Saskatchewan Adverse Event Following Immunization Report Form User Guide for Publicly Funded Immunizing Agents

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Saskatchewan

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Purpose and Introduction

This Saskatchewan user guide is a guidance document for 811 and community and public health healthcare immunizers to report an **Adverse Event Following Immunization** (AEFI) 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* (SIM) Chapter 11**.**

Case report criteria definitions in **Appendix 1: Summary of AEFI Reporting Criteria** are from the Brighton Collaboration. It is recommended that immunizers print our or bookmark Appendix 1 as a quick reference guide.

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.

AEFIs that should not be reported

Events/reactions that:

- Do not meet reporting criteria in **Appendix 1: Summary of AEFI Reporting Criteria**. **DO NOT REPORT these events to the Ministry of Health.**
- Are clearly attributed to other causes (e.g. related to a concurrent illness).
- Are a common/expected side effects that are mild, predictable and self-limiting.
    - Clients must be counselled to manage expected reactions following immunization .
    - **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.
- **Public Health should document such reports and any MHO consultations, etc. in the Panorama client record. in the vaccine detail comments section of each applicable vaccine agent and add a Client Warning.**

AEFIs that must be reported for review by a Medical Health Officer:

- Serious events: life threatening or resulting in death; requiring hospitalization; resulting in a residual disability; associated with congenital malformation.
- Events 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 precautions, contraindications or a reason to postpone a future immunization.
- Events managed as anaphylaxis.
- 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., 6 in a week, or 6 in a regional area) that require further assessment, even if the total number of AEFIs may not be higher than expected.
- **Reportable AEFIs MUST BE uploaded into the client's Panorama record as per the Uploading AEFI Reports into a Client's Panorama Record Policy.**

AEFI Reporting Timelines

- ASAP: When clusters of reactions occur that are temporally related to specific agent or lot number.

The Disease Control Regulations specify within:

  - **48 hours** after becoming aware of a serious [*or unusual or unexpected*] AEFI.
  - **Two weeks** after becoming aware of a non-serious AEFI.

- Recommendations following an AEFI review by a MHO must be discussed with the client, documented in Panorama and provided to the client's primary health care provider.

How to Complete the AEFI Reporting Form

On the top right-hand corner of the first page of the AEFI Reporting Form, **check one** of the boxes to indicate whether the AEFI report being submitted is an "**Initial report**" **or** a "**Follow up report**".

- For a (new) **Initial report**, a Unique Episode Number and Region Number are assigned (**Section 1**).
- For a **Follow up report**, provide the "Unique episode #" of the initial report. A follow-up report follows a previously reported AEFI when section 12 is completed.

Section 1 Provincial and Regional Identifying Information

Section 1a:
Unique Episode Number: A unique episode number is a mandatory case identification number and must be assigned to each AEFI report page upon submission to Public Health as per SIM **Chapter 11** in format YYYY-## The Unique Episode Number must be marked on the top of every page of the AEFI Reporting Form as an identifier to link the pages together. This number must only be filled in by public health personnel who are authorized to assign it.

Section 1b:
Region Number: The Region Number is a regional abbreviation is assigned to each AEFI report page by Public Health as noted in SIM **Chapter 11**. The Region Number must be marked on the top of every page of the AEFI Reporting Form as an identifier to link the pages together. This number must only be filled in by public health personnel who are authorized to assign it.

Athabasca	AHA
Cypress	CHR
Five Hills	FHHR
First Nation & Inuit Health –SK	FNIH-SK
Heartland	HHR
Keewatin Yatthé	KYHR
Kelsey Trail	KTHR
Mamawetan Churchill River	MCRHR
Northern Intertribal Health Authority	NITHA
Prairie North	PNHR
Prince Albert Parkland	PAPHR
Regina Qu'Appelle	RQHR
Saskatoon	SkHR
Sunrise	SHR
Sun Country	SCHR

Section 2 Pediatric Surveillance Reference Number

- A **pediatrics surveillance reference number** is only assigned by the active pediatric hospital surveillance network's system(e.g., SPRINT-KIDS) when an AEFI report is generated from one of their hospitals. The pediatrics surveillance reference number must be marked on the top of every page of the AEFI Reporting Form.
- **Leave this section blank if it does not apply to your facility** (e.g., if you are not a hospital that is part of the active pediatric hospital surveillance network

Section 3: Patient Identification

- Patient identification information: Provide the patient's first and last name, health number (if applicable), address of usual residence **including city/town** and postal code and a telephone number where the patient can be reached.
- Information source: If the source of the information for the AEFI report is the patient, document "Patient". If it is a parent or another care provider, provide their name and relation to the patient and provide their contact information (including their full mailing address and phone number where they can be reached) in Section 10, if it is different from the patient's.

Section 4: Information at Time of Immunization and AEFI Onset

Section 4a: At time of Immunization

- **Province/Territory of immunization:** Indicate the P/T where the immunization was received, as this may be different from the patient's P/T of residence and/or where the AEFI is being reported. If the vaccine was administered outside of Canada, indicate the country that it was administered in the space to capture P/T and comment if it was received at a Canadian operated clinic in that country. NOTE: Reports of vaccines not approved in Canada must be kept at the P/T level and not forwarded to PHAC.
- **Date vaccine administered (DVA):** Indicate the date and time of vaccine administration, remembering to specify if the vaccine was administrated in the "am" or "pm" by selecting the appropriate descriptor. If the complete date and time is unknown, provide as much information as possible (e.g., month and/or year) as this is now a mandatory field. All dates must be captured in format YYYY/MM/DD.
- **Date of birth:** Indicate the patient's date of birth in the space provided. If the complete date is unknown, provide as much information as possible (e.g., month and/or year). All dates must be captured in format YYYY/MM/DD.
- **Age:** Indicate the patient's age at the time of immunization, including the age units. Use days for infants aged less than 1 week; weeks for infants aged less than 1 month; months for infants aged less than 1 year; and years thereafter. If the patient's exact age is unknown, estimate the patient's age.
- **Sex at birth:** Refers to the patient's sex assigned at birth. Sex is typically assigned based on a person's reproductive system and other physical characteristics (e.g., male or female). Indicate by selecting "Male", "Female", or "Other", if unknown or ambiguous.
- **Gender:** Refers to the patient's personal and/or social identity. Patients must be asked which gender identity they self-identify as. Indicate by entering one of the following categories: **"Woman/Girl", "Trans woman", "Man/Boy", "Trans man", "Non-binary", "Or please specify this patient's gender", "Unknown", or "Not asked".** If "Or please specify this patient's gender", specify gender identity using the term given by the patient.
- **Pregnant at time of immunization:** Indicate by selecting the tick box if the patient is/was pregnant at time of immunization.
- **Gestation age in weeks/days:** Indicate in weeks/days how far along the pregnancy is/was at time of immunization.
- **Breastfeeding at time of immunization:** Indicate by selecting the tick box if the patient was breastfeeding a child at the time of immunization.

- **Race:** The primary purpose of measuring race-based health inequalities is to identify, monitor and address inequities that potentially stem from bias and racism — including at systemic, interpersonal and internal levels. Patients should be asked to identify which race category (or categories) best describes themselves. Indicate by entering one or more of the following categories: "**Black", "East/Southeast Asian", "Indigenous", "Latino", "Middle Eastern", "South Asian", "White", "Another race category", "Prefer not to answer", "Do not know", or "Not asked".** If "Another race category", please specify. Note that the option "Indigenous" refers to Indigenous origin outside of Canada.
- **Indigenous status:** Refers to whether the patient identifies with the Indigenous peoples of Canada. Patients must be asked which Indigenous identity they self-identify as. Indicate by entering one or more of the following categories: **"First Nations", "Métis", "Inuk/Inuit", "Other Indigenous", "Prefer not to answer", or "Not asked".** If "Other Indigenous", please specify.

Section 4b Vaccines

There is space to record 6 immunizing agents in Section 4b; however, if more than 6 were administered simultaneously, record the additional vaccines in Section 10. When completing Section 4b, provide all information in the table as outlined below:

- **Immunizing agent(s):** Record the proper name or accepted abbreviation as outlined in SIM Chapter 11 for all immunizing agents in separate rows. If the immunizing agent is not listed in SIM Chapter 11, record the name of the immunizing agent as accurately as possible, and ensure to specify the trade name and manufacturer for the vaccine in the proceeding columns.
- **Trade name:** Specify the trade name of each vaccine administered.
- Manufacturer: Specify the manufacturer name, as indicated on the product label, for each vaccine administered.
- **Lot number:** Document the complete lot number, including all letters and numbers, for each vaccine administered. This information is essential for conducting signal detection or future risk assessments.
- **Expiry date:** Indicate the expiration date for each vaccine administered. All dates must be captured in format YYYY/MM/DD.
- **Dose number:** Provide the dose number in the series (1, 2, 3, 4, 5, etc. or booster) for each vaccine administered.
    - **For influenza and COVID-19 vaccines,** unless a patient receives more than one dose in one season, the "Dose #"must be recorded as "1".
- **Dosage/unit:** Indicate the dose volume size (e.g., 0.5) per unit (e.g., mL) for each vaccine administered.
- **Route:** Specify the route of administration for each vaccine administered; these abbreviations are acceptable:
    - Intradermal: ID
    - Intramuscular: IM
    - Subcutaneous: SC
    - Intranasal: IN
    - Oral: PO
    - Other: please specify (no abbreviations)
- **Site:** Indicate the site of injection for each vaccine administered. These are acceptable:
    - Left arm: LA
    - Right arm: RA
    - Arm: Arm
    - Left leg: LL
    - Right leg: RL
    - Leg: Leg
    - Left gluteal: LG
    - Right gluteal: RG
    - Gluteal: Glut
    - Mouth: PO
    - Nose: IN
    - Multiple sites: MS
    - Other: please specify (no abbreviations)

Section 4c Medical History (Up to the Time of AEFI Onset)

Indicate the patient's medical history prior to the time of AEFI onset by choosing all that apply from the list provided below. Provide all additional details and descriptions, including medical investigations, dates, and timing prior to time of AEFI onset, when available, in Section 10.

- **Concomitant medication(s):** Provide the name of all medications, including prescription, over the counter and herbal supplements, which the patient had been taking immediately prior to the time of AEFI onset, including those taken only as needed, in Section 10. When available, provide the dose, frequency, route of administration and reason for taking each concomitant medication.
- **Known medical condition(s):** 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). Include only acute illnesses or injuries, such as animal bites or skin puncture injuries.
- **Recent immunization history:** Indicate any other vaccine(s) received within 30 days prior to the "date vaccine administered" in Section 4a. Indicate the immunizing agent, trade name, manufacturer, lot number, dose number in the series, and date of vaccine administration (DVA) for each immunization (if known). All dates must be captured in format YYYY/MM/DD.

Section 5 Previous AEFI

Indicate whether the patient had ever experienced an AEFI following a previous dose of any of the immunizing agents listed in Section 4b. Choose only one of the answers provided in Section 5, as described below:

- **Yes:** The patient had previously received immunization with at least one of the immunizing agents listed in Section 4b and had subsequently experienced an AEFI.
    - If the answer is "Yes", the patient had previously experienced an AEFI following a previous dose of one or more of the immunizing agents(s) listed in Section 4b, provide all details of the previous AEFI in Section 10, including the corresponding time to onset and duration, when known. When possible, provide information regarding the severity of the AEFI and if the previous AEFI was less or more severe than the currently reported AEFI.
- **No:** The patient had previously received immunization with one or more of the immunizing agents listed in Section 4b and had not experienced a subsequent AEFI.
- **Unknown:** It is unknown if the patient had previously received immunization with any of the immunizing agents listed in Section 4b and/or, if an AEFI followed.
- **Not applicable (no prior doses):** The patient had never previously received immunization with any of the immunizing agents listed Section 4b.
- NOTE: If there is uncertainty regarding which option to choose, or if there is additional information to provide (e.g., multiple vaccines were administered and not all the information regarding the patient's past AEFI experience can be captured in Section 5), please provide additional details in Section 10.

Section 6 Immunization Errors

Indicate whether the AEFI has followed an incorrect immunization (an immunization error, program error including cold chain issues, etc.) by choosing **"Yes", "No"**, or **"Unknown"**. If **"Yes"**, indicate all that apply in Section 6 by checking the box next to the situation that most closely reflects the error (as described below) and provide all known details in Section 10.

- **Vaccine administered at inappropriate site:** The vaccine was administered at a site not recommended for its administration (e.g., gluteal) or higher/lower in a limb than recommended (e.g., near shoulder joint during IM deltoid injection).
- **Inappropriate route of vaccination:** The vaccine was administered via a route not recommended for its administration (e.g., subcutaneous vs. intramuscular).
- **Inappropriate age at vaccine administration**: The vaccine was administered to an individual who was not within the recommended age limits for that specific vaccine.
- **Wrong vaccine administered:** An unintended vaccine was administered.
- **Other, specify:** If an error has occurred that is not accurately reflected in the list of provided errors, please choose "Other" and specify in the space provided. Provide all details in Section 10. Examples of other immunization errors include the following:
    - **Expired vaccine used:** The vaccine was administered after the expiry date as indicated on the vaccine label by the manufacturer.
    - **Extra dose administered:** An extra (unnecessary) dose of the vaccine was administered.
    - **Inappropriate dose of vaccine administered:** A larger or smaller dose of vaccine was administered than that recommended for the patient's age group.
    - **Inappropriate schedule of vaccine administered:** The vaccine administration did not follow an appropriate schedule (e.g., the dose was administered too soon after the previous dose in the series had been administered).
    - **Incorrect product storage:** Any excursion from conditions recommended during the transport, storage and handling of vaccines (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; etc.).
    - **Product preparation error:** Any errors in the preparation of vaccines prior to administration. This may include inappropriate processes used for mixing or reconstituting vaccines, and/or the use of an expired diluent, or an incorrect diluent type or volume.

Section 7 Impact Of AEFI, Outcome, and Level of Care Obtained

Section 7a Highest Impact of the AEFI

Indicate the highest perceived impact of the AEFI on the patient's daily activities (as assessed by the patient or the parent/caregiver) by choosing one of the provided responses in Section 7a:

- **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.).
- **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)
- **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).
- **Unknown:** The perceived impact of the AEFI on the patient's daily activities is unknown.

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.).

- **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.).
- **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.)

Section 7b Outcome at Time of AEFI 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 persistent or significant disability and/or incapacity or death, provide all available details in Section 10.

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

- **Death:** Patient died. Record the corresponding date of death in the space provided. All dates must be captured in format YYYY/MM/DD.
- **Persistent or significant disability/incapacity:** An injury, which impairs the physical and/or mental ability of a person to perform their normal work or non-occupational activities supposedly in a significant manner or for the remainder of their life.
- **Congenital anomaly/birth defect:** Structural or functional abnormalities of prenatal origin that are present at birth.
- **Not yet recovered:** Residual signs and/or symptoms remain (at the time of the report).
- **Fully recovered**: All signs and symptoms have resolved.
- **Unknown:** The outcome of the AEFI is unknown or unclear.

Section 7c Highest Level of Care Obtained

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

- **None:** No care was received for the reported AEFI.
- **Telephone/virtual consultation with Health Care Provider:** The patient had a telephone or virtual consultation with a health care provider (e.g., nurse, nurse practitioner, physician, etc.) regarding the reported AEFI.
- **Non-urgent visit:** The patient was seen by a health care professional (e.g., at a physician's office or walk in clinic) for the assessment and/or treatment of the reported AEFI. Document all investigations conducted and treatments received in Section 10.
- **Emergency visit** (no hospitalization): The patient was seen by a health care professional for an emergency visit for the assessment and/or treatment of the reported AEFI. Please note that emergency visits are not considered admission to hospital and therefore, admission and discharge dates are not required. Document all investigations conducted and treatments received in Section 10.
- **Unknown:** It is unknown if the patient received care for the reported AEFI.
- **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 in the spaces provided. All dates must be captured in format YYYY/MM/DD. Document all investigations conducted and treatments received in Section 10.
- **Resulted in prolongation of existing hospitalization:** If the 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 because of the AEFI. Indicate the date of hospital admission and discharge for the entire period of hospitalization (if known) in the spaces provided. All dates must be captured in format: YYYY/MM/DD. Document all investigations conducted, and treatments received in Section 10.

Section 7d Treatment received

- **I**ndicate whether the patient received any treatment, including self-treatment, for the reported AEFI by choosing "**Yes**", "**No**", or "**Unknown**". Provide details of all treatments received, following the onset of the AEFI, in Section 10 when applicable.

Section 8 Reporter Information

The reporter must complete all details in the reporter information section in full including:

- Your first and last names
- Your phone and fax contact number (including extensions when applicable) and
- Your full mailing address of the institution/setting/centre.
- Your work setting:
  - Long-term care home
  - Physician office
  - Community nursing station
  - Public health
  - Pharmacy
  - School/student clinic
  - Hospital
  - Workplace clinic
  - Local vaccination campaign clinic
  - CISSS/CIUSSS
  - CANVAS
  - Other, specify _____
- You must sign and date the AEFI Reporting Form in the space provided and
- You must specify your professional status or affiliation by selecting one of the following
  - MD: Medical Doctor
  - RN: Registered Nurse
  - Active Pediatric Surveillance Hospital
  - Pharmacist
  - CANVAS
  - Other, specify._____
- All dates must be captured in format: YYYY/MM/DD.

Section 9 AEFI Details

Indicate the details of the AEFI being reported by checking all sections that apply.

- All additional pertinent details, including clinical details, types of treatment, test results, and prior infections with the pathogen(s) being vaccinated against in Section 4b, must be provided in Section 10.
- **For each AEFI where a *Brighton Collaboration* *Case Definition* (BCCD) exists, the most current published version of the case definition has been cited.**
- For convenience and consistency, high level definitions have been provided for most events listed in Section 9. **Some conditions must be diagnosed by a physician or nurse practitioner, except in the case of anaphylaxis where objective signs can be reported by any health care practitioner (e.g., nurse, pharmacist).** Sufficient information must be provided in Section 10 to support the AEFI details selection(s).

- **Time to onset and duration of signs and symptoms:** For all AEFIs, indicate the time to onset (time from immunization to onset of first sign/symptom), and the duration (time from onset of first sign/symptom to resolution of all of signs and symptoms). The time to onset and the duration of the signs and symptoms of the specified AEFI must be documented according to the following guidelines for all AEFIs:
  - **If the time to onset or the duration is less than 1 hour, record in minutes (M).**
  - **If the time to onset or the duration is greater than or equal to 1 hour, but less than 1 day, record in hours (H).**
  - **If the time to onset or the duration is greater than or equal to 1 day, record in days (D).**

Section 9A Local Reaction at or Near Vaccination Site
Definition: Any description of morphological or physiological change at or near the vaccination site (BCCD: Vaccine 26 (2008) 6800–6813). Refer to Appendix 2: Definitions of Mucocutaneous Lesions for additional terms application to local reactions.

Indicate, by choosing all that apply, any local reactions at or near the vaccination site, as described below. For the indicated local reaction, specify the time to onset and duration in the table provided.

- **Infected abscess:** A localized collection of pus in a cavity formed by the disintegration of tissue, usually caused by microorganisms that invade the tissues (BCCD: Vaccine 25 (2007) 5821–5838). Note the 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 was temporally related to treatment.
- **Lymphadenitis:** Inflammation of one or more lymph nodes, usually caused by a primary focus of infection elsewhere in the body (Current Infectious Disease Reports, 2009).
- **Sterile abscess:** An abscess whose contents are not caused by pyogenic bacteria (BCCD: Vaccine 25 (2007) 5821–5838). Note the 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 was 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 (BCCD: Vaccine 25 (2007) 5803–5820). Note the 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 (BCCD: Vaccine 22 (2004) 575–585).
- **Reaction joint-to-joint/crosses joint(s), specify:**
  - **Reaction stretches joint-to-joint:** Reaction extending between two joints but not past either adjacent joint (National Centre for immunisation Research and Surveillance (NCIRS) Injection Site Reactions, 2019). Specify which joints in the space provided.
  - **Reaction crosses joint:** Reaction extending past at least one joint adjacent to the site of vaccine administration (NCIRS Injection Site Reactions, 2019). Specify which joint(s) is/are crossed in the space provided.
  - **Specify:** Specify which joints in the space provided. Specify all details of the reaction in Section 10 that are not already captured in Section 9a.

- **Other, specify:** Specify in the space provided. Provide 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 (BCCD: Vaccine 25 (2007) 5858–5874).
- **Pain:** An unpleasant sensation occurring in varying degrees of severity that could be described as discomfort, distress or agony (BCCD: Vaccine 30 (2012) 4558–4577).
- **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 (BCCD: Vaccine 25 (2007) 5839–5857).
- **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) (BCCD: Vaccine 25 (2007) 5697–5706).
- **Largest diameter of vaccination site reaction:** Indicate the diameter (in centimetres) of the largest vaccination site reaction that is present.
- **Site(s) of reaction:** Site(s) of the local reaction being reported, if known. (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 (BCCD: Vaccine 25 (2007) 5821–5838).
- **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/surgical drainage:**
    - **Spontaneous drainage:** Draining of fluid from a site without intervention (BCCD: Vaccine 25 (2007) 5821–5838). 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 (BCCD: Vaccine 25 (2007) 5821–5838). When available, describe drainage material (purulent or non-purulent, bloody, etc.) and provide all Gram stain/culture results.
- **Microbial results:** 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 intramuscular vaccination in the thigh, axillary adenopathy associated with an intramuscular vaccination in the deltoid, etc.).

Section 9b Allergic and Allergic-Like Events

Choose one of the following events below. For the indicated allergic event, **specify the time to onset and duration** in the table provided.

- **Anaphylaxis:** An acute hypersensitivity reaction with multi-organ-system involvement that can present as, or rapidly progress to, a severe life-threatening reaction (BCCD: Vaccine 41 (2023) 2605-2614). Check all applicable signs/symptoms referable to skin/mucosal, cardiovascular, respiratory and/or gastrointestinal systems that were observed during the event course and use Section 10 for additional details. Provide specific measurements, where available, for pulse, respiratory rate and blood pressure. For each, indicate if the measurement was taken before or after treatment with epinephrine, if applicable.
- **Oculo-Respiratory Syndrome (ORS):** The presence of bilateral "red eyes" plus one or more respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) that starts within 24 hours of vaccination, with or without facial oedema (Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2018-2019.
- **Other allergic events:** An event considered by the reporter to be allergic in nature but not anaphylaxis or ORS. Check all signs and symptoms in Section 9b that were present and use Section 10 for any additional details.
- **For any allergic and allergic-like events selected above, check all that apply below:**
    - **Epinephrine administered:** Indicate whether Epinephrine was used to treat the allergic event by choosing "**Yes**" or "**No**". If "**Yes**", please provide details in Section 10.
    - **Mast cell tryptase measured:** Indicate whether mast cell tryptase was measured by choosing "**Yes**" or "**No**". If "**Yes**", indicate whether the mast cell tryptase was elevated (>upper normal limit OR 1.2 X baseline + 2 ng/L) by checking the proceeding tick box. Provide the measurement and reference range in the spaces provided. Provide any additional details in Section 10.
    - **For cases of suspected anaphylaxis, was more than one body system** (skin/mucosal, cardiovascular, respiratory, gastrointestinal) **involved within the first hour after onset of signs or symptoms**?: Indicate by choosing "**Yes**", "**No**", or "**Unknown**". If "**Yes**", please provide details in Section 10.
    - For a chosen event above, 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)** (**not at vaccination site**): 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) at a site other than the vaccination site (BCCD: Vaccine 28 (2010) 4487–4498). Specify site of reaction in Section 10.
- **Generalized erythema with pruritus:** Abnormal redness of the skin without any raised skin lesions involving more than one body site (i.e., each limb is counted separately, as is the abdomen, back, head and neck) and accompanied by a sensation that provokes the desire to rub and/or scratch to obtain relief (BCCD: Vaccine 28 (2010) 4487–4498). Specify sites of reaction in Section 10.
- **Generalized erythema without pruritus:** Abnormal redness of the skin without any raised skin lesions involving more than one body site (i.e., each limb is counted separately, as is the abdomen, back, head and neck) without any sensation that provokes the desire to rub and/or scratch to obtain relief (BCCD: Vaccine 28 (2010) 4487–4498). Specify sites of reaction in Section 10.
- **Bilateral red itchy eyes (new onset):** Redness of the whites of the eyes (sclera) accompanied by a sensation that provokes the desire to rub and/or scratch to obtain relief (BCCD: Vaccine 28 (2010) 4487–4498).
- **Bilateral red eyes without itching:** Redness of the whites of the eyes (sclera) without any sensation that provokes the desire to rub and/or scratch to obtain relief (BCCD: Vaccine 28 (2010) 4487–4498).

- **Angioedema of skin at a site other than vaccination site (may include lip swelling):** Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites (other than the vaccination site) which may not be well circumscribed and are usually not itchy (BCCD: Vaccine 28 (2010) 4487–4498). **Angioedema should only be reported if there was visible skin or mucosal swelling**; sensation of 'swelling of the lip' or 'swelling of the tongue or throat' in the absence of visible swelling must not be documented as angioedema. Specify site of reaction in Section 10.

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

- **Measured hypotension (**must be documented**):** An abnormally low blood pressure and documented by appropriate measurement.
  - Infants and children: age specific systolic blood pressure of less than the 3rd to 5th percentile or greater than a 30% decrease from that person's baseline.
  - Adults: systolic blood pressure of less than 90 mmHg or greater than 30% decrease from that person's baseline (BCCD: Vaccine 28 (2010) 4487–4498).
- **Loss of consciousness (excluding vasovagal syncope(fainting)):** Total suspension of conscious relationship with the outside world as demonstrated by the inability to perceive and to respond to verbal, visual, or painful stimulus (BCCD: Vaccine 28 (2010) 4487–4498). Indicate duration of the event in Section 10.

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

- **Expiratory wheezing:** A whistling, squeaking, musical, or puffing sound made by breathing out (BCCD: Vaccine 28 (2010) 4487–4498). **This manifestation must be documented by a healthcare professional, which could be with/without a stethoscope.**
- **Inspiratory stridor:** A harsh and continuous sound made on breathing in (BCCD: Vaccine 28 (2010) 4487–4498). **This manifestation must be documented by a healthcare professional, which could be with/without a stethoscope.**
- **Upper airway swelling:** Indicate the observed location by checking "tongue", "pharynx", "uvula", and/or "larynx". **This manifestation must be documented by a healthcare professional.**
- **Tachypnea:** Rapid breathing which is abnormally high for age and circumstance (younger than 1 year: more than 60 breaths per minute; 1–2 years: more than 40 breaths per minute; 2–5 years: more than 35 breaths per minute; 5–12 years: more than 30 breaths per minute; older than 12 years: more than 16 breaths per minute) (same source as tachycardia) (BCCD: Vaccine 28 (2010) 4487–4498). **This manifestation must be documented by a healthcare professional.**
- **Cyanosis:** A dark bluish or purplish discolouration of the skin and/or mucous membranes due to lack of oxygen in the blood (BCCD: Vaccine 28 (2010) 4487–4498). **This manifestation must be documented by a healthcare professional.**
- **Grunting:** A sudden and short noise with each breath when breathing out (BCCD: Vaccine 28 (2010) 4487–4498). **This manifestation must be documented by a healthcare professional.**
- **Measured hypoxia with O2 saturation <90%:** (BCCD: Vaccine 41 (2023) 2605-2614). **This manifestation must be documented by a healthcare professional.**
- **Chest wall retractions:** Inward movement of the muscles between the ribs (intercostal), in the lower part of the neck (supra-clavicular or tracheal tug) or below the chest (subcostal) (BCCD: Vaccine 28 (2010) 4487–4498). These movements are usually a sign of difficulty breathing. **This manifestation must be documented by a healthcare professional.**

- **Increased use of accessory respiratory muscles:** Accessory respiratory muscles can include muscles in the neck (scalenus, sternocleidomastoids), muscles in the chest (pectoralis major and minor), and abdominal muscles (Mechanics of respiratory muscles, Respiratory Physiology & Neurobiology, 2008) https://www.sciencedirect.com/science/article/pii/S1569904808001134?via%3Dihub. **This manifestation must be documented by a healthcare professional.**
- **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.
- **Chest tightness:** Inability or perception of not being able to move air in or out of the lungs.
- **Hoarse voice:** An unnaturally harsh cry of infant or vocalization in a child or adult (BCCD: Vaccine 28 (2010) 4487–4498).
- **New onset and persistent** (recurring or lasting more than 5 minutes):
    - **Dry cough:** Rapid expulsion of air from the lungs to clear the lung airways and not accompanied by expectoration (a non-productive cough) (BCCD: Vaccine 28 (2010) 4487–4498).
    - **Sneezing:** An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose (BCCD: Vaccine 28 (2010) 4487–4498).
    - **Runny nose:** Discharge of thin nasal mucus (BCCD: Vaccine 28 (2010) 4487–4498).

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

- **New onset** (≥2 episodes if <12 months old; otherwise ≥1 episode):
    - **Vomiting:** The reflex act of ejecting the contents of the stomach through the mouth (BCCD: Vaccine 28 (2010) 4487–4498). Provide details in Section 10.
    - **Diarrhea:** Loose or watery stools which may occur more frequently than usual (BCCD: Vaccine 28 (2011) 4487–4498). Provide details in Section 10.

Section 9c Neurological Events

Indicate any neurologic events as described below. Check all applicable boxes in Section 9c and use Section 10 to record all additional pertinent clinical details and test results. For each selected neurological event, please specify the time to onset and duration in the table provided.

- **Meningitis:** Commonly defined as a syndrome characterized by acute onset of signs and symptoms of meningeal inflammation and cerebrospinal fluid (CSF) pleocytosis, independent of the presence or absence of microorganisms on Gram stain and/or routine culture (BCCD: Vaccine 25 (2007) 5793–5802**). Must be diagnosed by a physician or nurse practitioner**. Provide lumbar puncture (LP) results with cerebrospinal fluid analysis and blood cultures in Section 10.
    - **Aseptic Meningitis:** Meningitis as described above, in the absence of microorganisms on Gram stain and/or on routine culture (BCCD: Vaccine 25 (2007) 5793-5802). **Must be diagnosed by a physician or nurse practitioner**. Provide lumbar puncture results with cerebrospinal fluid analysis in Section 10.
- **Encephalopathy:** Refers to a state of being, in which consciousness or mental status is altered (BCCD: Vaccine 25 (2007) 5771–5792). **Must be diagnosed by a physician or nurse practitioner.**
- **Encephalitis:** Defined as inflammation of the parenchyma of the brain (BCCD: Vaccine 25 (2007) 5771–5792). **Must be diagnosed by a physician or nurse practitioner.** Use Section 10 to record all additional pertinent clinical details and test results, especially results of CT or MRI brain, EEG and/or lumbar puncture with cerebrospinal fluid analysis.
- **Meningoencephalitis:** Meningoencephalitis is acceptable terminology when both encephalitis and meningitis are present (BCCD: Vaccine 25 (2007) 5771–5792). **Must be diagnosed by a physician or nurse practitioner**. Use Section 10 to record all additional pertinent clinical details and test results, including computed tomography (CT) or MRI brain, electroencephalography (EEG), and/or lumbar puncture with cerebrospinal fluid analysis.

- **Guillain-Barré Syndrome (GBS):** A condition characterized by various degrees of weakness, sensory abnormalities, and autonomic dysfunction due to damage to peripheral nerves and nerve roots (BCCD: Vaccine 29 (2011) 599–612). **Must be diagnosed by a physician or nurse practitioner.** Use Section 10 to record all additional pertinent clinical details and test results, especially hyporeflexia/areflexia (weak or absent reflexes), electromyography (EMG) and/or lumbar puncture (LP) with results of cerebrospinal fluid analysis.
- **Bell's palsy:** A subset of peripheral facial nerve palsy with unknown cause. Inability to wrinkle the forehead or raise the eyebrows on the affected side must be specified (BCCD: Vaccine 35 (2017) 1972–1983). **Must be diagnosed by a physician or nurse practitioner.** Use Section 10 to record all additional pertinent clinical details and test results, including blood work and brain imaging where available.
- **Other paralysis:** Loss of ability to move. **Must be diagnosed by a physician or nurse practitioner.**
- **Seizure(s):** Episodes of neuronal hyperactivity most commonly resulting in sudden, involuntary muscular contractions. They may also manifest as sensory disturbances, autonomic dysfunction and behavioral abnormalities, and impairment or loss of consciousness (BCCD: Vaccine 22 (2004) 557–562**). Indicate the type of seizure and seizure details in the designated area at the bottom of Section c.**
- **Acute disseminated encephalomyelitis:** Described as a uniphasic syndrome of brain inflammation and demyelination, occurring in temporal association with an antecedent immunologic challenge, such as infection or an immunization (BCCD: Vaccine 25 (2007) 5771–5792). **Must be diagnosed by a physician or nurse practitioner.** Use Section 10 to record all additional pertinent clinical details and test results, including MRI brain and/or spine and/or lumbar puncture with cerebrospinal fluid analysis.
- **Myelitis/Transverse myelitis:** Defined as inflammation of the parenchyma of the spinal cord (BCCD: Vaccine 25 (2007) 5771-5792). **Must be diagnosed by a physician or nurse practitioner.** Use Section 10 to record all additional pertinent clinical details and test results, including MRI spine and/or lumbar puncture with cerebrospinal fluid analysis.
- **Other neurologic diagnosis, specify:** Specify in the space provided. **Must be diagnosed by a physician or nurse practitioner.** Use Section 10 to record all additional pertinent clinical details and test results.

For all neurologic events selected 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, listlessness, or lack of interest, combined with being tired, and having difficulty concentrating or doing simple tasks.
- **Personality changes lasting ≥ 24 hours:** Change in personal behaviour-response patterns.
- **Fever (≥ 38.0°C):** Endogenous elevation of at least one body temperature, regardless of measurement device, anatomic site, age or environmental conditions (BCCD: Vaccine 22 (2004) 551–556).
- **Focal or multifocal neurologic sign(s):** Neurological impairment which is caused by a lesion somewhere in the nervous system.
- **Formication:** Sensation of insects crawling over or within the skin. Indicate site of reaction in Section 10.
- **Anaesthesia (numbness)/Paraesthesia (prickling or tingling)/Burning:**
    - **Anaesthesia:** Loss of sensation resulting from pharmacologic depression of nerve function or from neurogenic dysfunction (Stedman's Medical Dictionary (2016)). Indicate site of reaction in Section 10.

  - **Paraesthesia:** A spontaneous abnormal usually nonpainful sensation (e.g., tingling, pricking); may be due to lesions of both the central and peripheral nervous systems (Stedman's Medical Dictionary (2016)). Indicate site of reaction in Section 10. Brief tingling immediately following immunization must be included under Section 9b. Allergic and Allergic-like Events.
  - **Burning:** Sensation of stinging or heat not necessarily accompanied by redness, or physical signs of skin irritation. Indicate site of reaction in Section 10.
- **Other, specify:** Specify and provide any additional details in Section 10.
- **CSF abnormality:** Alteration in normal cerebrospinal fluid (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 abnormality:** Abnormal electroencephalography (EEG) as **interpreted by a qualified health professional**.
- **EMG abnormality:** Abnormal skeletal electromyography (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, Magnetic Resonance Imaging (MRI), and 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.
- **Decreased or absent reflexes:** Please document any additional details in Section 10 as to whether physical examination revealed hyporeflexia or areflexia.

TYPES OF SEIZURES

- **Type of seizure:** Indicate the type of seizure by selecting either "Partial" or "Generalized".
- **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.
- **Generalized seizure:** A seizure with loss of consciousness and generalized motor movements due to generalized hyperactivity in the cerebral cortex.
  - **Specify further by selecting one of the following:**
    - **Tonic:** Sustained increase in muscle contraction lasting a few seconds to minutes.
    - **Clonic:** Sudden, brief (less than 100 milliseconds) involuntary contractions of the same muscle groups, regularly repetitive at a frequency of about 2 to 3 contractions per second.
    - **Tonic-Clonic:** A sequence consisting of a tonic phase followed by a clonic phase.
    - **Atonic:** Sudden loss of tone in postural muscles, often preceded by a myoclonic jerk, and may be precipitated by hyperventilation (in the absence of Hypotonic-Hyporesponsive Episode, syncope, or myoclonic jerks).
    - **Absence:** The occurrence of an abrupt, transient loss or 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:** Select the appropriate option for each of the following and record additional details in Section 10.
  - **Sudden loss of consciousness:** Sudden total unresponsiveness (suspension of conscious relationship with the outside world, inability to perceive and respond). Indicate by choosing "Yes", "No" or "Unknown". If "Yes", provide additional details in Section 10.
  - **Witnessed by healthcare professional:** Indicate if the event was witnessed by a healthcare professional (e.g., doctor, nurse, etc.) by choosing "Yes", "No" or "Unknown". If "Yes", provide additional details in Section 10.

- **Previous history of seizures:** For individuals who have had seizures at any time prior to this immunization, indicate the type by choosing "Febrile", "Afebrile" or "Unknown". Provide any additional details in Section 10.
- **Febrile:** With fever of at least 38.0°C.
- **Afebrile:** Without fever.
- **Unknown:** It is unknown if the seizure was febrile or afebrile. Provide all known details in Section 10.

Section 9d Other Events

For a selected event, describe the signs and symptoms by checking all that apply. Provide all additional details in Section 10. For each selected event, specify the time to onset and duration in the table provided.

- **Hypotonic-Hyporesponsive Episode (age <2 years):** Characterized by sudden onset of limpness (reduced muscle tone), change in skin colour (pallor or cyanosis) and reduced responsiveness (i.e., less responsive than usual to verbal or other sensorial stimuli) (BCCD: Vaccine 25 (2007) 5875-5881). 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 Hypotonic-Hyporesponsive Episode checkbox if the patient is 2 years of age or older**; instead, check "Other serious or unexpected event(s) not listed in the form" and describe in Section 10.

  Choose all that apply to the reported AEFI from the list provided below:
  - **Limpness:** Lacking firmness and strength; no muscle tone.
  - **Pallor:** Unnatural lack of colour in the skin (abnormal loss of colour from normal skin).
  - **Cyanosis:** A dark bluish or purplish discolouration of the skin and mucous membrane due to lack of oxygen of the blood (BCCD: Vaccine 28 (2010) 4487–4498).
  - **Decreased (↓) responsiveness/unresponsiveness**: Change in usual responsiveness to sensory stimuli or lack of responsiveness to sensory stimuli.
  - **Persistent crying (continuous and unaltered crying for ≥3 hours):** Crying, which is continuous, unaltered and lasts for 3 or more hours among young children (BCCD: Vaccine 22 (2004) 586-591).
- **Intussusception:** The prolapse of one part of the intestine into the lumen of an immediately adjacent part, causing partial or complete intestinal obstruction (BCCD: Vaccine 22 (2004) 569–574). **Must be diagnosed by a physician or nurse practitioner**. **Provide all pertinent details in Section 10.**
- **Arthritis:** Inflammation of the joint(s). Choose all that apply to the reported AEFI from the list provided 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. (Mayo Clinic)
  - **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) (Previous Cdn def'n—CCDR 1995; 21–13: page F–8).

- **Multisystem inflammatory syndrome in children (MIS-C):** A severe illness requiring hospitalization in a person aged less than 21 years, with laboratory evidence of current or previous (within 12 weeks) SARS-CoV-2 infection or prior SARS-CoV-2 immunization. Features of MIS-C include severe extrapulmonary organ dysfunction (including thrombosis), laboratory evidence of severe inflammation, and absence of severe respiratory disease (BCCD: Vaccine 39 (2021) 3037-3049). **Must be diagnosed by a physician or nurse practitioner. Include the following information in Section 10, if available**:
  1. If fever (38°C) was present and, if so, for how many consecutive days.
  2. Clinical features:
     1. Mucocutaneous (rash, erythema or cracking of the lips/mouth/pharynx, bilateral nonexudative conjunctivitis, erythema/edema of the hands and feet)
     2. Gastrointestinal (abdominal pain, vomiting, diarrhea)
     3. Shock/hypotension
     4. Neurological (altered mental status, headache, weakness, paraesthesia, lethargy)
  3. Laboratory evidence of inflammation:
     1. Elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), ferritin or procalcitonin
  4. Measures of disease activity:
     1. Elevated brain natriuretic peptide (BNP) or N-terminal pro b-type natriuretic peptide (NT-proBNP) or troponin
     2. Neutrophilia, lymphopenia, or thrombocytopenia
     3. Evidence of cardiac involvement by echocardiography or physical stigmata of heart failure
     4. Electrocardiogram (ECG) changes consistent with myocarditis or myopericarditis
- **Multisystem inflammatory syndrome in adults (MIS-A):** A severe illness requiring hospitalization in a person aged at least 21 years, with laboratory evidence of current or previous (within 12 weeks) SARS-CoV-2 infection or prior SARS-CoV-2 immunization. Features of MIS-A include severe extrapulmonary organ dysfunction (including thrombosis), laboratory evidence of severe inflammation, and absence of severe respiratory disease (BCCD: Vaccine 39 (2021) 3037-3049). **Must be diagnosed by a physician or nurse practitioner. Include the following information in Section 10, if available:**
  1. If fever (38°C) was present and, if so, for how many consecutive days.
  2. Clinical features:
     1. Mucocutaneous (rash, erythema or cracking of the lips/mouth/pharynx, bilateral nonexudative conjunctivitis, erythema/edema of the hands and feet)
     2. Gastrointestinal (abdominal pain, vomiting, diarrhea)
     3. Shock/hypotension
     4. Neurological (altered mental status, headache, weakness, paraesthesia, lethargy)
  3. Laboratory evidence of inflammation:
     1. Elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), ferritin or procalcitonin
  4. Measures of disease activity:
     1. Elevated brain natriuretic peptide (BNP) or N-terminal pro b-type natriuretic peptide (NT-proBNP) or troponin
     2. Neutrophilia, lymphopenia, or thrombocytopenia
     3. Evidence of cardiac involvement by echocardiography or physical stigmata of heart failure
     4. Electrocardiogram (ECG) changes consistent with myocarditis or myopericarditis

- **Thrombosis/Thromboembolism:** Thrombosis occurs when a thrombus (localized hemostatic plug or blood clot) forms in a blood vessel. This can lead to a blockage either at the site of origin, or the clot can become dislodged and cause a blockage in a different blood vessel (thromboembolism) (BCCD: Vaccine 40 (2022) 6431-6444). **Must be diagnosed by a physician or nurse practitioner. Include the following information in Section 10, if available:**
  1. Pathological findings, surgical findings, and/or imaging studies that confirm the presence of a thrombus.
  2. Clinical presentation, signs and/or symptoms consistent with thrombosis or thromboembolism.
  3. Elevated D-dimer level.
  4. Imaging studies suggestive of thrombosis or thromboembolism
- **Thrombosis with Thrombocytopenia syndrome (TTS):** A syndrome of concurrent thrombosis or thromboembolism and thrombocytopenia. TTS is a term that encompasses many different entities with varying pathogenesis. One of those entities is vaccine-induced immune thrombocytopenia and thrombosis (VITT), which is now understood to be a clearly defined syndrome associated with anti-PF4 antibodies (BCCD: Vaccine 42 (2024) 1799-1811). **Must be diagnosed by a physician or nurse practitioner. Include the following information in Section 10, if available:**
  1. Platelet count less than 150 X 109/L, that is new onset AND with no heparin exposure within the last 30 days.
  2. Evidence of confirmed thrombosis in any location.
  3. History of severe, persistent headache with an onset of at least 5 days post immunization.
  4. D-dimer results (ideally with reference range provided).
  5. Anti-PF4 results by enzyme-linked immunosorbent assay (ELISA) or by functional assay.
- **Single organ cutaneous vasculitis:** Refers to small vessel vasculitis of the skin where systemic involvement has been excluded (BCCD: Vaccine 34 (2016) 6561-6571). **Must be diagnosed by a physician or nurse practitioner. Include the following information in Section 10, if available:**
  1. Clinical: presence of hemorrhagic papules or urticarial lesions lasting more than 24 hours leaving bruising or hyperpigmentation or purpuric targetoid plaques on face, ears, extremities with edema and low-grade fever.
  2. Evidence of other organ involvement.
  3. Skin biopsy results.
- **Syncope with injury:** Details of the injury resulting from syncope that **required hospitalization, or urgent care** must be reported in Section 10.
- **Rash (elsewhere than at vaccination site):** 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) at site(s) other than the injection site (BCCD: Vaccine 25 (2007) 5697–5706). When possible, provide a written description of the rash, using the terminology provided.
- **Kawasaki disease:** A systemic vasculitis of infancy and childhood affecting medium-sized muscular arteries (BCCD: Vaccine 34 (2016) 6582- 6596). **Must be diagnosed by a physician or nurse practitioner**. Provide all pertinent details in Section 10.
- **Thrombocytopenia:** Platelets count of less than 150 X 109/L; accompanied by petechial rash or other clinical signs and/or symptoms of spontaneous bleeding (epistaxis, hematoma, hematemesis, hematochezia, hematuria, hemoptysis, petechia, purpura, ecchymosis) (BCCD: Vaccine 25 (2007) 5717-5724). **Must be diagnosed by a physician or nurse practitioner.** Indicate the lowest platelet count and the clinical evidence for spontaneous bleeding in the designated space at the end of Section 9d. Provide all additional details in Section 10.
- **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 (BCCD: Vaccine 28 (2011) 4487–4498).
- **Erythema multiforme:** An acute, immune-mediated condition characterized by the appearance of distinctive target-like lesions on the skin. These lesions are often accompanied by erosions or bullae involving the oral, genital, and/or ocular mucosae (Journal of American Academy of Dermatology 8 (1983) 763-775). **Must be diagnosed by a physician or nurse practitioner.**
- **Myocarditis:** Inflammation of the myocardium of the heart (BCCD: Vaccine 40 (2022) 1499-1511). **Must be diagnosed by a physician or nurse practitioner.** Include the following information in Section 10, if available:
  1. Clinical presentation.
  2. Histopathological examination of myocardial tissue either from autopsy or biopsy.
  3. Elevated myocardial biomarker (troponin T or troponin I or CK myocardial band).
  4. Cardiac MRI, echocardiogram and/or ECG results.
  5. Elevated biomarker of inflammation (i.e., CRP, ESR, d-dimer).
- **Pericarditis:** Inflammation of the pericardial sac surrounding the heart (BCCD: Vaccine 40 (2022) 1499-1511). **Must be diagnosed by a physician or nurse practitioner**. Include the following information in Section 10, if available:
  1. Clinical presentation.
  2. Histopathological examination of pericardial tissue either from autopsy or biopsy.
  3. Evidence of abnormal fluid collection or pericardial inflammation (echo, cardiac MRI, MRI/CT chest).
  4. Specific ECG abnormalities (diffuse concave up ST segment elevation, ST segment depression in aVR, PR depression throughout the leads without reciprocal ST segment depressions).
  5. Physical exam findings (pericardial friction rub, pulsus paradoxus, distant heart sounds).
- **Fever (≥ 38.0°C):** Endogenous elevation of at least one body temperature measurement, regardless of measurement device, anatomic site, age or environmental conditions (BCCD: Vaccine 22 (2004) 551–556). Report only if fever occurs in conjunction with a reportable event. For fever in a neurological event, indicate fever in Section 9c only.
- **Should injury related to vaccine administration (SIRVA):** Pain in the ipsilateral shoulder starting less than 48 hours after vaccination and lasting more than 7 days. This is a result of vaccination administered into or too close to underlying joint structures (BCCD: Vaccine 38 (2020) 1137-1143).
- **Other serious or unexpected event(s) not listed in the form:** Provide all details in Section 10.
- **Other serious adverse event:** An adverse event that results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, or is a congenital anomaly/birth defect must be considered serious. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious. For additional information regarding serious events, please refer to the WHO Global Manual on Surveillance of Adverse Events Following Immunization (2014): https://www.who.int/publications/i/item/9789241507769
- **Unexpected adverse event:** An adverse event whose nature, severity, or outcome is not consistent with the term or description used in the local/regional product labeling (e.g., Package Insert or Summary of Product Characteristics), or any adverse event that was previously observed but is occurring more frequently, must be considered unexpected. For additional information regarding unexpected events, please refer to the ICH Harmonised Tripartite Guideline (E2D 2003): https://database.ich.org/sites/default/files/E2D_Guideline.pdf

Section 10 Supplementary information

- Section 10 should be used to capture all information that is pertinent to the AEFI but that has not been fully captured elsewhere or that needs further explanation.

- Document all known details of any investigations or treatments for the recorded AEFI. This can include clinical details, types of treatment, test results, and prior infections with the pathogen(s) being vaccinated against in Section 4b.
- If additional space is required, please attach a separate sheet. Indicate the section of the AEFI Reporting Form that the information applies to, if applicable, when recording information in Section 10.

Section 11 Recommendations for future immunization(s)

- This section is to be completed by a SK Medical Health Officer (MHO) who provides recommendations for publicly funded vaccines.
- The MHO indicates recommendations for the patient with regard to future immunizations by selecting all that apply from the following: "**No change to immunization schedule**", "**Determine protective antibody level**", "**No further immunizations with, specify**", "**Expert referral, specify**", "**Active follow up for AEFI recurrence after next vaccine**", "**Controlled setting for next immunization**", or "**Other, specify**".
    - If "**No further immunizations with, specify**", please specify which vaccine(s) this recommendation is referring to in the space provided. If "**Expert referral, specify**" or "**Other, specify**", please provide details in the space provided.
    - A "**Comments**" section has been added for your convenience; however, should you require additional space for your recommendation(s), please capture this information in Section 10.
- The MHO must complete the reporter information section in full providing their full name and professional status by selecting one of the following: "**MOH/ MHO: Medical Officer of Health/Medical Health Officer**" or "**MD: Medical Doctor**". In addition, indicate a phone number where the MHO can be reached and sign and date the AEFI Reporting Form in the space provided. All dates should be captured in format: yyyy/mm/dd.

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 (i.e., vaccines given in series).

Choose one of the options 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 not administered:** A subsequent dose of the vaccine was not administered.
- **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 Reporting Form for the subsequent AEFI.
- **Vaccine administered without AEFI:** A subsequent dose of vaccine was administered without the occurrence of any AEFI.
- **Vaccine administered, other AEFI observed:** A subsequent dose of vaccine was administered and followed by the occurrence of a different adverse event than was previously experienced by the patient. Fill out a new AEFI Reporting Form for the subsequent AEFI.
- **Vaccine administered without information on AEFI:** A subsequent dose of vaccine was administered, and it is unknown if it was followed by the occurrence of any AEFI.

Appendix 1: Summary of Reportable AEFI Criteria

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

Abscess, Infected	• Spontaneous or surgical drainage of purulent (positive gram stain or culture) material from the abscess **OR**
	• There are one or more signs of localized inflammation (erythema, pain to light touch, swelling, warmth) **AND**
	  ○ Evidence of improvement/resolution on antimicrobial therapy **OR**
	  ○ Physician/NP-diagnosed
		0-7 days	BCG: Any
			
			Other: 0-7 days

Abscess, Sterile	• Physician/NP-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/NP-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/NP-diagnosed • Enlargement of one or more lymph nodes > 1.5 cm in diameter **AND/OR** • Draining sinus over a lymph node.	mRNA COVID-19: 0-30 days Other: 0-7 days	BCG: Any Other: 0-42 days
Nodule	• Firm nodule ≥ 2.5 cm in diameter at injection site **AND** • Persists for ≥ 1 month	0-7 days	
Pain/Swelling	• Swelling extends past the nearest joint **AND/OR** • Severe pain that interferes with the normal use of the limb lasts ≥ 4 days **AND/OR** • Reaction requires hospitalization	0-2 days	0-7 days

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	Live Attenuated Vaccines
Allergic-type Reactions			
Anaphylaxis	• Sudden onset **AND** rapid progression of signs and symptoms **AND** • Symptoms include 1 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** • Any event managed as anaphylaxis following immunization	0-24 hours Typically, within seconds to minutes, usually within 1 hour.	
Oculo-respiratory syndrome (ORS)	• Onset of bilateral red eyes **AND** • 1 or more respiratory symptoms: Cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness, sore throat **WITH or WITHOUT** facial edema.	Influenza vaccines: 0-24 hours	
Other Allergic Reactions	• Skin (hives, itching, edema) **AND/OR** • Respiratory (stridor, wheezing) **AND/OR** • Gastrointestinal manifestations	0-48 hours	
Rash	• **Live vaccines**✸: an expected rash following a live vaccine that requires hospitalization • **Inactivated vaccines:** unexpected rashes or eruptions lasting ≥ 4 days **AND** ○ 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 ✸Refer to *disseminated vaccine strain infection following vaccination* if varicella-containing vaccine was received to ensure correct AEFI is reported.
Neurological Events			
Acute Disseminated Encephalomyelitis (ADEM)	• Physician/NP-diagnosed encephalomyelitis **AND** • 1 or more focal or multifocal findings referable to the central nervous system	0-42 days	
Anaesthesia/Paraesthesia (tingling/numbness)	• Physician/NP-diagnosed anaesthesia **OR** • Paraesthesia lasting ≥ 24 hours	0-42 days	
Bell's palsy	Physician/NP-diagnosed Bell's palsy	0-3 months	
Brachial neuritis	Physician/NP-diagnosed	0-90 days	0-90 days

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	Live Attenuated Vaccines
Convulsion/Seizures (febrile or afebrile)	• Seizures (febrile or afebrile) with generalized, tonic, clonic, tonic-clonic, or atonic motor manifestations **AND** • Reported loss of consciousness	0-72 hours	5-42 days
Encephalopathy/ Encephalitis	• Physician/NP-diagnosed encephalitis **AND** • At least 1 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/NP-diagnosed GBS	0-56 days	
Meningitis	Physician/NP-diagnosed meningitis for which no other cause has been identified	0-15 days	5-42 days
Myelitis	• Physician/NP-diagnosed myelitis **AND** • 2 or more indicators suggestive of spinal cord inflammation.	0-42 days	5-42 days
Paralysis	• Physician/NP-diagnosed paralysis with no other cause identified **AND** • Lasting ≥ 24 hours	0-15 days	0-42 days
Other paralytic syndrome	• Peripheral neuropathy • Acute flaccid paralysis	0-42 days	
Subacute sclerosing panencephalitis (SSPE)	Physician/NP-diagnosed SSPE	N/A	Measles: Any
Vaccine-Associated Paralytic Poliomyelitis (VAPP)	Physician/NP-diagnosed paralysis	N/A	OPV: 5-30 days
Other Event of interest			
Arthritis or Arthralgia	• Physician/NP-diagnosed arthritis **AND** • Lasting ≥ 24 hours	0-30 days	5-42 days
Death within 30 days of immunization	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	Physician/NP-diagnosed rash specific to Erythema Multiforme	5 or more days	
Fever ≥38°C	Occurring **in conjunction** with another reportable AEFI.	0-3 days	0-42 days

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	**Live Attenuated Vaccines**
Hemorrhagic disease or bleeding disorders	E.g., abnormal uterine bleeding warranting urgent care	COVID-19 vaccines: 0-28 days	N/A
Henoch-Schonlein Purpura	Must be Physician/NP-diagnosed	0-42 days	
Hypotonic-hyporesponsive episode in child < 2 years old	• Physician/NP-diagnosed • Hypotonia (muscle limpness) **AND** • Hyporesponsiveness or unresponsiveness **AND** • Pallor or cyanosis	0-72 h	
Intussusception/ Hematochezia	• Physician/NP-diagnosed intussusception or hematochezia 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/NP-diagnosed	0-42 days	
Narcolepsy	Characterized by excessive daytime sleepiness **AND** episodes of muscle weakness brought on by emotions	0-4 weeks	
Orchitis	Physician/NP-diagnosed orchitis	N/A	Mumps: 5-30 days
Other severe or unusual events [B]	• Not clearly covered by other reporting categories and fits description above **OR** • Requires emergency room visit ≤ 72 hours of immunization	0-4 weeks	
Parotitis	Physician/NP-diagnosed parotitis	N/A	Mumps: 5-30 days
Persistent crying/screaming episode	Presence of continuous/unaltered screaming/crying for ≥3 hours	0-3 days	
Severe diarrhea/vomiting	• 3 or more episodes of vomiting or diarrhea in a 24-hour period **AND** • Symptoms are severe, i.e., projectile vomiting or explosive, watery diarrhea	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 ≥4 days	0-7 days	
Syncope with injury	Syncope with injury following immunization **AND required** hospital **or** urgent care services	0-30 minutes	
Thrombocytopenia	Physician/NP-diagnosed platelet count of less than 150 X 109/L	0-42 days COVID-19 vaccines: 0-28 days	
Thrombolytic events	• Must be physician/NP-diagnosed **AND** confirmed by medical imaging • 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 (e.g., 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	• Must be physician/NP-diagnosed • Disseminated intravascular coagulation (DIC) • Hemolytic uremic syndrome (HUS) • Complement disorders	COVID-19 vaccines: 0-28 days	N/A

Footnotes on next page

[A] The length of time between vaccine administration and onset of event is an important consideration in causality assessment.

[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.

Appendix 2: Definitions of Mucocutaneous Lesions

Primary mucocutaneous lesions (morphology):

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

Secondary mucocutaneous changes:

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