Adverse Events Following Immunization

BC Centre for Disease Control
An agency of the Provincial Health Services Authority

June 12 2013
Overview

- Background
- What’s changed in the BCCDC Manual?
  - Section IX: Adverse Events Following Immunization (AEFI)
  - Section V: Management of Anaphylaxis in a Non-Hospital Setting
  - Section X: Appendix
- What’s changed in the AEFI forms?
  - Enhanced Surveillance and Worksheet for Events Managed as Anaphylaxis Following Immunization
  - HLTH 2319: Report of Adverse Event (Reaction) Following Immunization
  - AEFI Reporting for Immunizing Pharmacists
- Resources
In February 2013 the BCCDC Manual, Chapter II Immunization Program, Section IX: the Vaccine Associated Adverse Events (2002) was replaced by Section IX: Adverse Events Following Immunization (AEFI)

The 2013 revisions have been:
- Reviewed by the BC public health community
- Approved by the BC Communicable Disease Policy Committee
What’s changed in the BCCDC Manual?

Section IX: Adverse Events Following Immunization (AEFI)
Section IX: AEFI

- Chart: Adverse Event Monitoring Information Flow
- Reporting Adverse Events
  - Specific events that should/not be reported
  - Freedom of Information and Protection of Privacy
- AEFI Recommendations
  - MHO
  - RN
Example: Adverse Event Monitoring
Information Flow

3.0 ADVERSE EVENT MONITORING INFORMATION FLOW
Refer to section 12.0 Background on adverse event surveillance for information on these agencies.

AEFI CASE

Reported directly to Public Health by parent/guardian of or individual experiencing the event or by primary care provider (e.g., physician, PHN, pharmacist, Nurse Practitioner (NP)) via the Report of Adverse Event (Reaction) Following Immunization form: HLTH 2319

Reported by IMPACT if admitted to BC Children's Hospital and recognized as an AEFI

Entry into iPHIS/PARIS

Local/Designated MHO

BC Centre for Disease Control

Canadian Adverse Events Following Immunization Surveillance System

Marketed Health Products Directorate, Health Canada

International AEFI Surveillance
WHO Drug Monitoring Program, Uppsala Monitoring Centre, Sweden
AEFI Recommendations

- Health Authorities have a process for assessing and decision-making for AEFIs

- The AEFI report may be reviewed by a Medical Health Officer and/or Registered Nurse (RN)
  - It is within a RN’s scope of practice to assess adverse events following immunization
  - A RN can determine a course of action that may include decision-making about subsequent doses of the vaccine(s)
Section IX: AEFI

- Chart: Summary of Reporting Criteria
- AEFI Explanation Headings
- Categorization of AEFIs
- New AEFIs
- Background on Adverse Event Surveillance
Chart: Summary of Reporting Criteria

- **Reporting Criteria Categories:**
  - Local Reactions at Injection Site
  - Systemic Reactions
  - Allergic Reactions
  - Neurological Events
  - Other Events of Interest

- **Temporal Criteria** is the timeline between immunization and onset of events for:
  - Inactivated Vaccines
  - Live Attenuated Vaccines
### 6.0 SUMMARY OF REPORTING CRITERIA

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
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LOCAL REACTION AT INJECTION SITE</strong></td>
<td></td>
<td>Inactivated Vaccines</td>
</tr>
<tr>
<td>Abscess, Infected</td>
<td>Material from abscess known to be purulent (positive gram stain or culture) OR</td>
<td>0 – 7 days</td>
</tr>
<tr>
<td></td>
<td>There are one or more signs of localized inflammation (erythema, pain to light touch, warmth) AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evidence of improvement on antimicrobial therapy OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physician-diagnosed</td>
<td></td>
</tr>
<tr>
<td>Abscess, Sterile</td>
<td>Physician-diagnosed AND any of the following:</td>
<td>0 – 7 days</td>
</tr>
<tr>
<td></td>
<td>Material from mass is known to be non-purulent</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Absence of localized inflammation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Failure to improve on antimicrobial therapy</td>
<td></td>
</tr>
<tr>
<td>Cellulitis</td>
<td>Physician-diagnosed AND characterized by at least 3 of the following: pain or tenderness to touch, erythema, induration or swelling, warmth</td>
<td>0 – 7 days</td>
</tr>
<tr>
<td>Nodule</td>
<td>Is more than 2.5 cm in diameter AND</td>
<td>0 – 7 days</td>
</tr>
<tr>
<td></td>
<td>Persists for more than 1 month</td>
<td></td>
</tr>
<tr>
<td>Pain or Redness or Swelling</td>
<td>Pain or redness or swelling that extends past the nearest joint AND/OR</td>
<td>0 – 48 hours</td>
</tr>
<tr>
<td></td>
<td>Pain or redness or swelling that persists for 10 days or more</td>
<td></td>
</tr>
</tbody>
</table>

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6. 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.
AEFI Explanation Headings

**THEN (2002)**
- Definition/Criteria for Reporting
- Cause/Significance
- Management
- Implications

**NOW (2013)**
- Definition
- Reporting Criteria
- Discussion
- Recommendation

THEN (2002) vs. NOW (2013)
10.2 Bell's Palsy

Definition:
Bell's palsy: a unilateral paralysis or weakness of facial muscles.

Reporting criteria:
- Physician-diagnosed Bell's palsy occurring within 3 months of immunization.

Discussion:
The cause of Bell’s palsy is not clear. There is a consideration that a viral infection such as viral meningitis or the herpes virus may be linked to Bell’s palsy, since these infections can cause inflammation that can damage the nerve that controls muscles on one side of the face.

Although some variation in the prevalence of Bell’s palsy has been reported, it does not appear to occur in a seasonal pattern. Influenza infection does not appear to be a precipitating event for Bell's palsy.

Bell’s palsy has only once been definitively linked to immunization. An intranasal inactivated influenza vaccine used only in Switzerland was removed from the market after an increase in cases of Bell’s palsy was noted.21

Recommendation:
A temporal association between vaccine receipt and Bell’s palsy onset is expected to be coincidental. Bell’s palsy would not be a contraindication to further doses of vaccine.
Categorization of AEFIs

**THEN (2002)**
- Fever
- Local reaction at injection site
- Systemic reactions
- Neurological symptoms/diagnosis
- Miscellaneous

**NOW (2013)**
- Local Reactions at Injection Site
- Systemic Reactions
- Allergic Reactions
- Neurological Events
- Other Events of Interest
New AEFIs

- **Local Reactions at Injection Site**
  - Cellulitis

- **Allergic Reactions**
  - Anaphylaxis
  - Oculo-Respiratory Syndrome (ORS)
  - Other allergic events

- **Excessive Somnolence and Paralysis** were **Removed** as AEFIs

- **Neurological Events**
  - Bell’s Palsy
  - Transverse Myelitis
  - Acute Disseminated Encephalomyelitis (ADEM)
  - Vaccine Associated Paralytic Poliomyelitis

- **Other Events of Interest**
  - Intussusception/Hematochezia
  - Syncope With Injury
9.2 Oculo-respiratory Syndrome (ORS)

**Definition:**
ORS: the onset of bilateral red eyes and respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) with or without facial oedema, following influenza vaccine.

**Reporting criteria:**
- Bilateral red eyes AND respiratory symptoms AND
- Onset within 24 hours of influenza vaccine receipt.

**Recommendation:**
Most people who have had ORS after a previous dose of influenza vaccine do not experience it again. The event recurs in about 5 to 34% but it is usually milder. Most people who have experienced ORS can be safely revaccinated.

When an individual has had severe ORS symptoms such as wheeze, chest tightness/discomfort, difficulty breathing or severe throat constriction/difficulty swallowing following influenza vaccine and has not received influenza vaccine since, this is considered to be a precaution to future receipt of influenza vaccine. Such individuals who wish to receive influenza vaccine should consult with their primary health care provider and Medical Health Officer for an expert review to distinguish between severe ORS and any anaphylaxis risk.
A new section on AEFI Surveillance includes:

- Objectives
- Surveillance Roles and Responsibilities for:
  - Regional public health and health authorities
  - BCCDC
  - Canada (National)
  - International
- Future Directions
What’s changed in the BCCDC Manual?

Section V: Management of Anaphylaxis in a Non-Hospital Setting
Section V: Anaphylaxis forms

- BCCDC Manual, Chapter II Immunization Program, Section V removed:
  - 11.0 WORKSHEET FOR EMERGENCY TREATMENT OF ANAPHYLAXIS
  - 12.0 ENHANCED SURVEILLANCE FOR CLUSTERS OF SUSPECTED ANAPHYLAXIS FOLLOWING VACCINATION

- Replaced by:
  - Enhanced Surveillance and Worksheet for Events Managed as Anaphylaxis Following Immunization
  - Downloadable at: www.bccdc.ca
### 11.0 WORKSHEET FOR EMERGENCY TREATMENT OF ANAPHYLAXIS

**Client Name:** ____________  **Surname/Given Name:** ____________
**PHN:** ____________  **Birthdate:** ____________  **Telephone:** (_____)
**yyyymm/dd**

<table>
<thead>
<tr>
<th>Immunization(s) given:</th>
<th>Dose:</th>
<th>Route:</th>
<th>Site:</th>
<th>Signature of provider:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunization(s) given:</th>
<th>Dose:</th>
<th>Route:</th>
<th>Site:</th>
<th>Signature of provider:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Date:** ____________  **(yyyymm/dd)**
**Approx. Time Given:** ____________
**Onset of Reaction:** ____________

**Details of Reaction (record in Adverse Events comments field in iPHIS):**

- Decreased level of consciousness
- Hives: [ ] Generalized or [ ] Localized at injection site
- Welts: [ ] Flushing
- Itchiness: [ ] With rash or [ ] Without rash
- Red and itchy eyes
- Wheezing: [ ] Rapid respiratory rate
- Difficulty breathing
- Hoarse voice: [ ] Sensation of throat closure
- Cyanosis: [ ] Grunting
- Upper airway swelling (lip, tongue, etc.): [ ] Dry cough
- Sweating: [ ] Use of accessory respiratory muscles
- Tingling or prickle sensation: [ ] Generalized or [ ] Around the mouth or in hands/feet
- Nausea: [ ] Vomiting: [ ] Diarrhea: [ ] Abdominal pain
- Dizziness: [ ] Syncope
- Swelling at injection site(s): [ ] OTHER (describe):

**Pulse:** _____  **Resp:** _____
**Epinephrine #1**
**Time:** _____
**Lot:** #

**Dose:** ____________  **Route:** ____________  **Site:** ____________  **Signature of provider:** ____________

**Pulse:** _____  **Resp:** _____
**Epinephrine #2**
**Time:** _____
**Lot:** #

**Dose:** ____________  **Route:** ____________  **Site:** ____________  **Signature of provider:** ____________

**Pulse:** _____  **Resp:** _____
**Epinephrine #3**
**Time:** _____
**Lot:** #

**Dose:** ____________  **Route:** ____________  **Site:** ____________  **Signature of provider:** ____________
12.0 ENHANCED SURVEILLANCE FOR CLUSTERS OF SUSPECTED ANAPHYLAXIS FOLLOWING VACCINATION

This form should be completed by public health staff for each case in a cluster of suspected anaphylaxis following administration of vaccine. Please submit the initial copy this form by email or fax to Dr. Monika Naus, Director Immunization Programs, BC Centre for Disease Control, at: monika.naus@bccdc.ca or fax 604 660 0197. Please also complete an iPHIS report on this adverse event. Updated reports and other supporting documentation can be submitted as information becomes available.

<table>
<thead>
<tr>
<th>Client Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last name:</td>
</tr>
<tr>
<td>First Name:</td>
</tr>
<tr>
<td>Date of Birth:</td>
</tr>
<tr>
<td>Sex: Male □ Female □</td>
</tr>
<tr>
<td>PHN:</td>
</tr>
<tr>
<td>iPHIS ID:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccine Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine(s) Given</td>
</tr>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td>Lot Number</td>
</tr>
<tr>
<td>Dose Number</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccine administered by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact information:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial post-reaction management coordinated by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact information:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Client History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthmatic under regular medical treatment:</td>
</tr>
<tr>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>If yes, give details of severity/medications.</td>
</tr>
<tr>
<td>Eczema:</td>
</tr>
<tr>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>History of allergies to any vaccine component(s):</td>
</tr>
<tr>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>If yes, give details of components/reaction.</td>
</tr>
<tr>
<td>History of allergies in immediate family:</td>
</tr>
<tr>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>If yes, list and give details.</td>
</tr>
</tbody>
</table>
What’s changed in the BCCDC Manual?

Section X: Appendix Adverse Events Following Immunization-Temporal Criteria
The BCCDC Manual, Chapter II Immunization Program removed Section X:1.0-Adverse Events following Immunization-Temporal Criteria

This content was combined into Section IX, chart: ‘6.0-Summary of Reporting Criteria’
1.0 ADVERSE EVENTS FOLLOWING IMMUNIZATION – TEMPORAL CRITERIA
The length of time between vaccine administration and onset of symptoms must fall within a particular time frame for the event to be considered an “adverse event following immunization”. Temporal criteria guidelines available for certain events and commonly used vaccines are given in the table below, from Health Canada and IMPACT information.

<table>
<thead>
<tr>
<th>Event</th>
<th>DTaP IPV</th>
<th>MMR</th>
<th>Varicella</th>
<th>Hepatitis B</th>
<th>Pneumococcal Meningococcal</th>
<th>Influenza</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Fever</td>
<td>0 - 72 hours</td>
<td>5 - 14 days</td>
<td>5 - 14 days</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
</tr>
<tr>
<td>Site cellulites or abscess</td>
<td>0 – 7 days</td>
<td>0 – 7 days</td>
<td>0 – 7 days</td>
<td>0 – 7 days</td>
<td>0 – 7 days</td>
<td>0 – 7 days</td>
</tr>
<tr>
<td>Adenopathy</td>
<td>0 – 7 days</td>
<td>5 – 30 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergic reactions</td>
<td>0 – 30 days</td>
<td>0 – 42 days</td>
<td>0 – 30 days</td>
<td>0 – 30 days</td>
<td>0 – 30 days</td>
<td>0 – 30 days</td>
</tr>
<tr>
<td>Rash</td>
<td>0 – 7 days</td>
<td>5 – 30 days</td>
<td>0 – 42 days</td>
<td>0 – 7 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>0 - 24 hours</td>
<td>0 - 24 hours</td>
<td>0 - 24 hours</td>
<td>0 - 24 hours</td>
<td>0 - 24 hours</td>
<td>0 - 24 hours</td>
</tr>
<tr>
<td>Hypotonic, hyporesponsive Episode (HHE)</td>
<td>0 - 48 hours</td>
<td>0 - 48 hours</td>
<td>0 - 48 hours</td>
<td>0 - 48 hours</td>
<td>0 - 48 hours</td>
<td>0 - 48 hours</td>
</tr>
<tr>
<td>Excessive somnolence</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
</tr>
<tr>
<td>Screaming/crying episode</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
</tr>
<tr>
<td>Seizure (febrile or afebrile)</td>
<td>0 - 72 hours</td>
<td>5 - 30 days</td>
<td>5 - 42 days</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
<td>0 - 72 hours</td>
</tr>
</tbody>
</table>
What’s changed in the AEFI Forms?

- Enhanced Surveillance and Worksheet for Events Managed as Anaphylaxis Following Immunization

- HLTH 2319: Report of Adverse Event (Reaction) Following Immunization
The 2013 revised form is completed for each event managed as anaphylaxis following immunization.

This form should be completed by the immunizing health care professional who observed and treated the client who experienced the anaphylaxis episode.
New features include:

- Downloadable at www.bccdc.ca
- 4 page PDF form can be saved and printed
- Text fields can be edited
- Completing page 1 of the form will auto-populate page 2 (name, date)
- Glossary for the abbreviations in the ‘route’ and ‘site’ drop down lists are in the Appendix
Enhanced Surveillance and Worksheet for Events Managed as Anaphylaxis Following Immunization

This form should be completed by the immunizing health care professional who observed and treated the client who experienced the anaphylaxis episode. Please submit the form to the appropriate Medical Health Officer for review. MHO or delegate (e.g. CDC Nurse Manager, Community Medicine Specialist) to submit completed form to Immunization Programs, BCCDC: Attn Dr. Monika Naus 604-707-2515 (fax). Please also complete an iPHIS report on this adverse event. Updated reports and other supporting documentation can be submitted as information becomes available.

PERSON COMPLETING FORM: ____________________________

DATE OF REPORT: __/__/____ (Last Name, First Name)  DATE OF EVENT: __/__/____

YYYY / MM / DD  YYYY / MM / DD

Client Information

Name: ____________________________

(Last Name, First Name)

PHN: ____________________________

Date of Birth: __/__/____  Sex: ☐ Male ☐ Female

YYYY / MM / DD

Parent/Guardian

Name: ____________________________

(Last Name, First Name)

Contact Number: ____________________________

Relationship to Client: ____________________________

Parent/Guardian Information

Medication Administered

<table>
<thead>
<tr>
<th>Medication Administered</th>
<th>Pulse (per min)</th>
<th>Resp (per min)</th>
<th>Time (24-hour)</th>
<th>Lot #</th>
<th>Route*</th>
<th>Dose (mL)</th>
<th>Site*</th>
<th>Administered By</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epinephrine #1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epinephrine #2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Enhanced Surveillance and Worksheet for Events Managed as Anaphylaxis Following Immunization

CLIENT NAME: ____________________________

(Last Name, First Name)

Time to onset of first symptoms: ____________________________

(minutes)

Rapid Progression of Symptoms: □

Table 1. Check all signs/symptoms present during course of the episode. See appendix for definition of terms.

<table>
<thead>
<tr>
<th>SYMPTOMS</th>
<th>YES</th>
<th>NO</th>
<th>UNKNOWN / DID NOT ASSESS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Skin/Mucosal</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angioedema (swelling) generalized or localized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erythema (redness), generalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus (itching or prickle sensation) WITH skin rash (raised), localized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus (itching or prickle sensation) WITHOUT skin rash, generalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urticaria localized at injection site (hives)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urticaria (rash, hives), generalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red and itchy eyes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breathing difficulty WITHOUT wheeze or stridor (sensation of chest tightness)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chest wall retractions (on inspiration)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cyanosis (bluish or purple discolouration of skin and/or mucosa)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grunting and nasal flaring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hoarse voice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased use of accessory muscles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persistent dry cough</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Enhanced Surveillance and Worksheet for Events Managed as Anaphylaxis Following Immunization

APPENDIX:

*GLOSSARY OF ABBREVIATIONS:

- VL - vastus lateralis
- IM - intramuscular
- (R) - right
- ALT - anterolateral thigh, fatty area
- SC - subcutaneous
- (L) - left
- UA - upper arm, lateral aspect
- ID - intradermal
- FA - forearm, anterior surface

DEFINITION OF TERMS:

GENERAL

- **Sudden Onset:** An event that occurred unexpectedly and without warning leading to a marked change in a subject’s previously stable condition

DERMATOLOGIC AND MUCOSAL (SKIN)

- **Urticaria (hives):** Localized swelling of superficial layers of skin that is itchy, raised, sharply demarcated, and transient (usually <12 hrs)¹
- **Erythema:** Abnormal redness of the skin without any raised skin lesions
- **Angioedema:** Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites which may not be well circumscribed and is usually not itchy. Typical sites in anaphylaxis include tongue, lips, around the eyes (periorbital), eyelids. Do not include hereditary angioedema.
- **Pruritus or prickle sensation:** An unpleasant skin sensation that provokes the desire to rub and/or scratch to obtain relief
- **Red and itchy eyes:** Redness of the whites of the eyes (sclera) with sensation that provokes the desire to rub and/or scratch to obtain relief.
- **Body location terms applicable to urticaria, erythema, pruritus, prickle sensation**
  - **Generalized:** Involving >1 body site with each limb counted separately as are the abdomen, back, head and neck.
  - **Localized:** Involving one body site, as defined above
Enhanced Surveillance and Worksheet for Events Managed as Anaphylaxis Following Immunization

CARDIOVASCULAR (CV)
- **Documented hypotension**: An abnormally low blood pressure documented by appropriate measurement
  - *Infants and children* - low systolic Blood Pressure (BP) (age specific) or > 30% decrease in BP
  - *Adults* – Systolic BP of less than 90mm Hg or greater than 30% decrease from that persons’ normal BP
- **Tachycardia**: A heart rate that is abnormally high for age and circumstance.
  - *Infants and children* - A heart rate that is above the upper limit expected for age
    - <1yr 160
    - 1 to 2 yrs 150
    - 2 to 5 yrs 140
    - 5 to 12 yrs 120
    - >12 yrs 100
  - *Adults and adolescents* - The term is usually applied to a heart rate >100 beats/min
- **Capillary refill time of greater than 3 seconds**: 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
- **Decreased central pulse volume**: Absent or decreased pulse in one of the following vessels – carotid, brachial or femoral arteries
- **Loss of consciousness**: Total suspension of conscious relationship with the outside world as demonstrated by an inability to perceive and respond to verbal, visual or painful stimulus
- **Decreased level 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

GASTROINTESTINAL (GI)
- **Nausea**: An unpleasant sensation vaguely referred to the upper abdominal region (upper region of the abdomen) and the abdomen, with a tendency to vomit
- **Abdominal pain**: Sensation of discomfort or pain in the abdominal region
- **Vomiting**: The reflex act of ejecting the contents of the stomach through the mouth
HLTH 2319: Report of Adverse Event (Reaction) Following Immunization

- This form is:
  - BC Ministry of Health form
  - **Not** in the BCCDC Immunization manual
  - Downloadable from: [www.bccdc.ca](http://www.bccdc.ca)

- Complete for any AEFI that meets the temporal and reporting criteria

- HLTH 2319 forms are entered by Public Health into the provincial electronic registries
# REPORT OF ADVERSE EVENT (REACTION) FOLLOWING IMMUNIZATION

## CLIENT INFORMATION

<table>
<thead>
<tr>
<th>CLIENT'S LAST NAME</th>
<th>GIVEN NAMES</th>
<th>PERSONAL HEALTH NUMBER</th>
<th>DATE OF BIRTH YYYY MM DD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>PARENT/GUARDIAN LAST NAME</th>
<th>GIVEN NAME(S)</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>CLIENT'S STREET ADDRESS</th>
<th>CITY/TOWN</th>
<th>POSTAL CODE</th>
<th>PHONE No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>NAME OF CLIENT'S PHYSICIAN</th>
<th>ADDRESS</th>
<th>PHONE No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>NAME OF PERSON WHO ADMINISTERED VACCINE</th>
<th>DATE VACCINE ADMINISTERED YYYY MM DD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## VACCINE INFORMATION

<table>
<thead>
<tr>
<th>AGENT OR VACCINE(S) GIVEN</th>
<th>MANUFACTURER</th>
<th>LOT NO.</th>
<th>INDICATE WHICH DOSE IN SERIES</th>
<th>SITE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

## ADVERSE EVENT (REACTION)

Report only events which cannot be attributed to coexisting conditions.

Reactions preceded by an asterisk(*) must be diagnosed by a physician.

*Time interval between vaccine administration and onset of each reaction must be recorded as number of minutes, hours or days

### LOCAL REACTION AT INJECTION SITE:

- [ ] Abscess, Infected
- [ ] Abscess, Sterile
- [ ] Cellulitis
- [ ] Nodule

<table>
<thead>
<tr>
<th>TIME IN NUMBER OF Min. or Hrs. or Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min. or Hrs. or Days</td>
</tr>
</tbody>
</table>

### NEUROLOGIC EVENTS:

- [ ] Acute disseminated encephalomyelitis (ADEM)
- [ ] Anaesthesia/paresthesia
- [ ] Bell's Palsy
- [ ] Convulsions/seizures

<table>
<thead>
<tr>
<th>TIME IN NUMBER OF Min. or Hrs. or Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min. or Hrs. or Days</td>
</tr>
</tbody>
</table>
Key tips for completing the HLTH 2319 form

- Myelitis/Transverse Myelitis is **not** listed in the Neurological Events section

- Report this condition under ‘Other neurological events’
**OUTCOME** To be completed when event(s) resolved or within 30 days of initiation of report

<table>
<thead>
<tr>
<th>SEEN BY PHYSICIAN?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOSPITALIZED BECAUSE OF REACTION?</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>DATE ADMITTED:</td>
<td>YYYY</td>
<td>MM</td>
</tr>
<tr>
<td>DATE DISCHARGED:</td>
<td>YYYY</td>
<td>MM</td>
</tr>
</tbody>
</table>

| FULLY RECOVERED | NO |
| NOT YET RECOVERED (describe below) | NO |
| PERMANENT DISABILITY / INCAPABILITY (describe below) | NO |
| UNKNOWN | NO |
| DEATH | NO |

| FREEDOM OF INFORMATION ISSUES DISCUSSED WITH CLIENT/PARENT/GUARDIAN? | YES | NO |
| INITIAL | |
| FORM COMPLETED BY (PLEASE PRINT) | |
| NAME: | |
| SIGNATURE: | |
| Date: | YYYY | MM | DD |

**TO BE COMPLETED BY MEDICAL HEALTH OFFICER OR DESIGNATE AFTER OUTCOME SECTION IS COMPLETED**

**RECOMMENDATION**

- NO CHANGE TO IMMUNIZATION SCHEDULE
- EXPERT REFERRAL (SPECIFY)
- DETERMINE PROTECTIVE ANTIBODY LEVELS
- CONTROLLED SETTING FOR NEXT IMMUNIZATION
- NO FURTHER IMMUNIZATIONS WITH RELEVANT VACCINE (SPECIFY)
- DO NOT VACCINATE AGAIN UNLESS CIRCUMSTANCES STRONGLY WARRANT USE
- OTHER (SPECIFY)

**CONSULTATION WITH BCCDC REQUESTED?**

- YES
- NO

**REASON CONSULTATION REQUESTED:**

**MEDICAL HEALTH OFFICER OR DESIGNATE (PLEASE PRINT)**

| NAME: | |
| SIGNATURE: | |
| Date: | YYYY | MM | DD |

**BCCDC USE ONLY**

| FOLLOW UP REQUIRED? | YES | NO |
| CONSULT COMPLETED? | YES | NO |
Key tips for completing the HLTH 2319 form

- **Outcome:** When completing this section please indicate which category best describes your client
  - ‘Hospitalized because of reaction’
    - **Do not** select this if a client was admitted and discharged from the Emergency Room on the same day
  - Hospitalization would typically be an admission with at least an overnight stay
Key tips for completing the HLTH 2319 form

- **Outcome:** When completing this section please indicate which category best describes your client and provide further detail as required
  - Fully recovered
  - Not yet recovered
  - Permanent disability/incapability
    - Do not select this if there are still information incoming related to the AEFI event or report
    - Do not select this if the client has some mild permanent effects such as a scar from a rash
  - Unknown
  - Death
# Adverse Events Following Immunization - Temporal Criteria

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

<table>
<thead>
<tr>
<th>Adverse Event Following Immunization</th>
<th>Temporal Criteria</th>
<th>Inactivated Vaccines</th>
<th>Live Attenuated Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain or Redness or Swelling</td>
<td></td>
<td>0 – 48 hours</td>
<td></td>
</tr>
<tr>
<td>Infected Abscess</td>
<td></td>
<td>0 – 7 days</td>
<td></td>
</tr>
<tr>
<td>Sterile Abscess</td>
<td></td>
<td>0 – 7 days</td>
<td></td>
</tr>
<tr>
<td>Nodule</td>
<td></td>
<td>0 – 7 days</td>
<td></td>
</tr>
<tr>
<td>Cellulitis</td>
<td></td>
<td>0 – 7 days</td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td></td>
<td>Timing in conjunction with other reportable adverse events</td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td></td>
<td>0 – 7 days</td>
<td>MMR: 0 – 30 days, Varicella: 0 – 42 days</td>
</tr>
<tr>
<td>Adenopathy / Lymphadenopathy</td>
<td></td>
<td>0 – 7 days</td>
<td>MMR: 5 – 30 days, Varicella: 5 – 42 days</td>
</tr>
<tr>
<td>Hypotonic-hypoansitive Episode (HHE)</td>
<td></td>
<td>0 – 48 hours</td>
<td></td>
</tr>
<tr>
<td>Screaming / Persistent Crying</td>
<td></td>
<td>0 – 72 hours</td>
<td></td>
</tr>
<tr>
<td>Parotitis</td>
<td></td>
<td>Not applicable</td>
<td>MMR: 5 – 30 days</td>
</tr>
<tr>
<td>Orchitis</td>
<td></td>
<td>Not applicable</td>
<td>MMR: 5 – 30 days</td>
</tr>
<tr>
<td>Severe Vomiting / Diarrhea</td>
<td></td>
<td>0 – 72 hours</td>
<td>0 – 7 days for rotavirus vaccine</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td></td>
<td>0 – 24 hours</td>
<td></td>
</tr>
<tr>
<td>Oculo-Respiratory Syndrome (ORS)</td>
<td></td>
<td>0 – 24 hours</td>
<td></td>
</tr>
<tr>
<td>Other Allergic Reactions</td>
<td></td>
<td>0 – 48 hours</td>
<td></td>
</tr>
</tbody>
</table>
Immunizer: What to do with a completed HLTH 2319 form

- Immunizing Health Care Professionals should submit a completed HLTH 2319 form and any relevant documentation to their Regional Health Authority.

- ‘Where to send a report of an adverse event following immunization’ is posted at www.bccdc.ca
Where to send a report of an adverse event following immunization

- **Northern Health**
  - Northern Health Preventative Public Health
  - 600-299 Victoria Street, Prince George, BC, V2L 5B8
  - Fax: 250.565.2640

- **Interior Health**
  - Send to local public health. Find the public health unit closest to you [here](#).

- **Vancouver Island Health Authority**
  - Send to local public health. Find the public health unit closest to you [here](#).

- **Fraser Health**
  - Fraser Public Health
  - 4946 Canada Way, Burnaby, BC, V5G 4J6
  - Attn: AEFI Communicable Disease Nurse Coordinator
  - Fax: 604.918.7630

*AEFI reports from residents of First Nations communities should be forwarded to the local or regional public health office as shown on this map, corresponding to the residence of the vaccine recipient or health provider.*
Public Health: What to do with a completed HLTH 2319 form

- A Regional Health Authority enters the completed HLTH 2319 forms into public health electronic registries in BC
- AEFI data entry guidelines for iPHIS are posted at www.bccdc.ca
- Panorama guidelines will be released in the future
Pharmacists: AEFI Reporting

- Immunizing Pharmacists should follow the AEFI reporting procedure set by their Regional Health Authority
- Pharmacists should report an AEFI using the HLTH 2319 form
- An algorithm has been created to guide Pharmacists through the AEFI reporting process
  - Outlines Pharmacist and Public Health responsibilities
Further Questions?

- Please follow your Regional Health Authority’s procedure for immunization questions
- Refer to the ‘Resources’ slides at the end of this presentation

Thank you for your time and interest
Adverse Events Following Immunization Forms

Adverse Events Following Immunization (AEFI) were formerly called Adverse Vaccine Reactions or Vaccine Associated Adverse Events. AEFI are voluntarily reportable in British Columbia to monitor vaccine safety. The HLTH 2319 form is published by the Ministry of Health to facilitate reporting by health care providers to their local health unit. After filling and printing the form, submit it to your local health unit office, or send fax to the central office in your jurisdiction. Data from the form are to be entered into PHIS or PARIS by public health staff. Criteria for reporting and management of adverse events are found in BC CDC Manual, Chapter II Immunization Program, Section 9 of the Immunization Program Manual.
BCCDC Manual, Chapter II, Immunization Program: Section IX, Section V

Administrative Circulars: 2013:04, 2013:05, 2013:07
http://www.bccdc.ca/dis-cond/commmmanual/AdminCircs/default.htm

Enhanced Surveillance and Worksheet for Events Managed as Anaphylaxis Following Immunization
http://www.bccdc.ca/NR/rdonlyres/C414854F-6793-4D4E-8FB3-44C69992C426/0/Anaphylaxis_AEFI_formApr2013FINAL.pdf

Reporting Guidelines for Adverse Events Following Immunization in iPHIS
Online Resources

- HLTH 2319: Report of Adverse Event (Reaction) Following Immunization

- Where to send a completed AEFI report in BC
  http://www.bccdc.ca/NR/rdonlyres/79CFFCFD-BF26-4A79-8AC3-2CBB84FEC701/0/adverse_event_2013Apr24_KK.pdf

- AEFI reporting procedure for Immunizing Pharmacists