Summary of AEFI Reporting Criteria for COVID-19 Vaccination

Older children, adolescents and adults

For events with reporting criteria for a physician diagnosis, where appropriate and based on current scope of practice, the diagnosis may be made by a Nurse Practitioner.

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]
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
	  ○ Evidence of improvement on antimicrobial therapy OR
	  ○ 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, redness or swelling that persists for 10 days or more	0-48 hours
Systemic Reactions		
Adenopathy / Lymphadenopathy	• Physician-diagnosed **AND** Enlargement of 1 or more lymph nodes, ≥ 1.5 cm in diameter AND/OR • Draining sinus over a lymph node	0-7 days
Fever	• Fever ≥ 38°C that occurs in conjunction with another reportable adverse event	Timing in conjunction with other reportable adverse event(s)
Rash	• 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	0-7 days
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

[A] 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, with room for discretion.

Adverse Event Following Immunization	Reporting Criteria	Temporal Criteria [A]
Allergic Reactions		
Anaphylaxis	• Any event managed as anaphylaxis following immunization	0-24 hours
Oculo-respiratory syndrome (ORS)	• Bilateral red eyes AND • Respiratory symptoms	0-24 hours
Other Allergic reactions	• Skin OR • Respiratory OR • Gastrointestinal manifestations of an allergic event	0-48 hours
Neurological Events		
Anaesthesia/Paraesthesia	• Anaesthesia or paraesthesia lasting 24 hours or more	0-15 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
Encephalopathy or Encephalitis OR Myelitis or Transverse myelitis OR Acute Disseminated Encephalomyelitis (ADEM)	• Physician-diagnosed encephalopathy, encephalitis, myelitis, transverse myelitis, or ADEM	0-42 days
Guillain-Barré syndrome (GBS)	• Physician-diagnosed GBS	0-56 days
Arthritis	• Physician-diagnosed arthritis lasting 24 hours or more	0-30 days
Syncope with injury	• Syncope with injury following immunization that required hospital or urgent care services	0-30 minutes
Thrombocytopenia	• Physician-diagnosed thrombocytopenia	0-30 days
Other severe or unusual events [B]		Variable based on event

[A] 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, with room for discretion.

[B] Other serious or unusual events may include those events which:

- require urgent medical attention
- require hospitalization
- result in a residual disability
- are life threatening or result in death
- are associated with a congenital malformation
- are unusual e.g., events not previously associated with vaccines such as thrombosis and thrombocytopenia syndrome, are 'expected' side effects but are occurring at a higher than expected frequency, are unusually clustered by features such as time, place or immunization service provider and thus may warrant an investigation