Field	Description

2. *Cardiovascular*	• **'Measured hypotension':** An abnormally low blood pressure documented by appropriate measurement.
	  o Infants and children - low systolic blood pressure (age specific) or >30% decrease in BP.
	  o Adults – systolic blood pressure of less than 90mm Hg or >30% decrease from that persons' normal BP.
	• **'Decreased central pulse volume':** Absent or decreased pulse in one of the following vessels –carotid, brachial or femoral arteries.
	• **'Capillary refill time > 3 sec':** The capillary refill time is the time required for the normal skin colour to reappear after a blanching pressure is applied. It is usually performed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue, indicated by a pink colour returning to the nail. Normally it is 3 seconds or less.
	• **'Tachycardia':** A heart rate that is abnormally high for age and circumstance.
	  o Infants and children- A heart rate that is above the upper limit expected for age:
	  • <1 year: 160
	  • 1 to 2 years: 150
	  • 2 to 5 years: 140
	  • 5 to 12 years: 120
	  • >12 years: 100
	  o Adults and adolescents - The term is usually applied to a heart rate >100 beats/min.
	• **'Decreased or loss of consciousness':** Partial suspension of conscious relationship with the outside world as demonstrated by a decreased ability to perceive and respond to verbal, visual or painful stimulus.

Field	Description
3. *Respiratory*	• **'Sneezing':** An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose. • **'Rhinorrhea':** Discharge of thin nasal mucus. • **'Hoarse voice':** An unnaturally harsh cry in an infant or vocalisation in a child or adult. • **'Sensation of throat closure':** Feeling or perception of throat closing with a sensation of difficulty breathing. • **'Stridor':** A harsh vibrating sound heard during respiration in cases of obstruction of the air passage. • **'Dry cough':** Rapid expulsion of air from the lungs and not accompanied by expectoration (a nonproductive cough) that will not abate during the period of observation including through measures such as taking a sip of water. • **'Tachypnea':** Abnormally rapid breathing which is high for age and level of physical activity o Infants and children - A respiratory rate that is above the upper limit expected for age o Adults – A respiratory rate in excess of 25 breaths per minute • **'Wheezing':** A whistling, squeaking, musical, or puffing sound on expiration (bilateral – both lungs). • **'Increased use of accessory muscles':** Vigorous movement of the muscles of breathing, generally best seen in the lower part of the neck (supra-clavicular or tracheal tug) or below the chest (sub-costal). The movements are usually a sign of difficulty with breathing. • **'Grunting':** A sudden and short noise with each breath when breathing out. • **'Cyanosis':** A dark bluish or purplish discolouration most easily seen in the facial or perioral area or tongue. • **'Difficulty breathing':** A sensation of difficulty breathing. • **'Indrawing/retractions':** Inward movement of the intercostal area upon inspiration • **'Chest tightness':** Inability or perception of not being able to move air in or out of the lungs. • **'Difficulty swallowing':** Sensation or feeling of difficulty in the passage of solids and liquids down to the stomach. • **'Sore throat':** Discomfort or pain in the throat.

Field	Description
4. *Gastrointestinal*	Only report GI signs/symptoms associated with an allergic event here. Report isolated GI signs/symptoms in the 'Other Defined Events of Interest' section. • **'Diarrhea':** Loose or watery stool. • **'Abdominal pain':** Sensation of discomfort or pain in the abdominal region. • **'Nausea':** An unpleasant sensation vaguely referred to the upper abdominal region (upper region of the abdomen) and the abdomen, with a tendency to vomit. • **'Vomiting:** The reflex act of ejecting the contents of the stomach through the mouth.
5. *Laboratory*	• **'Mast cell tryptase elevation':** Mast cell tryptase levels above upper normal limit. *In Panorama: record 'Mast cell tryptase elevation' in the comment box for this section.*
Comments	Provide any additional pertinent details in the comment box for this section. *In Panorama: once a comment is added, it cannot be modified or deleted.*

8.3 Neurologic events

Time to onset and, unless the unresolved checkbox is selected, duration of signs and symptoms are mandatory. The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit (day, hour, or minute).

Field	Description
Reactions	Indicate the neurologic event by choosing all that apply. Refer to Section 13 of the Yukon Immunization Manual. Events with an asterisk (*) (or 'MD' in Panorama) must be diagnosed by a physician, or where appropriate and based on current scope of practice, the diagnosis may be made by a nurse practitioner. • **'Seizure(s)'.** Sudden loss of consciousness in conjunction with involuntary generalized motor manifestations. If seizure is selected, users must provide additional details: Choose only one of: o **'Febrile':** Select if seizure being reported with fever. o **'Afebrile':** Select if seizure being reported in absence of fever. o **'Unknown type':** Select if unknown whether the seizure being reported was febrile or afebrile. Select either: • **'Focal/Partial':** Seizure that originates from a localized area of the cerebral cortex and involves neurologic symptoms specific to the affected area of the brain (also called partial seizures, which can be divided into simple and complex partial seizures). • *In Panorama: users must also select the redundant 'Focal/Partial' sub-option.* • **'Generalized':** Bilateral, with more than minimal muscle involvement. For generalized seizures users must specify one of the following: o **'Tonic':** Sustained increase in muscle contraction lasting a few seconds to minutes. o **'Clonic':** Sudden, brief (<100 milliseconds) involuntary contractions of the same muscle groups, regularly repetitive at a frequency of about two to three contractions/second. o **'Tonic-clonic':** A sequence consisting of a tonic followed by a clonic phase. o **'Atonic':** Sudden loss of tone in postural muscles often preceded by a myoclonic jerk and precipitated by hyperventilation (in the absence of Hypotonic-Hyporesponsive Episode, syncope, or myoclonic jerks). o **'Myoclonic':** Involuntary shock-like contractions, irregular in rhythm and amplitude, followed by relaxation, of a muscle or a group of muscles.

Field	Description
	○ **'Absence':** The occurrence of an abrupt, transient loss of impairment of consciousness (which may not be remembered), sometimes with light twitching, fluttering eyelids Provide the following details: **'Witnessed by healthcare professional' ('Yes', 'No', 'Unknown')** **'Sudden loss of consciousness' ('Yes', 'No', 'Unknown')** **'Previous history of seizures' ('Febrile', 'Afebrile', 'Unknown type')** • **'Anaesthesia/Paresthesia'.** Indicate whether the 'Anaesthesia/Paresthesia' was 'Generalized' or 'Localized' and choose the appropriate signs/symptoms: ○ **'Numbness'** ○ **'Tingling'** ○ **'Burning'** ○ **'Formication'** ○ **'Other'** • **'Meningitis*'** Must be diagnosed by a physician. • **'Encephalopathy/Encephalitis*'** Must be diagnosed by a physician. • **'Guillain-Barre Syndrome (GBS)*'** Must be diagnosed by a physician. • **'Bell's Palsy*'** Must be diagnosed by a physician. • **'Myelitis/Transverse myelitis*'** Must be diagnosed by a physician. • **'Other Paralysis*'.** Must be diagnosed by a physician. Includes vaccine-associated paralytic poliomyelitis. • **'Other neurologic diagnosis*'.** Must be diagnosed by a physician Includes ADEM and SSPE. Specify details in comments.
Descriptors	For neurologic events describe the signs, symptoms, and test results from the following list: • **'Depressed/altered level of consciousness, lethargy or personality change lasting >=24hrs'** • **'Focal or multifocal neurologic sign(s)'** • **'Fever (>=38.0 C)'** • **'CSF abnormality'** • **'EEG abnormality'** • **'EMG abnormality'** • **'Neuroimaging abnormality'** • **'Brain/spinal cord histopathologic abnormality'**
Comments	*Provide any additional pertinent details in the comment box for this section. In Panorama: once a comment is added, it cannot be modified or deleted. If an event is selected in the neurologic section, Panorama requires either a sign/symptom or*

Field	Description
	comment to be in this section to save the record. If signs/symptoms are unknown, or none of the options apply, users can report "No additional details", or describe the signs/symptoms, in the neurologic event comment box, as applicable.

8.4 Other defined events of interest

Time to onset and, unless the unresolved checkbox is selected, duration of signs and symptoms are mandatory. The time to onset and the duration of the signs and symptoms of the specified AEFI should be documented using the appropriate time unit (day, hour, or minute).

Field	Description

Reactions	Indicate the event by choosing the events that apply. For a selected event, describe the signs and symptoms by checking all the sub-level items that apply. Refer to Section 13 of the Yukon Immunization Manual for definitions and reporting criteria. Events with an asterisk (*) (or 'MD' in Panorama) must be diagnosed by a physician, or where appropriate and based on current scope of practice, the diagnosis may be made by a nurse practitioner.
	• **'Hypotonic-Hyporesponsive Episode (age <2 years)*':** Must be diagnosed by physician. Select all sign/symptoms that apply:
	  o 'Limpness'
	  o 'Pallor/cyanosis'
	  o 'Reduced responsiveness/unresponsiveness'
	• **'Persistent crying (crying which is continuous and unaltered for >= 3hrs)'**
	• **'Rash':** Only report rash here if both not localized at injection site and non-allergic. Otherwise report the rash in the appropriate earlier section as above. Check whether the rash is 'Generalized' or 'Localized at non-injection site', and when possible provide a written description of the rash primary lesion(s) (bulla, cyst, macule, nodule, papule, plaque, pustule, vesicle, wheal), and/or secondary skin change(s) (scaling, atrophy, excoriation, fissure ulcer). If localized at non-injection site is selected, specify the location of the site in 'Comments'.
	• **'Intussusception*':** Must be diagnosed by physician.
	• **'Hematochezia*':** Must be diagnosed by physician.
	• **'Arthritis*':** Must be diagnosed by physician. Select at least one of the following sub-items:
	  o Joint redness'
	  o 'Joint warm to touch'
	  o 'Joint swelling'
	  o 'Inflammatory changes in synovial fluid'
	• **'Parotitis*':** Parotid gland swelling with pain and/or tenderness after mumps-containing vaccine. Must be diagnosed by physician.
	• **'Orchitis*':** Must be diagnosed by physician.
	• **'Thrombocytopenia*':** Must be diagnosed by physician. Select at least one of the following subitems:
	  o 'Platelet count <150x109/L'

Field	Description
	○ 'Petechial rash' ○ 'Other clinical evidence of bleeding' • **'Fever ≥ 38°C':** For fever occurring with non-neurologic conditions. Only reportable in conjunction with another reportable event. • **'Syncope with injury'** • **'Severe vomiting'** • **'Severe diarrhea'** • **'Other serious or unexpected event(s) not listed above':** Choose this category ONLY if the event cannot be reported using a more appropriate existing category. If selected, must provide a description and any other pertinent additional details in the corresponding comment box that could guide possible classification of the event.
Comments	Provide any additional pertinent details in the comment box for this section. When 'Other serious or unexpected event(s) not listed above' is selected details must be provided in the comment box. In Panorama: once a comment is added, it cannot be modified or deleted.

9. IMPACT OF AEFI, OUTCOME, AND LEVEL OF CARE SECTION

Field	Description
Highest impact of AEFI	Indicate the highest impact of the AEFI to the client's daily activities, definitions of daily activities differ between adult (work, exercise, social commitment, etc.) and child (eating, sleeping, playing, etc.). Choose from: 'Did not interfere with daily activities', 'Interfered with but did not prevent daily activities', or 'Prevented daily activities'.
Outcome at time of report	Indicate the outcome of the AEFI at the time of completion of the report. • **'Fatal':** Client died. Record the date of death (if known) or date at which found out about fatal outcome (if date of death unknown) in the respective date field. • **'Permanent disability/incapacity'**: An injury 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. • **'Fully recovered':** All signs and symptoms have resolved. Duration fields for the appropriate section(s) should be complete for this outcome. • **'Not yet recovered':** Residual signs and/or symptoms remain at the time of completion of the report. Select this if at least one of the reported AEFIs is unresolved. • **'Unknown':** The outcome of the AEFI is unknown (e.g., client lost to follow-up) or unclear. *If the outcome is fatal, after recording the AEFI, also follow Panorama standards to update the client's record.*
Highest level of care required	Indicate the highest level of care obtained for the reported AEFI by selecting one of the provided response options: • **'Admitted to hospital':** Must have been admitted to hospital, not seen on an outpatient basis or only visited ER. If hospitalized, enter admission and discharge dates for analysis of length of stay, which is used as a seriousness criterion. • **'Emergency visit':** The client was seen by a health care professional for an emergency visit for the assessment and/or treatment of the reported AEFI. Emergency visits are not considered admission to hospital and therefore, admission and discharge dates are not required. • **'Non urgent visit':** Seen by a health care professional (e.g., at a physician's office or walk in clinic) for the assessment and/or treatment of the reported AEFI. • **'Resulted in prolongation of existing hospitalization':** Patient was already in hospital at the time of immunization and the AEFI resulted in a longer hospital

Field	Description
	stay. Indicate the number of additional days stayed in hospital as a result of the AEFI. • **'Telephone advice from a health professional':** The client received telephone advice from a health care professional (e.g., nurse, nurse practitioner, physician, etc.) regarding the reported AEFI. • **'None':** No care was received for the reported AEFI. • **'Unknown':** It is unknown if the patient received care for the reported AEFI. Provide any additional pertinent details in the corresponding comment box. *In Panorama: once a comment is added, it cannot be modified or deleted.*
Treatment received	Indicate whether the patient received any treatment, including self-treatment, for the reported AEFI by choosing 'No', 'Unknown' or 'Yes'. Provide details of all treatments received following the onset of the AEFI in the comments box when applicable.

10. PUBLIC HEALTH RECOMMENDATIONS

Public health recommendations for AEFI reports should be completed by the CMOH or Yukon Immunization Program. **Do not use this section.**

In Panorama: this section displays upon saving and submitting the AEFI for review. CMOH team or Yukon Immunization Program can complete this section after the AEFI is submitted and saved. After completing the review, if the client has contraindication to a vaccine or needs precautionary arrangement before the next immunization visit, the reporter should enter the relevant information in Special Considerations.

Yukon Immunization Program Manual

Section 13- Adverse Event Following Immunization (AEFI)

SECTION 13 – ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI)

Table of Contents

1.0 INTRODUCTION

An **adverse event following immunization** (AEFI) is defined as:
"Any untoward medical occurrence in a vaccinee which follows immunization and which does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be any unfavourable and/or unintended sign, abnormal laboratory finding, symptom or disease" (1). Temporal association alone (i.e., onset of an event following receipt of vaccine) is not proof of causation.

Vaccine safety is a focus of pre-licensure studies. An acceptable safety profile must be observed in order for vaccines to progress to phase III (clinical) trials in humans. These studies provide frequency data on the occurrence of common adverse events such as local reactions at the injection site or systemic events, and grading of the severity of these events.

Uncommon and rare adverse events are usually not identified in pre-licensure studies and reliance is placed on phase IV studies or post-marketing surveillance; this is especially important in the first year following introduction of a vaccine (see Canadian Immunization Guide, Part 2 – Vaccine Safety) (2).

The Canadian Immunization Guide outlines the importance of AEFI reporting as part of comprehensive vaccine safety surveillance:

- Vaccine pharmacovigilance has been defined as the science and activities related to the detection, assessment, understanding and communication of adverse events following immunization and other vaccine-related or immunization-related issues, and to the prevention of untoward effects of the vaccine or immunization.

- Health care providers have essential and pivotal roles to play in gaining and maintaining public confidence in the safety of vaccines. These include providing evidence-based information on the benefits and risks of vaccines; helping clients and patients to interpret media and Internet vaccine safety messages; and identifying and reporting adverse events following immunization.

- Any single occurrence of an unusual event following immunization may be coincidental or caused by the vaccine. An accumulation of reports, sometimes as few as four or five, may signal a risk due to the vaccine. Thus, each and every report submitted by vaccine providers is important.

2.0 PURPOSE

The Yukon Immunization Program monitors AEFIs that involve vaccines and biologicals; this is an important component of evaluating the territorial program. Reporting and monitoring AEFI's is important because:

- Increases public confidence in vaccine programs;
- Essential to vaccine safety surveillance;
- Confirms results of pre-licensure clinical trials;
- Provides a process to identify previously unknown concerns for each product.

The Public Health Agency of Canada (PHAC) and the vaccine manufacturers depend on accurate, timely and ongoing reporting of AEFI from those who administer the vaccines in order to provide the best analysis of reactogenicity of each new vaccine. AEFI's are reported to PHAC and data is stored in the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) (3). CAEFISS has the following objectives:

1. To monitor the safety of vaccines in Canada;
2. To identify vaccine related reaction frequency and severity;
3. To identify unknown or unexpected AEFIs;
4. To identify areas of further investigation and or research; and
5. To provide AEFI reporting profiles for vaccines marketed in Canada which informs immunization related decisions.

Details on AEFI reporting are provided in this document, including case definitions and reporting requirements. Common or expected side effects of a vaccine are usually mild, predictable and self-limited. These events do not need to be reported. It is often difficult to confirm whether or not the health concern is in any way related to either the vaccine or the immunization process, therefore immunization providers should encourage parents and clients to report any symptoms that are not expected following an immunization.

The purpose of this document is to provide AEFI reporting guidance to Yukon immunization providers.

3.0 REPORTING ADVERSE EVENTS

A health professional who is aware of an adverse event following immunization must report the event to the Yukon Immunization Program. The Yukon Immunization Program reviews all AEFIs and submits these to the Chief Medical Officer of Health (CMOH) for review and recommendation(s).

3.1 WHEN TO REPORT

An AEFI must be reported to the Yukon Immunization Program **within 3 days** of determining or being informed that a client has experience an adverse event following immunization.

3.2 WHAT TO REPORT

Events that **must be reported** include the following:

a) follows immunization
b) cannot be attributed to a pre-existing condition, and
c) meets one or more of the following criteria:
    - the health occurrence is life threatening, could result in permanent disability, requires hospitalization or urgent medical attention, or for any other reason is considered to be of a serious nature;
    - the health occurrence is unusual or unexpected, including, without limitation, an occurrence that
        - has not previously been identified (i.e., Oculo-Respiratory Syndrome was first identified during the 2000/2001 influenza season), or
        - has previously been identified but is being reported at increased frequency (i.e., extensive local reactions);
    - the health occurrence cannot be explained by anything in the patient's medical history, including, without limitation, a recent disease or illness, or consumption of medication.
    - Clusters of events: known or new events that occur in a geographic or temporal cluster (i.e., 6 in a week, or 6 in a Health Service Delivery Area) that require further assessment, even if the total number of AEFIs may not be higher than expected.

When an AEFI follows the administration of a passive immunizing agent (i.e., immune globulin) do not complete an AEFI, instead please follow the established procedures for reporting an adverse drug reaction to the Canadian Adverse Drug Reaction Monitoring Program (4).

When an AEFI follows the administration of an active immunizing agent (i.e., vaccine) that is administered simultaneously with a passive immunizing agent (i.e., immune globulin) and/or a diagnostic agent (i.e. tuberculin skin test), complete the AEFI form in Panorama.

3.3 HOW TO REPORT

1. The AEFI report is to be completed in Panorama by the health care provider immediately upon knowledge of an adverse reaction. If unsure or if you have questions, contact the Yukon Immunization Program.

2. Notification of the completed AEFI report is to be sent to the Yukon Immunization Program by emailing or calling with the client's Panorama ID number and message that an AEFI has been documented.

3. Yukon Immunization Program nurse reviews the AEFI report and adds the Unique Episode Number. The nurse identifies if further information is required prior to sending the file on for review. Once the AEFI report is complete it is then forwarded to Yukon CMOH/MOH who will make public health recommendations regarding the future use of vaccine product(s) associated with the AEFI.

4. The CMOH/MOH will review the AEFI report, document the recommendations, and notify the Yukon Immunization Program. Any recommendations are recorded on the client's immunization record in Panorama under the section titled *public health recommendations*.

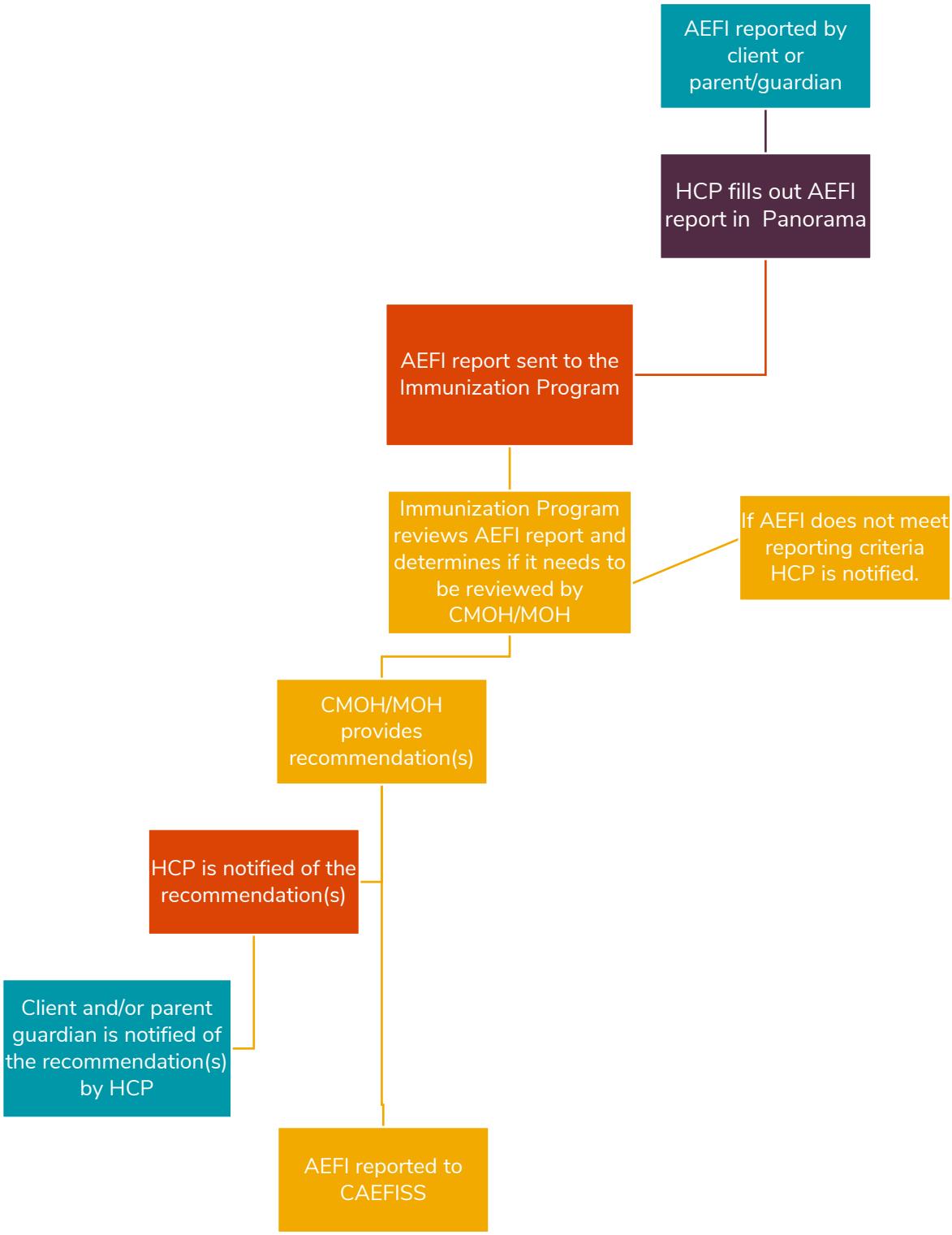
5. The reporting healthcare provider will be notified by e-mail once the recommendations have been entered into Panorama and will be responsible for follow up with the client advising of the public health recommendations. COVID-19 immunization follow a different process; the Immunization Program nurse follows up with the client directly to inform them of public health recommendations. Refer to Appendix B-E for COVID-19 AEFI reporting based on immunizing facility.

6. The completed AEFI will be sent by the Immunization Program to PHAC to be stored in the CAEFISS database for ongoing national surveillance to ensure continued safety of vaccine.

***Documentation is to be completed by the practitioner who becomes aware of the adverse reaction following the vaccine. If Panorama access is not available, please complete the AEFI Case Report Form and submit to the Immunization Program for upload and review.**

See Appendix A, B, C, D for the COVID-19 vaccine AEFI reporting flow for each facility (i.e. Health Centres, ER, Continuing Care, Mass Clinic)

Figure 3.3.1 Adverse Event Information Flow (Routine Vaccines)



3.4 WHAT NOT TO REPORT

Local injection site reactions and non-specific systemic reactions (e.g. headache, myalgia) should not be reported as an AEFI **unless these are more frequent or severe than expected based on clinical trial findings (rates and severity are typically found in the product monograph).**

- Always counsel clients about expected reactions following immunization and how to manage these reactions.
- Events which have another obvious cause (e.g. co-existing conditions).

3.4.1 Non-Reportable Adverse Events Following Immunization

Fever: By itself, is no longer reportable. It is an expected reaction following immunization. Fever is also a common occurrence in children with illnesses unrelated to immunization. Do not report the occurrence of fever unless it accompanies one or more reportable AEFI.

Local inflammation, swelling, and/or pain (moderate severity): Do not report less severe local reactions. Mild or moderate local reactions are expected reactions to immunization. See Swelling with/ without pain to see if reaction meets reporting requirements.

High pitched unusual crying: This reaction was almost exclusively related to whole cell pertussis vaccine, which is no longer used; this category is no longer reportable. Unusual crying episodes should be considered under Screaming episode/persistent crying.

Screaming episode/persistent crying (less severe): Do not report an episode of consolable but persistent screaming or crying with duration between one to three hours. This is likely related to discomfort from the injection. It is considered an expected reaction in children less than two years of age.

Allergic reaction (mild): Do not report using this code. Mild and severe allergic reactions have been combined into one category: Report allergic reactions meeting the criteria Allergic reaction.

Excessive somnolence: Excessive somnolence or prolonged sleeping with difficulty rousing is not considered to be an adverse reaction.

Irritability: Responses to pain and the assessment of the level of irritability are highly variable. Irritability is considered to be an expected response of infants to fever, discomfort, or disruptions in schedule. It may also be an indication of an intercurrent condition or illness, unrelated to immunization.

Coma: Report using code OTHER SEVERE OR UNUSUAL EVENTS.

Apnoea: Do not report apnoea.

3.5 HEALTH INFORMATION PRIVACY MANAGEMENT ACT (HIPMA)

Inform the client that the information is collected will be reported to the Yukon Immunization Program, CMOH and reported to the Public Health agency of Canada (after the removal of personal health identifiers). The information will be handled confidentially, stored safely and not disclosed without authority as per the HIPMA regulation. As well, inform the client of whom to call for more information about HIPMA issues.

4.0 RECOMMENDATIONS FOLLOWING AN ADVERSE EVENT

It is within an immunizer's scope of practice to assess adverse events following immunization and determine a course of action that may include decision-making about subsequent doses of the vaccine(s).

The following are **recommended** criteria for events to be reviewed by the Chief Medical Officer of Health:

- events which the client's health care provider considers to confer precautions, contraindications or a reason to postpone a future immunization
- all events managed as anaphylaxis
- all neurological events including febrile and afebrile convulsions
- allergic events
- all events where medical attention is required, and
- all events that are serious (resulting in hospitalization, residual disability, death, or congenital malformation)
- all major reactions

Upon receiving recommendations from the Chief Medical Officer of Health, discuss with the client. Any questions or consults for the Chief Medical Officer of Health are to be directed to the Immunization Program. Do not contact the Chief Medical Officer directly.

5.0 SUMMARY OF REPORTING CRITERIA

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria❶	
		Inactivated Vaccines	Live Attenuated Vaccines
Local Reaction at Injection Site			
Abscess, Infected	• Material from abscess known to be purulent (positive gram stain or culture) **OR** • There are one or more signs of localized inflammation (erythema, pain to light touch, warmth) **AND** o Evidence of improvement on antimicrobial therapy **OR** o Physician-diagnosed	0-7 days	
Abscess, Sterile	Physician-diagnosed **AND** any of the following: • Material from mass is known to be non-purulent • Absence of localized inflammation • Failure to improve on antimicrobial therapy	0-7 days	
Cellulitis	Physician-diagnosed **AND** characterized by at least 3 of the following: pain or tenderness to touch, erythema, induration or swelling, warmth	0-7 days	
Nodule	• Is more than 2.5 cm in diameter **AND** • Persists for more than 1 month	0-7 days	
Pain or Redness or Swelling	• Pain or redness or swelling that extends past the nearest joint **AND/OR** • Pain or redness or swelling that persists for 10 days or more	0-48 hours	

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

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria ❶	
		Inactivated Vaccines	Live Attenuated Vaccines
Systemic Reactions			
Adenopathy/ Lymphadenopathy	• Enlargement of 1 or more lymph nodes, ≥ 1.5 cm in diameter **AND/OR** • Draining sinus over a lymph node	0-7 days	MMR: 5-30 days Varicella: 5-42 days
Fever	Fever ≥ 38°C that occurs in conjunction with another reportable adverse event	Timing in conjunction with the other reportable adverse event(s)	
Hypotonic-Hyporesponsive Episode (HHE)	Physician-diagnosed **AND** • Reduced muscle tone **AND** • Hyporesponsiveness or unresponsiveness **AND** • Pallor or cyanosis **AND** • Child < 2 years of age	0-48 hours	
Parotitis	Physician-diagnosed parotitis following immunization with a mumps-containing vaccine	N/A	MMR: 5-30days
Orchitis	Physician-diagnosed orchitis following immunization with a mumps-containing vaccine	N/A	MMR: 5-30days
Rash	• Inactivated vaccines: generalized rash for which medical attention is sought, when the rash is believed to be caused by the vaccine, and for which no alternative cause has been identified **OR** • Live vaccines: an expected rash following a live vaccine that requires hospitalization	0-7 days	MMR: 0-30 days Varicella: 0-42 days
Screaming/ Persistent Crying	• Crying is continuous/unaltered **AND** • Lasting for 3 or more hours	0-72 hours	
Severe Vomiting/ Diarrhea	• 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 hours	0-72 hours **0-7 days for rotavirus vaccine

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

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria❶	
		Inactivated Vaccines	Live Attenuated Vaccines
Allergic Reactions			
Anaphylaxis	Any event managed as anaphylaxis following immunization	0-24 hours	
Oculo-respiratory syndrome (ORS)	• Bilateral red eyes **AND** • Respiratory symptoms • Following influenza vaccine	0-24 hours	
Other allergic reactions	• Skin **OR** • Respiratory **OR** • Gastrointestinal manifestations	0-48 hours	
Neurological Events			
Anaesthesia/ Paraesthesia	Physician-diagnosed anaesthesia or paraesthesia lasting 24 hours or more	0-15 days	MMR: 0-30 days Varicella: 0-42 days
Bell's palsy	Physician-diagnosed Bell's palsy	0-3 months	
Convulsion/seizure	• Seizures (febrile or afebrile) • Include temperature if febrile seizure reported	0-72 hours	MMR: 5-30 days Varicella: 5-42 days
Encephalopathy or Encephalitis or Acute Disseminated Encephalomyelitis (ADEM)	Physician-diagnosed encephalopathy or encephalitis or ADEM	0-42 days	MMR: 5-30 days Varicella: 5-42 days
Guillain-Barre syndrome (GBS)	Physician diagnosed GBS	0-56 days	
Meningitis	Physician-diagnosed meningitis for which no other cause has been identified	N/A	MMR: 5-30 days Varicella: 5-42 days
Sub-acute sclerosing panencephalitis (SSPE)	Physician diagnosed SSPE	N/A	Up to 10 years following immunization with a measles containing vaccine
Vaccine-Associated Paralytic Poliomyelitis	Physician diagnosed paralysis	N/A	OPV: 5-30 days

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