

Appendix B: Provincial Case Definitions for Reportable Diseases

Disease: Adverse Events Following Immunization (AEFIs)

Adverse Events Following Immunization (AEFIs)

1.0 Provincial Reporting

Confirmed cases of disease

2.0 Type of Surveillance

Case-by-case

3.0 Case Classification

The following present the confirmed case classifications for an adverse event following immunization:

3.1 Local Reaction Following an Injection:

- Swelling at or near injection site
OR
- Abscess at injection site
OR
- Nodule at injection site
OR
- Cellulitis
OR
- Induration at or near injection site

3.2a Anaphylaxis

- ≥ 1 minor cardiovascular **OR** respiratory criterion
AND
- ≥ 1 minor criterion from each of ≥ 2 different systems/categories

OR

- ≥ 1 major cardiovascular **AND** ≥ 1 major respiratory criterion
OR
- ≥ 1 major cardiovascular **OR** respiratory criterion
AND
- ≥ 1 minor criterion involving ≥ 1 different system/category (other than cardiovascular or respiratory system)
OR
- ≥ 1 major dermatological **AND** ≥ 1 minor cardiovascular **AND/OR** respiratory criterion

OR

- ≥ 1 major dermatological
AND
- ≥ 1 major cardiovascular **AND/OR** ≥ 1 major respiratory criterion

3.2b Allergic Reaction

- ≥ 1 minor dermatological (hives)

OR

- ≥1 minor respiratory criterion (wheezing)

OR

- ≥1 major dermatological (local or generalized edema)

3.3 Neurologic Reaction

- Encephalopathy/ Encephalitis

OR

- Meningitis

OR

- Seizure(s)

OR

- Guillian-Barré Syndrome

OR

- Bell's Palsy

OR

- Paralysis other than Bell's Palsy

3.4 Other Defined AEFIs of Interest

- Hypotonic-Hyporesponsive Episode

OR

- Persistent crying

OR

- Rashes

OR

- Arthritis

OR

- Thrombocytopenia

OR

- Parotitis

OR

- Oculo Respiratory Syndrome (ORS)

3.5 Other Severe or Unusual Event(s) Not Listed Above (e.g., Intussusception)

Any adverse event believed to be temporally related to immunization that does not fit any of the categories listed above and for which no other cause is clearly established. Report events of clinical interest which require medical attention, and particularly events that are (i) fatal, (ii) life-threatening, (iii) require hospitalization, or (iv) result in residual disability.

4.0 Laboratory Evidence

4.1 Laboratory Confirmation

Local Reaction Following an Injection

- Gram stain or positive culture of microbiological organisms

4.2 Approved/Validated Tests

Local Reaction Following an Injection

- Standard culture
- Gram stain

4.3 Indications and Limitations

N/A

5.0 Clinical Evidence

5.1 Local Reaction Following an Injection:

i. Swelling at or near injection site:

- Visible enlargement of injected limb with or without objective measurement. Swelling is caused by fluid infiltration in tissue and is typically soft.

ii. Abscess at injection site:

- Localized soft tissue collection of material occurring at the site of injection.
 - Abscess of infectious etiology – spontaneous or surgical drainage of material from mass and lab confirmation i.e. gram stain or positive culture, of microbiological organisms
 - Sterile abscess - spontaneous or surgical drainage of material from mass negative for infectious etiology

iii. Nodule at injection site:

- The presence of a discrete or well demarcated soft tissue mass or lump that is firm in the absence of abscess formation, erythema, or warmth.
- There may be additional less discrete softer swelling surrounding the nodule at the injection site.

iv. Cellulitis:

Acute infectious and expanding inflammatory condition of the skin with at least three of the following four signs:

- Localized pain or tenderness
- Erythema
- Induration or swelling
- Warmth

AND

- The reaction is at the injection site

v. Induration at or near injection site:

- Palpable thickening, firmness or hardening of soft tissue. It may clearly include the injection site or may not clearly include the injection site.

5.2 Anaphylaxis and Other Allergic Reactions:

Table 1: Minor Criteria

<p>Dermatologic or mucosal -</p> <ul style="list-style-type: none">○ Generalized pruritus without skin rash○ Generalized prickle sensation○ Localized injection site urticaria○ Red and itchy eyes <p>Cardiovascular -</p> <ul style="list-style-type: none">○ Reduced peripheral circulation as indicated by the combination of at least 2 of tachycardia and○ A capillary refill time of >3 seconds without hypotension○ A decreased level of consciousness <p>Respiratory –</p> <ul style="list-style-type: none">○ Persistent dry cough○ Hoarse voice○ Difficulty breathing without wheeze or stridor○ Sensation of throat closure○ Sneezing, rhinorrhea <p>Gastrointestinal –</p> <ul style="list-style-type: none">○ Diarrhea○ Abdominal pain○ Nausea○ Vomiting <p>Laboratory –</p> <ul style="list-style-type: none">○ Mast cell tryptase elevation > upper normal limit

Table 2: Major Criteria

<p>Dermatologic or mucosal -</p> <ul style="list-style-type: none">○ Generalized urticaria (hives) or generalized erythema○ Angioedema*, localized or generalized○ Generalized pruritis with skin rash <p>Cardiovascular -</p> <ul style="list-style-type: none">○ Measured hypotension○ Clinical diagnosis of uncompensated shock, indicated by the combination of at least 3 of the following:<ul style="list-style-type: none">○ Tachycardia○ Capillary refill time >3 seconds○ Reduced central pulse volume○ Decreased level of consciousness or loss of consciousness <p>Respiratory –</p> <ul style="list-style-type: none">○ Bilateral wheeze○ Stridor○ Upper airway swelling (lip, tongue, throat, uvula, or larynx)○ Respiratory distress – 2 or more of the following:<ul style="list-style-type: none">○ Tachypnea○ Increased use of accessory respiratory muscles (sternocleidomastoid, intercostals, etc.)○ Recession○ Cyanosis○ Grunting
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5.3 Neurologic Reaction

- i. Encephalopathy/ Encephalitis may be manifested by any of the following:**
 - Depressed/altered level of consciousness, lethargy or personality change lasting for ≥ 24 hrs
 - Lethargy
 - Focal or multifocal neurologic sign(s)
 - CSF pleocytosis >5 wbc/mm³
 - EEG consistent with encephalitis
 - Brain pathology consistent with encephalitis
 - Neuroimaging consistent with encephalitis

- ii. Meningitis**

An infection or inflammation of the membranes covering the brain and spinal cord, characterized by acute onset of fever with neck stiffness and pain, severe headache and vomiting.

- iii. **Seizure(s)**
 - Sudden loss of consciousness with or without fever
 - Paroxysms of generalized tonic skeletal muscle contractions and clonic jerking usually associated with decreased consciousness.
- iv. **Guillian-Barré Syndrome**

Acute febrile polyneuritis or acute idiopathic polyneuritis.
Usually a symmetrical ascending paralysis with associated sensory disturbances.
- v. **Bell's Palsy**

Bell's palsy involves damage to the seventh cranial (facial) nerve. This nerve controls the movement of the muscles of the face. Symptoms usually start suddenly, and range from mild to severe and may include any of the following:

 - Change in facial expression (for example, grimacing)
 - Difficulty with eating and drinking
 - Drooling due to lack of control over muscles of the face
 - Droopy eyelid or corner of mouth
 - Dry eye or mouth
 - Face feels stiff or pulled to one side
 - Facial paralysis of one side of the face, makes it hard to close one eye
 - Headache
 - Loss of sense of taste
 - Pain behind or in front of the ear
 - Sensitivity to sound (hyperacusis) on the affected side of the face
 - Twitching in face
 - Weakness in face
- vi. **Paralysis other than Bell's Palsy**

Abnormal loss of muscle function or of sensation.

5.4 Other Defined AEFIs of Interest

- i. **Hypotonic-Hyporesponsive Episode**
 - <2yrs old
 - Limpness
 - Reduced responsiveness / unresponsiveness
 - Pallor/Cyanosis
- ii. **Persistent crying**
 - The presence of crying which is continuous
AND
 - Unaltered for ≥ 3 hours.
- iii. **Rashes**
 - Generalized
 - Localized at injection site
 - Localized at non-injection site
- iv. **Arthritis**

Joint pain lasting at least 24 hours, includes the following.

 - Joint swelling
 - Joint redness
 - Sensation of warmth over the joint

- Inflammatory changes in synovial fluid
- v. **Thrombocytopenia:**
- Platelet count less than $150 \times 10^9 \text{ L}^{-1}$
AND
 - Confirmed by blood smear exam
OR
 - The presence of clinical signs and symptoms of excessive and spontaneous bleeding (e.g., petechiae, purpura, epistaxis, hematoma, prolonged bleeding after cuts or surgery)
- vi. **Parotitis**
Parotid gland swelling with pain and/or tenderness.
- vii. **Oculo Respiratory Syndrome (ORS)**
Symptoms must include bilateral red eyes AND at least one respiratory sign/symptom with or without facial edema, occurring within 24 hours of influenza vaccination.
- Respiratory sign/symptoms can include any of the following:
- cough,
 - sore throat,
 - difficulty swallowing,
 - wheeze,
 - difficulty breathing,
 - hoarseness and
 - chest tightness.

5.5 Other Severe or Unusual Event(s) Not Listed Above (e.g., Intussusception)

- *Surgical criteria*
The demonstration of invagination of the intestine at surgery; and/or
- *Radiologic criteria:*
The demonstration of invagination of the intestines by either air or liquid contrast enema; or the demonstration of an intra-abdominal mass by abdominal ultrasound with specific characteristic features that is proven to be reduced by hydrostatic enema on postreduction ultrasound; and/or
- *Autopsy criteria:*
The demonstration of invagination of the intestine.

6.0 ICD Code(s)

ICD 10 Code T88.1

7.0 Comments

Neurologic Reaction:

Guillain-Barré Syndrome

- Indicate whether EMG and/or LP done and results, as well as any other relevant investigation including tests to look for possible causes, especially *Campylobacter*.

Bell's Palsy

- About 60 - 80% of cases go away completely within a few weeks to months. Sometimes the condition results in permanent changes.

8.0 References

- Ministry of Health and Long-Term Care, Public Health Division. iPHIS manual. Toronto, ON: Queen's Printer for Ontario; 2005.
- The Brighton Collaboration. Definitions and guidelines. Basel, Switzerland: The Brighton Collaboration; 2009 [cited 2008 July 2]. Available from http://www.brightoncollaboration.org/internet/en/index/definition_guidelines.html
- British Columbia Centre for Disease Control. Communicable disease control immunization program. Vancouver, BC: British Columbia Centre for Disease Control; 2007. Available from <http://www.bccdc.org/content.php?item=193>.

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