

Summary of Adverse Event Following Immunization (AEFI) Reporting Criteria

Adverse Event	Reporting Criteria
LOCAL REACTIONS AT THE INJECTION SITE	
Pain, redness and swelling at the injection site	Extends past the nearest joint OR persists for 4 days or more <i>*Must occur within 48 hours of immunization</i>
Abscess at the injection site	Confirmed by spontaneous/surgical drainage from the mass OR demonstration of material by an imaging technique OR fluctuance <i>*Must occur within 7 days of immunization</i>
Nodule	≥2.5cm in diameter AND persists for more than one month <i>*Must occur within 7 days of immunization</i>
Cellulitis	Diagnosed as cellulitis by a physician AND has 3 of the 4 following local symptoms: pain or tenderness to touch, erythema, induration or swelling, warmth to touch <i>*Must occur within 7 days of immunization</i>
SYSTEMIC REACTIONS	
Fever in conjunction with another reportable event	≥38°C AND occurs in conjunction with another reportable event
Rash	<i>*Must occur within 7 days of an inactivated vaccine or between 5 and 42 days following a live vaccine</i>
Adenopathy/lymphadenopathy	Enlargement of one or more lymph nodes that are ≥1.5cm in diameter AND/OR draining sinus over a lymph node AND IS physician-diagnosed <i>*Must occur within 7 days of an inactivated vaccine or between 5 and 42 days following a live vaccine</i>
Hypotonic-Hyporesponsive Episode (HHE)	Sudden onset in a child less than 2 years of age of hypotonia AND hyporesponsiveness or unresponsiveness AND pallor or cyanosis AND IS physician-diagnosed <i>*Must occur within 48 hours following immunization</i>
Persistent Crying/Screaming	The presence of crying in infants and young children that is continuous, unaltered and lasts for 3 or more hours <i>*Must occur within 72 hours following immunization</i>
Severe Vomiting/Diarrhea	3 or more episodes of vomiting and/or diarrhea in a 24 hour period where vomiting and/or diarrhea is severe (i.e. projectile vomiting or explosive, watery diarrhea) <i>*Must occur within 72 hours of an inactivated vaccine or 42 days following a live vaccine</i>
Parotitis	Must be physician-diagnosed and follow receipt of mumps vaccine <i>*Must occur between 5 to 30 days following immunization</i>
ALLERGIC REACTIONS	
Event Managed as Anaphylaxis	An event managed as anaphylaxis at the time of occurrence <i>*Must occur within 24 hours of immunization</i>
Oculorespiratory Syndrome (ORS)	Bilateral red eyes and one or more of the following symptoms: cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat, with or without facial swelling <i>*Must occur within 25 hours of immunization</i>

Allergic Reaction - Skin	Allergic reaction of the skin including urticarial (hives), erythema, pruritus, prickle sensation, and localized or generalized edema <i>*Must occur within 48 hours of immunization</i>
NEUROLOGIC EVENTS	
Convulsions/Seizure	An episode of unconsciousness accompanied by generalized motor manifestations that may be tonic, clonic, tonic-clonic or atonic <i>*Must occur within 72 hours following an inactivated vaccine or 42 days following a live vaccine</i>
Encephalopathy/Encephalitis	Must be physician-diagnosed with no other cause identified <i>*Must occur within 15 days of an inactivated vaccine or between 5 and 42 days following a live vaccine</i>
Meningitis	Must be physician-diagnosed with no other cause identified <i>*Must occur within 15 days of an inactivated vaccine or between 5 and 42 days following a live vaccine</i>
Anaesthesia/Paraesthesia	Must be physician-diagnosed AND last 24 hours or more <i>*Must occur within 15 days of an inactivated vaccine or between 5 and 42 days following a live vaccine</i>
Paralysis	Must be physician-diagnosed with no other cause identified <i>*Must occur within 15 days of an inactivated vaccine or between 5 and 42 days following a live vaccine</i>
Bell's Palsy	Must be physician-diagnosed <i>*Must occur within 3 months of immunization</i>
Guillan-Barré Syndrome (GBS)	Must be physician-diagnosed <i>*Must occur between 1 and 8 weeks following immunization</i>
OTHER NEUROLOGIC DIAGNOSIS	
Myelitis	Must be physician-diagnosed <i>*Must occur within 15 days of an inactivated vaccine or between 5 and 42 days following a live vaccine</i>
Acute Disseminated Encephalomyelitis (ADEM)	Must be physician-diagnosed <i>*Must occur within 15 days of an inactivated vaccine or between 5 and 42 days following a live vaccine</i>
OTHER EVENTS OF INTEREST	
Thrombocytopenia	Must be physician-diagnosed <i>*Must occur within 30 days following vaccination</i>
Arthritis/Arthralgia	Must be physician-diagnosed AND last 24 hours or longer <i>*Must occur within 15 days of an inactivated vaccine or between 1 and 3 weeks following a live vaccine</i>
Intussusception	Must be physician-diagnosed AND follow receipt of rotavirus vaccine <i>*Must occur within 42 days following immunization</i>
Syncope with injury	A vasovagal reaction that results in injury to the recipient <i>*Must occur within 30 minutes of immunization</i>
Other severe/unusual events	Temporally associated with immunization and no other known cause May include: <ul style="list-style-type: none"> • Death of a recipient within one month • Fetal death following immunization of a pregnant woman • Respiratory manifestations not associated with an event managed as anaphylaxis

The AEFI reporting form can be found at www.publichealthontario.ca on the Immunization Resources page under Infectious Diseases.