Appendix 4.8 - Data Dictionary for Completing the New Brunswick AEFI Reporting Form

AEFI form section	AEFI form data fields	Definition
	Cover page	Indicate what type of an AEFI is being reported on the form by ticking the appropriate category: • Serious; • Required urgent medical attention; • Unusual or unexpected; or • Other (non-serious and expected).
	Initial report	Indicate whether this is an initial report or follow-up.
	Follow up report	
1	**Unique episode #** **(Provincial identifying number)**	A unique case number is to be assigned to each AEFI report. This number will be assigned automatically if the AEFI form is completed electronically. The format of this number: year/NB/Region N/ case number. The unique case number should be marked on the top of the 2nd, 3rd and 4th pages of the AEFI form as an identifier to link the pages together. If you are not authorized to assign this number, please leave this field blank for paper forms.
2	**Client Information**	
	First Name	First and last name.
	Last Name	
	Date of birth	Date of birth: Indicate the client's date of birth in the space provided. If the complete date is unknown, please provide as much information as is available (yyyy/mm/dd format).
	Gender	Indicate client's gender (e.g., male or female).
	Medicare number	Provincial Medicare number.
	Address of usual residence	Address of usual residence including postal code (with the understanding that this address might be in a different province than where the vaccine(s) was administered or where the AEFI is being reported).
	Province /Territory	Telephone number (either residential or business or both), where the client can be reached.
	Postal code	
	Phone:	
	Information source	
	First Name	If the source of the information for the AEFI report is a parent, or another care provider, provide their name, relation to the client and contact information (including their full mailing address and phone number where they can be reached) if it is different from the clients.
	Last Name	
	Relation to client	
	Contact info, if different:	
	Clients physician	• Name of clients family physician; • Address; **AND** • Phone number.

3	**Vaccine Information**	Provide all information pertaining to the immunizing agent(s) administered just prior to the onset of the reported AEFI(s). There is space to record three immunizing agents in this section; however, if more than three were administered simultaneously, record the additional vaccines in Section 9.
	At time of immunization:	
	Province/Territory	Record the province where the vaccine was administered (it could be different from the province of residency).
	Date of vaccine administration	Indicate the date and exact time of vaccine administration remembering to specify if the vaccine was administrated in the "a.m." or "p.m." by circling the appropriate descriptor. If complete information is unknown, provide as much detail as is available (e.g. month and/or year).
	Time AM_PM	
	Immunizing agent(s)	Please record the proper name or accepted abbreviation for all active immunizing agent(s). NOTE: if an active immunizing agent cannot be found in CSDS, please send an urgent request to the CDC unit and the agent will be added to the database.
	Trade Name	Indicate the trade name(s) of all vaccines received.
	Manufacturer	Specify the name of the manufacturer as indicated on the product label.
	Lot number	Document the complete lot number including all letters and numbers. This information is essential for conducting future risk assessments.
	Dose #	Provide the number in series (1, 2, 3, 4, or 5) or indicate if known. For the Influenza vaccine, unless a patient receives two doses in one season, the "dose #" should be recorded as one.
	Dosage/unit	Indicate the dose (e.g., 0.5) and unit (e.g., ml) for each vaccine.
	Route	Specify the route of administration for each vaccine received. Abbreviations (as described below) are acceptable: • Intradermal: ID • Intramuscular: IM • Subcutaneous: SC • Intranasal: IN • Oral: PO • Other: please specify (no abbreviations)

	Site	Indicate the site of injection for each vaccine administered. Abbreviations (as described below) are acceptable: • Left arm: LA • Right arm: RA • Arm: Arm • Left leg: LL • Right leg: RL • Leg: Leg • Left gluteal: LG • Right gluteal: RG • Gluteal: Glut • Mouth: Mo • Nose: Nose • Multiple sites: MS • Other: please specify (no abbreviations)
4	**Immunization errors**	
	Did this AEFI follow an incorrect immunization?	Indicate whether the AEFI has followed an incorrect immunization (an immunization error, program error, etc.) by choosing "No", "Unknown" or "Yes".
	If Yes, indicate all that apply	If "yes", please indicate all that apply in section 4 by checking the box next to the situation that most closely reflects the error (as described below) and provide all known details in section 9.
	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 exceed that recommended for age	A larger dose of vaccine was administered than is recommended for the patient's age group.
	Wrong dose	Incorrect dose of vaccine was given.
	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).
	Other, specify	If an error has occurred that is not accurately reflected in the list of provided errors, please choose "other" and provide all details.

5	**Previous AEFI**	Indicate whether the client had ever experienced an AEFI following a previous dose of any of the immunizing agents as listed Section 3. Choose only one of the answers provided in Section 5, as described below;
		No: The patient had previously received immunization with one or more of the immunizing agents listed in section 3 and had not experienced a subsequent AEFI.
		Yes: The patient had previously received immunization with at least one of the immunizing agents listed in section 3 and had subsequently experienced an AEFI (any AEFI including expected and non-serious).
		Unknown: It is unknown if the patient had previously received immunization with any of the immunizing agents listed in section 4c and/or, if an AEFI followed.
		Not applicable: The patient had never previously received immunization with any of the immunizing agents listed section 4c.
		Note: If the answer is "yes," the client had previously experienced an AEFI following a previous dose of one or more of the immunizing agent(s) listed in Section 3, provide all details of the previous AEFI in Section 9, including the corresponding time to onset and duration, when known. Also, when possible, provide information regarding the severity of the AEFI and if the previous AEFI was less or more severe than the currently reported AEFI. *If there is uncertainty regarding which option to choose, or if there is additional information to provide (e.g., multiple vaccines were administered and not all of the information regarding the client's past AEFI experience can be captured in Section 6), please provide additional details in Section 9.

6	**Level of care and outcome**	
6a	**Highest level of care obtained**	Indicate the highest perceived impact of the AEFI by choosing one of the provided responses in section 6a based on the patient's assessment of the impact on their daily activities;
		Telephone advice from a healthcare professional: The client received a telephone advice from a health care professional (e.g., nurse, nurse practitioner, physician, etc.) regarding the reported AEFI. This can also include a telephone advice from a provincial health information line such as Tele-Care (811).
		Non-urgent visit: The client 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 9.
		Emergency visit: The client was seen by a health care professional for an emergency visit for the assessment and/or treatment of the reported AEFI. Please note that emergency visits are not considered admission to hospital and therefore, admission and discharge dates are not required. Document all investigations conducted in Section 9.
		Required hospitalization: Indicate if client was hospitalized for the assessment and/or treatment of the reported AEFI. If yes, provide the date of admission and the date of discharge. If a client was already in hospital at the time of immunization and the AEFI resulted in a longer hospital stay, please also indicate the date of hospital admission and discharge for the entire period of hospitalization (if known). Document all investigations conducted in Section 9.
		Unknown: It is unknown if the client received care for the reported AEFI.
		None: No care was received for the reported AEFI.

6b	**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 6b. If the client is not yet recovered, provide all available details in Section 9 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 9. When completing Section 6b, provide the information as outlined below:
		***Death:** Patient died (record the corresponding date of death in the space provided).
		Unknown: The outcome of the AEFI is unknown or unclear.
		***Not yet recovered:** Residual signs and/or symptoms remain (at the time of the report).
		***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.
		Recovered: All signs and symptoms have resolved at the time of reporting. Please record the date in the space provided. If the reaction lasted >1 hour, but <1 day also provide the exact time of recovery.
6c	**Treatment received**	Indicate whether the client received any treatment, including self-treatment, for the reported AEFI by choosing "**yes**," "**no**" or "**Unknown**". If "**yes**" was chosen, provide all details of treatments received, following the onset of the AEFI in the same section. Use Section 9 if more space is needed.

6d	**Medical history (up to the time of AEFI onset)**	Indicate the client's medical history prior to the time of AEFI onset by choosing all that apply from the list provided below. Provide all additional details, when available, in the same section or in Section 9 if more space is needed. Enclose a print out if available.
		Concomitant medication(s): Provide the name of all medications, including prescription, over the counter and herbal supplements that the client had been taking immediately prior to the time of AEFI onset, including those taken only as needed. When available, provide the dose, frequency, route of administration and reason for taking each concomitant medication.
		Known medical conditions/allergies: Indicate all known medical conditions and/or allergies that the client experienced prior to the time of immunization with a corresponding date of onset. 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 client is taking a concomitant medication including chronic conditions with intermittent symptoms such as migraine headaches. Also, specify in this section if the subject was pregnant at the time of immunization.
		Acute illness/injury: Indicate if the client had an acute illness and/or injury immediately prior to the time of immunization and specify a corresponding date of onset 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).

7	**Reporter information**	Complete the reporter information section in full including the reporter's first and last names, a phone and fax contact number (including extensions when applicable) and the full mailing address of the institution/ setting/centre. Indicate the setting in which the reporter is located (e.g., physician office, public health clinic, hospital) or specify if other. Sign and date the AEFI form in the space provided and specify your professional status (e.g., MD: Medical Doctor; RN: Registered Nurse) or your affiliation (e.g., IMPACT) by choosing one of the options provided. If your professional status or affiliation is not listed, specify beside other.
	Setting:	Physician office; Public health; Hospital; **OR** Other, specify.
	Name	
	Phone, Extension	
	Fax	
	Address	
	City	
	Province/Territory	
	Postal code	
	Date reported	
	Signature:	MD; RN; **OR** Other.
8	**AEFI details**	Indicate the details of the reported AEFI by checking all that apply. All additional pertinent details (e.g., associated fever, medical investigation, treatment, etc.) should be provided in Section 9. For convenience and consistency, high level definitions have been provided for most events listed in Section 8. However, if an asterisk (*) is present beside an AEFI term, this specific event must be diagnosed by a physician and thus a corresponding definition has not been provided within the body of this document. Please refer to Standard 3.8 *Reporting of Adverse Events Following Immunization in New Brunswick*.
8a	**Local reaction at or near vaccination site**	Choose one of the following events below: Time to onset/interval and duration of signs and symptoms: The time to onset/interval and the duration of the signs and symptoms of the specified AEFI should be documented using the most appropriate time unit: Days, Hours, or Minutes. • If the time to onset/interval or the time to resolution is less than one (1) hour, record in minutes. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) hour, but less than one (1) day, record in hours. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) day, record in days.

	Infected abscess	• Physician diagnosed; **AND** • Material from the abscess is purulent (positive gram stain or culture); **OR** • Signs of localized inflammation (erythema, pain to touch, warmth); **AND** • Evidence of improvement with antimicrobial therapy.
	Sterile abscess	• Persists for >1 month, is >2.5cm in diameter and/or drainage is evident; **AND** • Material from the mass is non-purulent; **AND** • Absence of localized inflammation; **OR** • Failure to improve on antimicrobial therapy.
	Cellulitis	• Physician diagnosed; **AND** • Characterized by at least 3 local signs or symptoms: pain or tenderness to touch, erythema, induration or swelling, warmth to touch.
	Nodule	• Is >2.5cm in diameter. • Persists for >1 month.
	Reaction crosses joint	Reaction extending past at least one joint adjacent to the site of vaccine administration.
	Lymphadenitis	Inflammation of one or more lymph nodes, usually caused by a primary focus of infection elsewhere in the body.
	Other, specify	Specify all details of the vaccination site reaction in section 9 that are not already captured in section 9 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 9	
	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 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 temporary eruption on the skin.
	Largest diameter of vaccination site reaction (cm), Site(s) of reaction (e.g. LA, RA)	Indicate the diameter (in centimetres) of the largest vaccination site reaction that is present.
	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/surgical drainage	Draining of fluid from a site without intervention. When available, provide all Gram stain/culture results.
	Microbial results	Tests that are carried out to identify organisms that can cause disease or infection.
	Lymphangitic streaking	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.).
8b)	**Allergic and allergic-like events**	Choose one of the following events below: Time to onset/interval and duration of signs and symptoms: The time to onset/interval and the duration of the signs and symptoms of the specified AEFI should be documented using the most appropriate time unit: Days, Hours, or Minutes. • If the time to onset/interval or the time to resolution is less than one (1) hour, record in minutes. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) hour, but less than one (1) day, record in hours. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) day, record in days.
	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 hrs. of vaccination, with or without facial oedema.
	Other allergic events	An event considered by reporter to be allergic in nature but not anaphylaxis, or ORS. Check all symptoms/signs in section 8b that were present and use section 9 for any additional details.
	For any allergic reaction indicated above, check all that apply	
	Skin/mucosal: Choose all that apply from the list provided below, and indicate the site of reaction:	
	Urticaria	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.

	Prickle sensation	Tingling or smarting (stinging) sensation. Specify site of reaction.
	Rash (For these events, specify site of reaction)	Generalized rash for which urgent medical attention is sought and believed to be related to vaccine. Any rash requiring hospitalization or treatment in ER.
	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 and if "other" is checked, provide details.	
		Tongue Throat Uvula Larynx Lip Eyelids Face Limbs Other, specify
	Eyes(s):	
	Red bilateral	Redness of the white(s) of the eye (s) (sclera).
	Red unilateral	
	Itchy	A sensation that provokes the desire to rub and/or scratch to obtain relief.
	Cardio-vascular	
	Measured hypotension	An abnormally low blood pressure 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 <90mm 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 > 3sec	Capillary refill time is the time required for the normal skin colour to reappear after a blanching pressure is applied. It is usually performed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue, indicated by a pink colour returning to the nail. Normally it is <3 seconds.

	Tachycardia	An extremely rapid heart rate above established normal that varies by age. Heart (pulse) rate per minute, Upper Limit / Respiratory rate per minute, Upper Limit <1year old: 160 / 60 1 – 2 yrs: 150 / 40 2-5 yrs: 140 / 35 5-12 yrs: 120 / 30 >12 yrs: 100 / 16 (BCCD: Vaccine 28 (2010) 4487-4498)
	Decreased or loss of consciousness: duration (sec)	Reduced alertness or awareness of the outside world. Indicate duration of the event.
	Respiratory	
	Sneezing	An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose.
	Rhinorrhea	Discharge of thin nasal mucous.
	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.
	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. (same source as tachycardia). See Table above.
	Wheezing	A whistling, squeaking, musical or puffing sound made by breathing out.
	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.
	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	
	Diarrhea	Loose and/or watery stool which may occur more frequently than usual. Please provide details.
	Abdominal pain	Sensation of discomfort or pain in the abdominal region.

	Nausea	An unpleasant sensation vaguely referred to the upper abdominal region and the abdomen, with a tendency to vomit.
	Vomiting	The reflex act of ejecting the contents of the stomach through the mouth. Provide details.
8c)	**Neurologic events**	Time to onset/interval and duration of signs and symptoms: The time to onset/interval and the duration of the signs and symptoms of the specified AEFI should be documented using the most appropriate time unit: Days, Hours, or Minutes. • If the time to onset/interval or the time to resolution is less than one (1) hour, record in minutes. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) hour, but less than one (1) day, record in hours. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) day, record in days.
	***Meningitis**	Physician diagnosed meningitis for which no other cause was identified.
	***Encephalopathy/ Encephalitis**	Physician diagnosed encephalopathy or encephalitis.
	***Guillain-Barre Syndrome (GBS)**	Physician diagnosed GBS.
	***Bell's Palsy**	Physician diagnosed Bell's palsy.
	Seizure	Seizures (febrile or afebrile) if they meet the temporal criteria.
	***Other Paralysis, specify**	Physician diagnosed paralysis lasting 24 hours or more.
	***Other neurologic diagnosis, specify**	Specify and provide all details.
	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 change lasting for ≥ 24 hrs.	Change in personal behaviour-response patterns.
	Focal or multifocal neurological sign(s)	Neurological impairment which is caused by a lesion in one particular focus or many foci of the central nervous system.
	Fever ≥ 38.0° C	Report **ONLY** if fever occurs in conjunction with a reportable event. For fever in a neurological event, use section 8c.
	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 abnormality	Abnormal EEG as interpreted by a qualified health professional.
	EMG 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, Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) scans.

	Brain/spinal cord histopathological 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.
	Seizure details:	Check all that apply and record additional details in section 9. Indicate if the event was witnessed by a health care professional by choosing yes or no/unknown.
	Witnessed by healthcare professional	
	Yes	
	No	
	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.
	Yes	
	No	
	Unknown	
	Generalized (Specify:	Bilateral, with more than minimal muscle involvement.
	Tonic	Sustained increase in muscle contraction lasting a few seconds to minutes.
	Clonic	Sudden, brief (<100 milliseconds) involuntary contractions of the same muscle groups, regularly repetitive at a frequency of about 2 to 3 contractions/second.
	Tonic-clonic	A sequence consisting of a tonic followed by a clonic phase.
	Atonic	Sudden loss of tone in postural muscles often pre-ceded by, a myoclonic jerk and precipitated by hyperventilation (in the absence of Hypotonic-Hyporesponsive Episode, syncope, or myoclonic jerks).
	Absence	The occurrence of an abrupt, transient loss of impairment of consciousness (which may not be remembered), sometimes with light twitching, fluttering eyelids, etc.
	Myoclonic	Involuntary shock-like contractions, irregular in rhythm and amplitude, followed by relaxation, of a muscle or a group of muscles.
	Partial	Seizure that originates from a localized area of the cerebral cortex and involves neurologic symptoms specific to the affected area of the brain.
	Previous history of seizures: specify	Individuals who have had seizures at any time prior to this vaccination.
	Febrile	With fever of ≥ 38.0°C.
	Afebrile	Without fever.
	Unknown type	It is unknown if the seizure was febrile or afebrile. Provide all known details.

8d)	**Other Events**	For a selected event, describe the signs and symptoms by checking all that apply. Provide all additional details in section 9.
	Time interval - Mins Time interval - Hrs Time interval - Days Duration - Mins Duration - Hrs Duration - Days	Time to onset/interval and duration of signs and symptoms: The time to onset/interval and the duration of the signs and symptoms of the specified AEFI should be documented using the most appropriate time unit: Days, Hours, or Minutes. • If the time to onset/interval or the time to resolution is less than one (1) hour, record in minutes. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) hour, but less than one (1) day, record in hours. • If the time to onset/interval or the time to resolution is greater than or equal to one (1) day, record in days.
	Hypotonic-Hyporesponsive Episode (age < 2yrs)	• Physician diagnosed; **AND** • Reduced muscle tone; **AND** • Hyporesponsiveness; **AND** • Pallor or cyanosis; **AND** • Child <2 years of age.
	Limpness	Lacking firmness and strength, no muscle tone.
	Pallor/cyanosis	Unnatural lack of colour in the skin (abnormal loss of colour from normal skin).
	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 3 or more hours.
	Intussusception	Intussusception or Hematochezia following rotavirus vaccine receipt.
	Arthritis	arthritis that follows the receipt of rubella-containing vaccine and lasting at least 24 hours.
	Joint redness	Redness of the skin at the joint(s).
	Joint warm to touch	Sensation of increase in temperature, above body temperature, at the joint(s) to touch.
	Joint swelling	An abnormal increase in the size of the joint(s).
	Inflammatory changes in synovial fluid	Laboratory synovial or joint fluid analysis indicative of inflammatory response.
	Parotitis	Parotid gland(s) swelling with pain and/or tenderness.
	Rash (Non-allergic)	• Generalized rash for which urgent medical attention is sought and believed to be related to vaccine. • Any rash requiring hospitalization or treatment in ER.
	Generalized	Systemic eruption in 2 or more parts of the body.
	Localized (site)	Eruption localized at another part of the body, away from the vaccination site.

	Thrombocytopenia* Platelet count < 150x10^9/L Petechial rash Other clinical evidence of bleeding	Physician diagnosed occurring within 30 days post-immunization.
	Anaesthesia	The loss of normal feeling or sensation.
	Paraesthesia	Abnormal physical sensation such as tingling, burning, prickling, formication, etc.
	Numbness	Loss of sensation often accompanies by tingling. Indicate site of reaction.
	Tingling	Sensation commonly described as 'pins and needles'. 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.
	Other, specify	Specify in section 9.
	Rash (non-allergic)	Generalized or Localized provide site.
	Fever ≥ 38.0°C	Report **ONLY** if fever occurs in conjunction with a reportable event. (For fever in a neurologic event, use section 8c)
	Other serious or unusual/unexpected event(s) not listed elsewhere on the form.	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.
9	**Supplementary Information** (Please indicate the section number when providing details). Please provide details of any investigation or treatment for the recorded AEFI. If not, provide sufficient information to support the selected item(s)	Section 9 should be used to capture information pertinent to the AEFI but that has not been fully captured elsewhere on the form or that needs further explanation. Document all known details of investigations that support or refute the event(s), treatments, course of the event(s), and diagnosis for the recorded AEFI. The narrative should serve as a comprehensive, stand-alone "medical story." The information should be presented in a logical time sequence; ideally this should be presented in the chronology of the client's experience, rather than in the chronology in which the information was received. In follow-up reports, new information should be clearly identified. Also, indicate the section of the AEFI report that the information applies to, if applicable, when recording information in Section 9.

10	**Recommendation for further immunization according to Federal/Provincial/ Territorial best practices** (Provide comments, use section 9 if extra space needed)	This section is to be completed by the MOH or his or her designate that provides recommendation(s) for further immunization(s). Indicate, by choosing all that apply in Section 9, your recommendations for the client with regard to future vaccinations and specify additional information when requested. A comments section has been added for your convenience; however, should you require additional space for your recommendation(s), please capture this information in Section 9. Complete the MOH's or his or her designate information section in full providing your full name and professional status (Medical Officer of Health [MOH]; Public Health Nurse [PHN]). In addition, indicate a telephone number where you can be reached and sign and date the AEFI form in the space provided.
	No change to immunization schedule	
	Expert referral, specify	
	Determine protective antibody level	
	Controlled setting for next immunization	
	No further immunizations with: specify,	
	Active follow-up for AEFI recurrence after next vaccine	
	Other, specify	
	Name:	
	Professional status	
	MOH/MHO	
	MD	
	RN	
	Other, specify	
	Comments	
	Phone: Ext	