseline) occurring within a 24 hour period.
- **Fever ($\geq 38.0^{\circ}\text{C}$):** Endogenous elevation of at least one body temperature, regardless of measurement device, anatomic site, age or environmental conditions.
- **Other serious adverse event:** Is any untoward medical occurrence that at any dose results in: death; is life-threatening; requires inpatient hospitalization or results in prolongation of existing hospitalization; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect; or is a medically important event or reaction.
- **Unexpected adverse event:** Is 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.

9e. COVID-19 Adverse Events of Special Interest (AESI)

Report following COVID-19 vaccine only. Please indicate if one of the following has been diagnosed by a physician. Provide in section 10 details on signs, symptoms and investigations leading to the diagnosis of the AESIs listed below. Document investigations that confirmed the diagnosis include supportive imaging studies, pathology (biopsy or autopsy) and/or laboratory findings and results.

<input type="checkbox"/> Vaccine-associated enhanced disease <input type="checkbox"/> Multisystem inflammatory syndrome (MIS) in children (MIS-C) <input type="checkbox"/> Multisystem inflammatory syndrome (MIS) in adults (MIS-A) <input type="checkbox"/> Acute respiratory distress syndrome <input type="checkbox"/> Acute cardiovascular injury (microangiopathy, heart failure, stress cardiomyopathy, coronary artery disease arrhythmia, myocarditis) <input type="checkbox"/> Coagulation disorder <ul style="list-style-type: none"> ○ Thrombosis /Thromboembolism ○ Thrombocytopenia ○ Thrombosis with Thrombocytopenia syndrome <input type="checkbox"/> Acute kidney injury <input type="checkbox"/> Acute liver injury	<input type="checkbox"/> Anosmia <input type="checkbox"/> Ageusia <input type="checkbox"/> Chilblain – like lesions <input type="checkbox"/> Single organ cutaneous vasculitis <input type="checkbox"/> Erythema multiforme <input type="checkbox"/> Meningoencephalitis <input type="checkbox"/> Acute disseminated encephalomyelitis <input type="checkbox"/> Subacute thyroiditis <input type="checkbox"/> Acute pancreatitis <input type="checkbox"/> Rhabdomyolysis <input type="checkbox"/> Acute aseptic arthritis <input type="checkbox"/> Other, Specify:
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In light of the evolving state of science around COVID-19, the list of COVID-19 AESIs and detailed case definitions are being continuously developed and updated. To ensure harmonized and consistent methods are used, those reporting an AESI for COVID-19 should visit the Brighton Collaboration website for the most up-to-date information: <https://brightoncollaboration.us/covid-19/>.

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, MD, or NP. Provide the 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:** identify referral specialist.
- **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.

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). Choose one of the responses as defined 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. **Fill out a new AEFI form for the subsequent AEFI and assign a new unique identifier.**
- **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. **Fill out a new AEFI form for the subsequent AEFI and assign a new unique identifier.**
- **Vaccine administered without information on AEFI:** A subsequent dose of vaccine was administered and it is unknown if it was followed by the occurrence of any AEFI.
- **Vaccine not administered:** A subsequent dose of the vaccine was not administered.

Appendix 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 NP.

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria ^A	
		Inactivated Vaccines	Live Attenuated Vaccines
Local Reaction at Injection Site			
Abscess, Infected	<ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Evidence of improvement on antimicrobial therapy OR Physician-diagnosed 	0-7 days	BCG: Any Other: 0-7 days
Abscess, Sterile	<ul style="list-style-type: none"> Physician-diagnosed AND any of the following: <ul style="list-style-type: none"> Material from mass is known to be non-purulent Absence of localized inflammation Failure to improve on antimicrobial therapy 	0-7 days	
Cellulitis	<ul style="list-style-type: none"> Physician-diagnosed AND characterized by at least three of the following: pain or tenderness to touch, erythema, induration, swelling, warmth 	0-7 days	BCG: Any Other: 0-7 days
Lymphadenopathy/Adenopathy	<ul style="list-style-type: none"> Physician-diagnosed 	0-7 days mRNA COVID-19 5-30 days	BCG: Any Other: 0-42 days
Nodule	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Sudden onset* AND rapid progression of signs and symptoms AND Symptoms include one or more of the following: <ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Skin AND/OR Respiratory AND/OR Gastrointestinal manifestations 	0-48 hours	
Rash	<ul style="list-style-type: none"> Rashes or eruptions on the skin that are not expected, with an onset within 7 days of immunization and lasts \geq 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)	<ul style="list-style-type: none"> Physician-diagnosed encephalomyelitis AND One or more focal or multifocal findings referable to the central nervous system 	0-42 days	
Anaesthesia/Paraesthesia (tingling/numbness)	<ul style="list-style-type: none"> Physician-diagnosed anaesthesia or paraesthesia lasting 24 hours or more 	0-42 days	
Bell's palsy	<ul style="list-style-type: none"> Physician-diagnosed Bell's palsy 	0-3 months	
Brachial neuritis		0-90 days	0-90 days
Convulsion/ Seizures (febrile or afebrile)	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> Physician-diagnosed GBS 	0-56 days	
Meningitis	<ul style="list-style-type: none"> Physician-diagnosed meningitis for which no other cause has been identified 	0-15 days	5-42 days
Myelitis	<ul style="list-style-type: none"> Physician-diagnosed myelitis AND Two or more indicators suggestive of spinal cord inflammation. 	0-42 days	5-42 days

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria ^A	
		Inactivated Vaccines	Live Attenuated Vaccines
Paralysis	<ul style="list-style-type: none"> Physician-diagnosed paralysis with no other cause identified AND Lasting more than 24 hours 	0-15 days	0-42 days
Other paralytic syndrome	<ul style="list-style-type: none"> Peripheral neuropathy and acute flaccid paralysis 	0-42 days	
Sub-acute sclerosing panencephalitis (SSPE)	<ul style="list-style-type: none"> Physician-diagnosed SSPE 	N/A	Measles: Any
Vaccine-Associated Paralytic Poliomyelitis (VAPP)	<ul style="list-style-type: none"> Physician-diagnosed paralysis 	N/A	OPV: 5-30 days
Other Event of interest			
Arthritis or Arthralgia	<ul style="list-style-type: none"> Physician-diagnosed arthritis AND Lasting 24 hours or more 	0-30 days	5-42 days
Death within 30 days of immunization	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Varicella-like rash with ≥ 50 lesions OR Requiring hospitalization 	N/A	Varicella: 0-42 days
Erythema Multiforme	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Ex. abnormal uterine bleeding warranting urgent care 	COVID-19 vaccines: 0-28 days	N/A
Henoch-Schonlein Purpura	<ul style="list-style-type: none"> Must be physician-diagnosed 	0-42 days	
Hypotonic-hyporesponsive episode	<ul style="list-style-type: none"> Hypotonia (muscle limpness) AND Either hyporesponsiveness or unresponsiveness AND Either pallor or cyanosis 	0-72 h	
Intussusception or hematochezia	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Must be physician-diagnosed 	0-42 days	
Narcolepsy	<ul style="list-style-type: none"> Narcolepsy is characterized by excessive daytime sleepiness and episodes of muscle weakness brought on by emotions 	0-4 weeks	
Orchitis	<ul style="list-style-type: none"> Physician-diagnosed orchitis 	N/A	Mumps 5-30 days
Other severe or unusual events ²	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Physician-diagnosed parotitis 	N/A	Mumps 5-30 days
Persistent crying/screaming episode	<ul style="list-style-type: none"> Presence of screaming or crying > 3 hours 	0-3 days	
Severe diarrhea and/or vomiting	<ul style="list-style-type: none"> Three or more episodes of vomiting or diarrhea within a 24-hour period AND 	0-72 h	

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria ^A	
		Inactivated Vaccines	Live Attenuated Vaccines
	<ul style="list-style-type: none"> Vomiting and/or diarrhea is severe 		
Shoulder injury related to vaccine administration (SIRVA)	<ul style="list-style-type: none"> 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 <u>with</u> injury	Syncope otherwise not reportable	0-30 minutes	
Thrombocytopenia	<ul style="list-style-type: none"> Physician-diagnosed platelet count of less than 150 X 10⁹/L 	0-42 days	
		COVID-19 vaccines: 0-28 days	
Thrombolytic events	<ol style="list-style-type: none"> Pulmonary embolism Venous thromboembolism (VT) e.g., deep vein thrombosis (DVT), phlebitis, thrombophlebitis Ischemic stroke (if it is possible to confirm if the stroke was embolic or hemorrhagic, please specify) Limb ischemia Intra-abdominal thrombosis (such as adrenal vein thrombosis, portal/mesenteric vein thrombosis) Cerebral venous sinus thrombosis Myocardial infarction 	COVID-19 vaccines: 0-28 days	N/A
Other coagulation or blood disorders	<ol style="list-style-type: none"> Disseminated intravascular coagulation (DIC) Hemolytic uremic syndrome (HUS) 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.