THIS CHAPTER MEETS THE FOLLOWING IMMUNIZATION COMPETENCIES FOR HEALTH PROFESSIONAL (PHAC, 2008): https://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf

- **#9: Adverse Events Following Immunization**
  - Competency: Anticipates, identifies, and manages adverse events following immunization, as appropriate to the practice setting.
- **#10: Documentation**
  - Competency: Documents information relevant to each immunization encounter in accordance with national guidelines for immunization practices and jurisdictional health information processes.

1.0 INTRODUCTION

Defining an Adverse Event Following Immunization

An Adverse Event Following Immunization (AEFI) is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the administration of the vaccine(S). The AEFI may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. Specific criteria must be met to define the events as true adverse events, and there must be no coexisting condition that could explain the reaction that occurs. It is important to note that the occurrence of a reportable adverse event does not mean that further immunization with that product or specific antigens is contraindicated.

Safety has always been an important consideration with respect to vaccine licensure. As the incidence of vaccine-preventable diseases is reduced by increasing coverage with efficacious vaccines, adverse reactions may become more frequent and prominent than cases of the disease. Timely assessment of adverse reactions is necessary to prevent the loss of confidence in vaccines, decreasing vaccine coverage, and the possible return to epidemic situations.

The nature and frequency of adverse reactions are linked to the intrinsic characteristics of the biological agent and an individual's immune response to the vaccine. The relatively frequent and predictable reactions to most vaccinations (i.e., local reactions and fever) are most often mild and disappear spontaneously. In rare instances, serious or unforeseen reactions can occur (i.e., anaphylaxis).

Health-care professionals must inform clients about the benefits and risks of being immunized vs. unimmunized. Health-care professionals need to be familiar with the frequency and nature of all reactions that may occur post-immunization. They must also report serious or unusual adverse events temporally associated with immunization to officials at their local public health office. **Reporting an adverse event with a temporal association to a vaccine does not imply causality.** Causality assessment involves the consideration of vaccine attributable risk (whether there is a causal association between a vaccine and an adverse event) and determining whether the vaccine(s) caused the adverse event or whether the event would have occurred anyway.

1.1 Reporting Adverse Events in Saskatchewan

1.1.1 Publicly Funded Active Immunizing Agents

Reportable AEFIs occurring after administration of **publicly funded** active immunizing agents are documented on the national reporting form for adverse events following immunization (Appendix 11.1B) using Appendix 11.1C *Saskatchewan Adverse Event Following Immunization Report Form User Guide* for guidance. NOTE: Non-Public Health immunizer should refer to Appendix 11.2 *Process for Non-Public Health Immunizers to Report Publicly Funded Vaccine AEFIs* for directives. The Ministry of Health forwards reportable AEFIs for publicly funded agents to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), a federal, provincial and territorial (FPT) public health post-market vaccine safety surveillance system to monitor AEFIs, and

- Includes passive (spontaneous reports from FPTs) and active surveillance data.
- Continuously monitors the safety of marketed vaccines in Canada.
- Identifies increases in the frequency or severity of previously identified vaccine-related reactions.
- Identifies previously unknown adverse events following immunization that could possibly be related to a vaccine (unexpected AEFI).
- Identifies areas that require further investigation and/or research.
- Provides timely information on AEFI reporting profiles for vaccines marketed in Canada that can help inform immunization-related decisions.

1.1.2 Non-Publicly Funded Active Immunizing Agents

- **Currently, AEFIs following any non-publicly funded active immunizing agent are to be reported directly to CVP (Appendix 11.1E) by the immunizer.**

1.1.3 Other Pharmaceuticals

AEFIs occurring after the administration of a monoclonal antibody, immune globulin, anti-toxin (**excluding** anti-toxins received under Health Canada's Special Access Program) and diagnostic agent (e.g., tuberculin skin test) are to be reported to Health Canada's Canada Vigilance Program (**CVP**) (Appendix 11.1E) per Vanessa's Law, using the Side Effect Reporting Form, **unless** they were administered simultaneously with a publicly funded active immunizing agent (report on the national reporting form for adverse events following immunization).

1.2 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.

1.3 Adverse Events Following Immunization That Should Not Be Reported

Events/reactions that:

- Do not meet reporting criteria in **Appendix 11.4**. **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. **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 product monograph information 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.**

1.4 Adverse Events Following Immunization That Must be Reported

AEFIs that must be reported as per Appendix 11.4 for review by a Medical Health Officer include:

- 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 Appendix 11.6.**

1.5 Adverse Event Following Immunization Reporting Timelines (to a Medical Health Officer or the Canada Vigilance Program)

- **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.

1.6 Active Pediatric Hospital-Based Surveillance System

To enhance timely detection and assessment of serious adverse events involving children, an active pediatric hospital-based surveillance system (Surveillance Program for the Rapid IdeNtification and TracKing of Infectious Diseases in KidS (SPRINT-KIDS)) exists in selected larger centres (e.g., Saskatoon). AEFI reports completed by the surveillance staff are sent to the appropriate provincial/territorial jurisdiction as well as to PHAC directly. Special numbering of the AEFI reports is done to avoid duplication in the jurisdiction.

1.7 Vaccine Injury Support Program

The Vaccine Injury Support Program (VISP) launched across Canada (excluding Quebec) in June 2021**. Claimants may be eligible if they have experienced a serious and permanent injury after receiving a Health Canada authorized vaccine, administered in Canada since December 8, 2020.**

Public health and other health care professionals who become aware of individuals with residual deficits following an event that may have been caused by a vaccine or immunization **should i**nform these individuals about VISP. Financial support may be available to dependents of individuals who died after being immunized since December 8, 2020. Information on eligibility, the claims assessment process and how to apply can be found at: (https://vaccineinjurysupport.ca/en)

The VISP is independent of the adverse event following immunization (AEFI) reporting and surveillance process designed to advise about future immunization and monitor vaccine safety. VISP does not share any applicant information to federal, provincial and territorial agencies.

2.0 REFERENCES

Government of Saskatchewan. *The Disease Control Regulations.* Available at: http://www.qp.gov.sk.ca/documents/english/Regulations/Regulations/p37-1r11.pdf

Public Health Agency of Canada (Evergreen) *Canadian Immunization Guide* (Evergreen Ed.). Available at: http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php

3.0 APPENDICES

Appendix 11.1 AEFI Resources and Information

11.1A: Unique Episode Identifiers

Unique Episode Identifiers must be assigned by public health staff in the former health regions/First Nations Jurisdictions according to year report is received and annual episode number (e.g., Regional acronym (below) 20YY-##) **and** must be noted on all of the AEFI report pages.

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

11.1B National Adverse Events Following Immunization Report Form:

https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization.html#a4

11.1C: Saskatchewan Adverse Event Following Immunization Report Form User Guide for Publicly Funded Immunizing Agents

https://www.ehealthsask.ca/services/Manuals/Documents/SK%20AEFI%20User%20Guide.pdf

11.1D User Guide to Completion and Submission of the AEFI Report (National Guide)

https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/user-guide-completion-submission-aefi-reports.html

11.1E: Canada Vigilance Program

(for non-publicly funded vaccines, monoclonal antibodies, Tubersol and passive immunizing agents)
https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html

Contact the Canada Vigilance Program 3 ways:

1. Report a side effect **online** at https://hpr-rps.hres.ca/side-effects-reporting-form.php?form=voluntary&lang=en
2. Calling toll-free at 1-866-234-2345
3. Completing a Side Effect Reporting Form and send by:
    a) Fax: 1-866-678-6789 **or**
    b) Mail: Canada Vigilance Program
    Health Products Surveillance and Epidemiology Bureau
    Marketed Health Products Directorate
    Health Products and Food Branch
    Health Canada
    Address Locator 1908C
    Ottawa ON K1A 0K9

Appendix 11.2: Process for Non-Public Health Immunizers to Report Publicly Funded Vaccine AEFIs

Standard Work		
	Name of Activity:	**Process for Non-Public Health Immunizers to Report Publicly Funded Vaccine AEFIs**
	Role Performing Activity:	**Pharmacists, Physicians, Nurse Practitioners and other non-Public Health immunizers who administer publicly funded vaccines**
	Date Prepared: February 2025	**Document Owner: Ministry of Health**

Sequence	Procedure
1.	A healthcare provider is informed of AEFI by client or directly observes AEFI in client who received a publicly funded vaccine.
2.	Healthcare providers reviews either: A. Appendix 1: Summary of Reporting AEFI Criteria in the online *Saskatchewan Adverse Event Following Immunization Report User Guide* **or** B. Appendix 11.4: Summary of Reportable AEFI Criteria in SIM Ch. 11 to confirm that client-reported AEFI meets reportable AEFI criteria.
3.	Upon the AEFI being confirmed as meeting reportable criteria, the healthcare provider completes the national reporting form for adverse events following immunization sections as noted in the *Saskatchewan Adverse Event Following Immunization Report User Guide.*
4.	The healthcare provider makes copy of AEFI report form for self/agency record and submits the AEFI report form to the closest public health officer in their area for review by a Medical Health Officer, who will provide recommendations.
5.	Upon receiving the AEFI report form back from Public Health, the healthcare provider must contact the client and inform them of the MHO's recommendations.
6.	The Healthcare provider documents the interaction and refers the client to Public Health if they have further questions.

Appendix 11.3: Canadian Biological Product Abbreviations

The National Vaccine Catalogue should be consulted for additional abbreviations.

Biological Product	Abbreviation
Anthrax	Anth
Bacillus Calmette-Guérin	BCG
Botulism antitoxin	BAT
Botulism immune globulin (IV)	BIG-IV
Chikungunta	Chik
Cholera - *E.coli* - oral	Chol-Ecol-O
COVID-19 (any)	COVID-19
Diphtheria antitoxin	DAT
Diphtheria, tetanus , acellular pertussis, hepatitis B, inactivated poliomyelitis, *Haemophilus influenzae* type b	DTaP-HB-IPV-Hib
Diphtheria, tetanus, acellular pertussis, inactivated polio, hepatitis B	DTaP-HB-IPV
Diphtheria, tetanus, acellular pertussis, inactivated polio	DTaP-IPV
Diphtheria, tetanus, acellular pertussis, inactivated polio, *Haemophilus influenzae* type b	DTaP-IPV-Hib
Ebolavirus - Zaire	EZV
Haemophilus influenzae type b	Hib
Herpes zoster – live vaccine	LZV
Herpes zoster – recombinant vaccine	RZV
Hepatitis A	HA
Hepatitis A and B	HAHB
Hepatitis A-typhoid	HA-Typh-I
Hepatitis B	HB
Hepatitis B immune globulin	HBIg
Human papillomavirus-nonaivalent (types 6, 11, 16, 18, 31, 33, 45, 52, 58)	HPV-9
Human papillomavirus-quadrivalent (types 6, 11, 16, 18)	HPV-4
Human papillomavirus-bivalent (types 16 and 18)	HPV-2
Immune globulin-intramuscular	Ig
Immune globulin, intravenous	IVIg
Influenza-inactivated, intramuscular	Inf
Influenza-inactivated, intradermal	Inf-ID
Influenza-live, attenuated, intranasal	LAIV
Influenza, thimerosal free	InfTmf
Japanese encephalitis	JE
Meningococcal conjugate	Men-C-C
	Men-C-ACYW-135
	Men-C-ABCYW-135
Measles, mumps, rubella	MMR
Measles, mumps, rubella, varicella	MMR-Var (MMRV)

Biological Product		Abbreviation
Pneumococcal conjugate	Pneu-C-7	Pneu-C-15
	Pneu-C-10	Pneu-C-20
	Pneu-C-13	Pneu-C-21
Pneumococcal polysaccharide		Pneu-P-23
Polio, inactivated		IPV
Polio, oral		OPV
Rabies		Rab
Rabies immune globulin		RabIg
Rh_O(D) immune globulin		RhIg
Rotavirus - monovalent		Rot-1
Rotavirus - pentavalent		Rot-5
Respiratory syncytial virus – any vaccine		RSV
Respiratory syncytial virus monoclonal antibody		RSVAb
Smallpox (historical)		Sma
Smallpox and mpox		SMV
Tetanus		T
Tetanus immune globulin		TIg
Tickborne encephalitis		TBE
Tetanus, diphtheria		Td
Tetanus, diphtheria, acellular pertussis		Tdap
Tetanus, diphtheria, acellular pertussis, inactivated polio		Tdap-IPV
Tetanus, diphtheria, inactivated polio		Td-IPV
Tuberculin-purified protein derivative		PPD
Typhoid-injectable		Typh-I
Typhoid-oral		Typh-O
Varicella		Var
Varicella immune globulin		VarIg
Yellow fever		YF

Appendix 11.4: Summary of Reportable AEFI Criteria

(Adapted from User Guide to Completion and Submission of the AEFI Report (2025 National Guide)

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	Live 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
Allergic-type Reactions			
Anaphylaxis	• Sudden onset **AND** rapid progression of signs and symptoms **AND** • Symptoms include one or more of the following: progressive painless swelling around face or mouth, new onset of wheezing, shortness of breath, and/or stridor, hypotension/collapse **OR** • Any event managed as anaphylaxis following immunization	0-24 hours Typically, within seconds to minutes, usually within 1 hour.	

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	Live Vaccines
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** • One 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
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	

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	Live Vaccines
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 or more	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
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

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	Live Vaccines
			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	
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	Occurred 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)	COVID-19 vaccines: 0-28 days	N/A

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]	
		Inactivated Vaccines	Live Vaccines
	• Cerebral venous sinus thrombosis • Myocardial infarction		
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

[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 11.5: Reportable AEFI Definitions and Criteria

Section 9a) Local reaction at or near vaccination site

- **Infected abscess:** A localized collection of pus in a cavity formed by the disintegration of tissue, usually caused by microorganisms that invade the tissues. 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.
- **Sterile abscess:** An abscess whose contents are not caused by pyogenic bacteria. 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. 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.
- **Reaction joint-to-joint/crosses joint(s), specify:**
  - **Reaction stretches joint-to-joint:** Reaction extending between two joints but not past either adjacent joint. Specify which joints in the space provided.
  - **Reaction crosses joint:** Reaction extending past at least one joint adjacent to the site of vaccine administration. Specify which joint(s) is/are crossed in 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.
- **Swelling:** Visible enlargement of the vaccinated limb that is assessed by any person, with or without objective measurement.
- **Pain:** An unpleasant sensation occurring in varying degrees of severity that could be described as discomfort, distress or agony.
- **Tenderness:** Abnormal sensitivity to touch or release of pressure.
- **Erythema:** Abnormal redness of the skin.
- **Warmth:** A tactile sensation/perception of an increase in temperature.
- **Induration:** Palpable thickening, firmness or hardening of soft tissue (subcutaneous tissue, fat, fascia or muscle) that is assessed by a health care provider.
- **Rash:** A morphologically described change in the appearance of the skin or mucosa at or near vaccination site that consists of one or more clearly identified primary lesion(s) (macule, papule, vesicle, nodule, bulla, cyst, plaque, pustule), and/or secondary skin change(s) (scaling, atrophy, ulcer, fissure, excoriation).
- **Largest diameter of vaccination site reaction:** Indicate the diameter (in 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.
- **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. When available, describe drainage material (purulent or non-purulent, bloody, etc.) and provide all Gram stain/culture results.
  - **Surgical drainage:** Withdrawal of fluids from the site through needle aspiration or incision which could be complete or partial. When available, describe drainage material (purulent or non-purulent, bloody, etc.) and provide all Gram stain/culture results.
- **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

- **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, cardiovascular, respiratory and/or gastrointestinal systems that were observed during the event 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 edema.
- **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.
- **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 tickbox. 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.

Skin/Mucosal

- **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. 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. 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. 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.
- **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.
- **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. 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 should not be documented as angioedema. Specify site of reaction in Section 10.

Cardiovascular

- **Measured hypotension:** 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. This manifestation must be documented by a healthcare professional. Report measured blood pressure (in mmHg) in the space provided.
- **Loss of consciousness (excluding vasovagal syncope):** 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. Indicate duration of the event in Section 10.

Respiratory

- **Expiratory wheezing:** A whistling, squeaking, musical, or puffing sound made by breathing out. 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. 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. 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. This manifestation must be documented by a healthcare professional.
- **Grunting:** A sudden and short noise with each breath when breathing out. This manifestation must be documented by a healthcare professional.
- **Measured hypoxia with O2 saturation <90%:**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). 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 (scalenes, sternocleidomastoids), muscles in the chest (pectoralis major and minor), and abdominal muscles. 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.
- **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).
    - **Sneezing:** An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose.
    - **Runny nose:** Discharge of thin nasal mucus.

Gastrointestinal

- **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

- **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. **Must be diagnosed by a physician or nurse practitioner.** Please 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. **Must be diagnosed by a physician or nurse practitioner.** Please 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. **Must be diagnosed by a physician or nurse practitioner.**
- **Encephalitis:** Defined as inflammation of the parenchyma of the brain. **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. **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. **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. **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. Indicate the type of seizure and seizure details in the designated area at the bottom of Section 9c.
- **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. **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. **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.
- **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 change 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.
- **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. 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. Indicate site of reaction in Section 10. Brief tingling immediately following immunization should 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

- **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

- **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

Section 9d) Other events

- **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). 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 two (2) years of age or older**; instead, please 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.
  - **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**.
- **Intussusception:** The prolapse of one part of the intestine into the lumen of an immediately adjacent part, causing partial or complete intestinal obstruction. **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.
  - **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).
- **Multisystem inflammatory syndrome in children (MIS-C):** A severe illness requiring hospitalization **in a person aged less than 18 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. **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:
     a. Mucocutaneous (rash, erythema or cracking of the lips/mouth/pharynx, bilateral nonexudative conjunctivitis, erythema/edema of the hands and feet)
     b. Gastrointestinal (abdominal pain, vomiting, diarrhea)
     c. Shock/hypotension
     d. Neurological (altered mental status, headache, weakness, paraesthesia, lethargy)
  3. Laboratory evidence of inflammation:
     a. Elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), ferritin or procalcitonin
  4. Measures of disease activity:
     a. Elevated brain natriuretic peptide (BNP) or N-terminal pro b-type natriuretic peptide (NT-proBNP) or troponin
     b. Neutrophilia, lymphopenia, or thrombocytopenia
     c. Evidence of cardiac involvement by echocardiography or physical stigmata of heart failure
- Electrocardiogram (ECG) changes consistent with myocarditis or myopericarditis

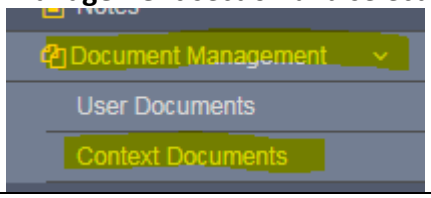
- **Multisystem inflammatory syndrome in adults (MIS-A):** A severe illness requiring hospitalization **in a person aged at least 18 year**s, with laboratory evidence of current or previous (within 12 weeks) SARS-CoV-2 infection or prior SARS-CoV-2 immunization. Features of MIS-A include severe extrapulmonary organ dysfunction (including thrombosis), laboratory evidence of severe inflammation, and absence of severe respiratory. **Must be diagnosed by a physician or nurse practitioner**. I**nclude 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:
     a. Mucocutaneous (rash, erythema or cracking of the lips/mouth/pharynx, bilateral nonexudative conjunctivitis, erythema/edema of the hands and feet)
     b. Gastrointestinal (abdominal pain, vomiting, diarrhea)
     c. Shock/hypotension
     d. Neurological (altered mental status, headache, weakness, paraesthesia, lethargy)
  3. Laboratory evidence of inflammation:
     a. Elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), ferritin or procalcitonin
  4. Measures of disease activity:
     a. Elevated brain natriuretic peptide (BNP) or N-terminal pro b-type natriuretic peptide (NT-proBNP) or troponin
     b. Neutrophilia, lymphopenia, or thrombocytopenia
     c. Evidence of cardiac involvement by echocardiography or physical stigmata of heart failure
     d. 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). **Must be diagnosed by a physician or nurse practitioner.** I**nclude 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. **Must be diagnosed by a physician or nurse practitioner.** I**nclude the following information in Section 10, if available:**
  1. Platelet count less than 150 X 10^9/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. **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 should 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.
- **Kawasaki disease:** A systemic vasculitis of infancy and childhood affecting medium-sized muscular. **Must be diagnosed by a physician or nurse practitioner.** Provide all pertinent details in Section 10.

- **Thrombocytopenia:** Platelets count of less than 150 X 10^9/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.
- **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. **Must be diagnosed by a physician or nurse practitioner.**
- **Myocarditis:** Inflammation of the myocardium of the heart. **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. **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. Report only if fever occurs in conjunction with a reportable event. For fever in a neurological event, indicate fever in Section 9c only.
- **Shoulder 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.
- **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 should be considered serious. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious.
  - **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, should be considered unexpected.

Appendix 11.6: Policy - Uploading AEFI Reports into a Client's Panorama Record

Saskatchewan	**Name of Activity:**	**Uploading AEFI Reports into a Client's Panorama Record**	
	Role Performing Activity:	**Public Health Nurse or appointed staff**	
Policy	**Location: Public Health Centre**	**Department: Immunization - Panorama**	
	Document Owner: Ministry of Health	**Region/Organization where this Work Standard originated: eHealth Saskatchewan**	
	Date Prepared: September 22, 2021	**Last Revision: February 2025**	**Date Approved: September 22, 2021**

Policy: Reportable Adverse Event Following Immunization (AEFI) reports must be uploaded into a client's Panorama profile as per the procedure outlined below. The **completed report** including the MHO's recommendation must **be uploaded**.

Sequence	Procedure
1.	User logs into Panorama. - Ensure that PDF AEFI report is available for uploading.
2.	Search for client and put them into context. - Create a client record if non-existent.
3.	From the left-hand navigation bar in the client's record, expand the **Document Management** section and select **Context Documents** 
4.	Click the **Add New** button.
5. 5.	Click the **Choose File** button, navigate to the location the file is saved in, select the file and click **Upload File.**
6. 6.	Complete all mandatory fields: • Document Title (refer to SIM Appendix 11.1 A Unique Episode Identifiers) • Effective Date (Date of MHO recommendation) • Status (only indicate as '**Complete**') Optional fields: • Expiration Date - **do not use.** • Enter Key word – **do not use.** • Description (Vaccine brand name(s))
7. 7.	Click Submit once the required information is entered.
8. 8.	Document the AEFI as per Appendix 4.2 *Where do I document* in the Saskatchewan Immunization Manual https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter4.pdf.