Vaccine Safety Surveillance Workshop

Date: January 21, 2013

Location: Boardroom 350, 3rd Floor, 480 University Ave, Toronto
Vaccine Safety Surveillance Workshop

Objectives
- To understand the objectives of vaccine safety surveillance
- To review case definitions for Adverse Events Following Immunization (AEFI) and the new Ontario AEFI Surveillance form through interactive case studies.
- To translate new recommendations in the AEFI iPHIS user guideline into iPHIS data entry requirements through interactive case studies application

*Titles link directly to presentation of the same name.

Program Outline

<table>
<thead>
<tr>
<th>TIME</th>
<th>TOPIC</th>
<th>PRESENTER</th>
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<tbody>
<tr>
<td>9:00 – 9:05</td>
<td>Welcome and introduction to the team</td>
<td>Jill Fediurek</td>
</tr>
<tr>
<td>9:05 – 9:45</td>
<td>Vaccine Safety Framework*</td>
<td>Dr. Shelley Deeks</td>
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<tr>
<td></td>
<td>Overview of AEFI Reporting in Ontario*</td>
<td>Tara Harris</td>
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<tr>
<td>9:45 – 10:15</td>
<td>Overview of AEFI Appendix B and the new Ontario AEFI Surveillance Form*</td>
<td>Tara Harris</td>
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<tr>
<td>10:15 – 10:30</td>
<td>Introduction to case study exercise*</td>
<td>Jill Fediurek</td>
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<td>10:30 – 10:45</td>
<td>Break</td>
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<tr>
<td>10:45 – 11:30</td>
<td>Small group work on case studies</td>
<td>IVPD team to facilitate</td>
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<tr>
<td>11:30 – 11:50</td>
<td>Large group report back on case study groups</td>
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<td>12:00 – 13:00</td>
<td>PHO Rounds – Public Health Physicians and vaccine safety*</td>
<td>Dr. Shelley Deeks – CME accredited event</td>
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<td>13:00 – 13:30</td>
<td>Lunch</td>
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<tr>
<td>13:30 – 13:40</td>
<td>Recap of morning session</td>
<td>Jill Fediurek</td>
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<tr>
<td>13:40 – 14:10</td>
<td>Overview of changes to iPHIS and AEFI iPHIS user guide*</td>
<td>Tara Harris</td>
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<tr>
<td>14:10 – 15:15</td>
<td>Demonstration of iPHIS data entry on case study 1</td>
<td>Lori Newman/Tara Harris</td>
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<td>15:15 – 15:30</td>
<td>Break</td>
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<tr>
<td>15:30 – 16:00</td>
<td>Independent iPHIS data entry on case studies from morning session</td>
<td>IVPD team to facilitate</td>
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<tr>
<td>16:00 – 16:20</td>
<td>Q &amp; A on data entry and other issues</td>
<td>Lori Newman/Tara Harris</td>
</tr>
<tr>
<td>16:20 – 16:30</td>
<td>Thank you and evaluation</td>
<td>Jill Fediurek</td>
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</table>
Vaccine Safety Surveillance

January 21, 2013

Shelley Deeks, Medical Director
Immunization and Vaccine Preventable Diseases
Social context

- Well organised consumer groups
- Popularity of alternative health care
- Increased competition in media
- Rapid communication technologies
The importance of vaccine safety

• Decrease in disease risks and increased attention on vaccine risks

• Vaccination universally recommended and subject to “mandatory choice”

• Public confidence in vaccine safety is critical and key to success of programs
  • Higher standard of safety is expected of vaccines
  • Lower risk tolerance = need to search for rare reactions
  • Vaccinees generally healthy (vs. ill for drugs)
Keeping public and providers well informed may help avoid misconceptions

• May be supported by:
  • Understanding that rate of adverse vaccine reactions is considerably lower than the rate of complications resulting from the disease
  • Being aware of benefits and risks of vaccines
Balancing efficacy and safety of a vaccine

Vaccine efficacy: Ability to work to protect from illness

Vaccine-associated risk: potential to harm
Global Advisory Committee on Vaccine Safety (GACVS), rotavirus vaccine assessment, Dec 2011

- Both rotavirus vaccines have good safety profile however may be associated with an increased (up to 6-fold) intussusception risk after 1st dose in some populations*
- Risk substantially lower than associated with RotaShield®
- Benefits of rotavirus vaccination for all infants, without age restriction, greatly exceeds risks particularly in developing countries with moderate and high mortality from rotavirus
- Continued surveillance for intussusception encouraged

*http://www.who.int/wer/2012/wer8706.pdf
Is there a perfect vaccine?

Vaccines should cause no adverse reactions and completely prevent the infection that they target.

Current technology does not allow for such perfection.

Key is to minimize adverse events and ensure safe use of vaccines.

AEFI surveillance monitors adverse events and follows up on severe events that may result from the vaccine.
Monitoring vaccine safety: Pre-licensure

• Clinical trials

• Vaccines are tested in thousands of persons before being licensed

• Common reactions are identified pre-licensure
Monitoring vaccine safety: Post licensure

- Identify rare reactions not detected during pre-licensure studies;
- Monitor increases in known reactions
- Identify risk factors or pre-existing conditions that may promote reactions
- Identify whether there are particular vaccine lots with unusually high rates or certain types of events
- Identify signals of possible adverse reactions that may warrant further study or affect current immunization recommendations
Post-licensure Vaccine Safety Activities

- Phase IV Trials
  - about 10,000 participants
  - better but still limited
- Regulatory oversight
- Large-Linked Databases
- Passive surveillance
- Active surveillance
- Observational Studies
Post marketing surveillance

• Surveillance is meant to generate signals
  • It is a starting point; not a stopping point
  • Subsequent investigation may often be required

• Investigation
  • Begin with better understanding of reported cases
  • More extensive understanding:
    • Identify risk factors
    • Identify mechanism (Clinical studies)
    • Management / Reimmunization?
An example: Post-marketing safety surveillance: intussusception

- Conflicting data regarding association between rotavirus vaccination and intussusception
- Mexico/Australia: risk of intussusception within one week of first dose about 4–6 times higher than in later periods after vaccination *
- USA: recent study demonstrated no increase intussusception risk observed after 786,725 doses*
- Any risk, where found, substantially lower than found with Rotashield

Types of vaccine safety issues

• Not all safety issues are related to the vaccine per se

• Vaccine administration errors
  • Storage and handling
  • Administration
  • Documentation

• Adverse events following immunization (AEFI)
  • Temporal associations
  • Causal associations
Types of Administrations Errors

- Wrong vaccine or diluent
- Wrong dosage
- Expired vaccine
- Incorrect route/site/needle size
AEFI surveillance: Definition of an AEFI*

• Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

Coincidence versus Causality

Recognition of ASD

MMR Vaccine

Months of Age
Considerations for causal association

- Event occurs during a plausible time period following vaccination
- Event corresponds to ones previously associated with a particular vaccine
- Event conforms to a specific clinical syndrome whose association with vaccination has strong biologic plausibility (e.g., anaphylaxis) or occurs following the natural disease
- A laboratory result confirms the association (e.g., isolation of vaccine strain varicella virus from skin lesions of a patient with rash)
- Event recurs on re-administration of the vaccine ("positive rechallenge")
- A clinical trial or epidemiologic study shows greater risk of specific adverse event among vaccinated versus unvaccinated groups
Each vaccine component can potentially lead to adverse reaction

**ANTIGENS**
(processed through attenuation, inactivation, recombination DNA technology.)

**Components and processes ENHANCING IMMUNE RESPONSE, e.g.**
- Adjuvants
- Protein conjugation.

**Components REDUCING CONTAMINATION**
during the manufacturing process, transport and storage:
- Antibiotics
- Stabilizers
- Preservatives.
# Frequency of vaccine reactions

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Occurrence among persons vaccinated in percent</th>
<th>Severity of reactions</th>
</tr>
</thead>
</table>
| **Very common** | ≥ 10%                                          | Common and usually minor reactions:  
1. Part of the immune response to vaccine,  
2. Reactions resolve on own,  
3. Examples include:  
  – Fever  
  – Malaise |
| **Common (frequent)** | ≥ 1% and < 10%                                | Rare, usually more severe reactions:  
1. Usually require clinical management,  
2. Examples:  
  • Severe allergic reaction (e.g., anaphylaxis) including an exaggerated response to the vaccine antigen or component,  
  • Vaccine specific reactions, such as vaccine-associated measles |
| **Uncommon (infrequent)** | ≥ 0.1% and < 1%                               |                       |
| **Rare**       | ≥ 0.01% and < 0.1%                            |                       |
| **Very rare**  | < 0.01%                                       |                       |
Types of adverse events

• Local Reactions
  • More common with non-live vaccines containing adjuvants
  • Pain, redness, swelling at injection site

• Systemic Reactions
  • Generally more common following live vaccine, but less severe with subsequent doses
  • Fever, headache, loss of appetite

• Allergic Reaction
  • Anaphylaxis/Severe systemic allergic reaction
## Roles and responsibilities in AEFI surveillance

<table>
<thead>
<tr>
<th>Immunization provider</th>
<th>Public health units</th>
<th>Public Health Ontario</th>
<th>Public Health Agency of Canada</th>
<th>WHO/ Uppsala Monitoring Centre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inform and counsel re: risks/benefits</td>
<td>Case assessment &amp; management</td>
<td>Provincial surveillance</td>
<td>National AEFI database</td>
<td>Global AEFI database</td>
</tr>
<tr>
<td>Recognize and report AEFIs</td>
<td>Reporting of AEFIs (iPHIS)</td>
<td>Case / cluster management advice</td>
<td>Signal detection</td>
<td>Signal detection</td>
</tr>
<tr>
<td>Manage AEFIs</td>
<td>Advice re: future immunization</td>
<td>Public health action</td>
<td>Causality assessment</td>
<td>Expert advisory Group</td>
</tr>
</tbody>
</table>
Global Advisory Committee on Vaccine Safety

GACVS is key mechanism to provide prompt and efficient response to concerns about vaccine-related adverse events.

GACVS’s committee (14 members) provides:

- **Independent and unbiased** recommendations regarding all aspects of vaccine safety.
- **Broad expertise**, including familiarity with drug regulatory process and special needs of low-income countries.
- **Analysis undertaken with Scientific rigor** based on best available fact, scientific evidence, and process.
Examples of Concerns GACVS has addressed

- RV vaccine and intussusception
- Hepatitis B vaccine and multiple sclerosis
- MMR vaccine and autism
- Intranasal influenza vaccination and the risk of Bell's Palsy
- The safety of pneumococcal conjugate and HPV vaccines
Acknowledgements

• Patrick Zuber, WHO
• Natasha Crowcroft, PHO
• Barbara Law, PHAC
• Sarah Wilson, PHO
Vaccine Safety Surveillance Workshop
January 21, 2013

AEFI reporting in Ontario
Objectives of provincial AEFI surveillance

• To identify and investigate serious or unexpected occurrences of AEFI, particularly for new vaccines
• To detect and investigate safety signals (e.g. lot specific problems)
• To estimate provincial rates of reported AEFI by vaccine
• To report to stakeholders on the safety of publicly funded vaccines in Ontario
• To maintain public confidence in vaccine programs
AEFI reporting in Ontario: Guiding documents

- Health Protection and Promotion Act (HPPA), Reg. 38
- Ontario Public Health Standards
- Infectious Disease Protocol, Appendix B
- iPHIS AEFI User Guide
- ON AEFI reporting form / PHAC reporting form

Appendix B: Provincial Case Definitions for Reportable Diseases
Assessment of AEFI surveillance in Ontario

• Public health architecture January 1, 2012
  • Provincial responsibility for AEFI surveillance and case management issues transferred from MOHLTC to PHO

• PHO assessment of status of provincial AEFI surveillance and opportunities for enhancement

• Key components
  • Vaccine Safety Surveillance Meeting (March 1, 2012)
  • Review of key guidance documents
  • Interviews with key informants
  • Weekly review of all reported AEFI cases to assess iPHIS data
  • HPV AEFI assessment
Assessment of AEFI surveillance: Key observations

Challenges

• Inconsistency across key AEFI surveillance documents (e.g. Appendix B, iPHIS User Guide, AEFI reporting form)

• Data quality issues

• Limited configuration possible in iPHIS

• Limited analysis and reporting of AEFI data
Assessment of AEFI surveillance: Key observations

Opportunities

• Committed network of staff across HUs
• Established collaboration with other P/Ts, PHAC
• Broad support for system improvements
• Timely opportunity to implement changes due to ID protocol revisions
HPV4 AEFI assessment

• Report distributed to HUs in Nov. 2012

• 2 main objectives
  • HPV vaccine program evaluation
  • Assessment of provincial AEFI data quality

• In-depth description of provincial AEFI surveillance data strengths and limitations

• 3 key inter-related issues identified which have an important impact on data quality - Reporting rate, case classification, event (reaction) classification
Plan for provincial AEFI surveillance enhancements (2012-2013)

- Ontario AEFI Reporting Form (New)
- AEFI Appendix B (Revised)
- Vaccine Safety Surveillance Working Group (VSSWG)
  Education and training
- Periodic data quality reviews
- Enhanced signal detection
- Annual Provincial AEFI Surveillance Report
- iPHIS application (Updated)
- iPHIS User Guide (Revised)
Provincial AEFI Surveillance Outcomes (2012-2013)

- Improved quality, validity and timeliness of provincial AEFI surveillance data
- Better alignment with National vaccine safety reporting
- Greater ability to detect and investigate vaccine safety signals
- Ability to report on the safety of publicly-funded vaccines
- Contribute towards maintaining public confidence in vaccines
Next steps

• Education / training (E.g. workshops, tools, site visits, telephone consultation)

• Complete implementation of all surveillance enhancements
  • ON AEFI reporting form

• Refine documents / guidance where required
  • Finalize draft iPHIS user guide

• Continued collaboration with stakeholders
  • VSSWG, VPD / CD Managers’, VVWG

• Evaluation of provincial AEFI surveillance system
Acknowledgements

VSSWG Members
• Jill Feduirek* (Chair)
• Dr. Shelley Deeks*
• Dawn Williams
• Marlon Drayton
• Tsui Scott
• Ruth Gratton
• Joanne Orr
• Christina Taylor
• Lois Lacroix
• Katie Souliere
• Joanne Vieira

• Mary Ann Holmes
• Karen Dowsett
• Susan O’Gorman
• Julie Lafleche
• Dr. Vinita Dubey
• Dr. Ian Gemmill

IVPD team members*
• Margaret McIntyre
• Laurie Stanford
Questions about vaccine safety? 
Send an email to ivpd@oahpp.ca
Vaccine Safety Surveillance Workshop
January 21, 2013

Overview of AEFI Appendix B & ON
AEFI Reporting Form
Provincial AEFI Surveillance Changes (2012-2013)

- Ontario AEFI Reporting Form (New)
- AEFI Appendix B (Revised)
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AEFI Appendix B revisions

• Complete re-write of 2009 AEFI Appendix B
• Review of evidence and environmental scan of guidance documents from other jurisdictions
• Input from HUs provided via Vaccine Safety Surveillance Working Group
• Key components include:
  • Definition of a confirmed case
  • New / revised definitions of specific AEFI
  • Temporal criteria for specific AEFI
  • Additional supporting information for each specific AEFI
Case classification

**Confirmed case**
- Any reported event listed in sections 5.0 in a vaccine recipient which follows immunization which cannot be clearly attributed to other causes. A causal relationship with the administration of the vaccine does not need to be proven.

**Does not meet**
- Any reported event in a vaccine recipient which follows immunization which has been clearly attributed to other causes.

- Classification is for surveillance purposes *only*
- Classifying a case as confirmed does not imply that the vaccine caused the event nor is it a diagnosis of causation
- Most reported AEFI will be meet the definition of confirmed unless a clear alternative cause is established
  - E.g. Report of GBS with laboratory-confirmed campylobacter
2009

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.

2013

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 (8) and is:

- $\geq 2.5$ cm in diameter; and
- Persists for more than one month.

**Temporal criteria:**
A nodule is generally seen within 7 days of vaccine receipt

**Discussion:**
Nodules are mainly associated with aluminum-adsorbed vaccines, particularly if the dose is deposited subcutaneously rather than intramuscularly. Sterile nodules can take up to 1 year or more to resolve, but most commonly resolve within 2 to 3 months.

Nodules are not a contraindication to further doses of vaccine.
AEFI Appendix B revisions: Highlights

- Local injection site reactions **lasting longer than 4 days** or extending **beyond the nearest joint**
- Fever of ≥38°C **in conjunction** with another reportable event
- Severe vomiting / diarrhea
- Allergic reactions, Event managed as **anaphylaxis**
- Anaesthesia / paraesthesia
- Syncope **with injury**
- Other severe / unusual events
Tour of AEFI Appendix B

ON AEFI Reporting Form

• Decision to implement an Ontario-specific form based on
  • Input from individual HUs & consultation with VSSWG
  • Environmental scan of AEFI reporting forms used in other Canadian jurisdictions
  • Identification of specific data quality issues occurring as a result of misalignment between PHAC AEFI reporting form and iPHIS

• Format adapted from AEFI reporting form used by British Columbia Centre for Disease Control

• Most fields map directly to iPHIS data entry fields

• Aligned with PHAC AEFI reporting form where possible (where iPHIS data entry fields exist)
ON AEFI Reporting Form (cont.)

• Can be completed in electronic (but not saved) or hard copy format

• Q & A document accompanies the form to address questions about reporting of AEFI to public health and completion of the form

• Form is intended for use by
  • Health care providers reporting an AEFI to the HU (either spontaneously or upon request by the HU e.g. following a telephone report)
  • HU staff to assist with collection of case details required for provincial reporting via iPHIS

• Use of the form is highly recommended but not required
Tour of AEFI Reporting Form

http://www.oahpp.ca/resources/documents/2013Jan17_ON%20AEFI%20Form_final%20draft.pdf
ON AEFI Reporting Form: Sample process flow

• Receive phone call from physician reporting a possible AEFI
• Fax or send link to physician requesting completion of the **AEFI reporting form**

• Review of initial **AEFI reporting form** by case manager to identify missing / incomplete information required for
  • Provincial AEFI reporting via iPHIS; or MOH recommendations re: future immunization

• Conduct additional investigation / follow-up as necessary (e.g. interview vaccinee, request ER / hospital records, etc.)

• Document additional investigation / follow-up as per HU protocol (e.g. progress notes)
• Attach new / photocopy of initial **AEFI reporting form** and update missing / incomplete details based on case investigation / follow-up

• Use complete **AEFI reporting form** to enter case information into iPHIS
Questions?
Vaccine Safety Surveillance Workshop
January 21, 2013

Introduction to case study exercises
Objectives

• Become familiar with the *new/revised* provincial AEFI documents
  • Ontario AEFI Reporting Form
  • AEFI Appendix B (Infectious Diseases Protocol, 2013)
  • iPHIS User Guide for AEFI

• Gain practical experience in the use of provincial AEFI surveillance documents throughout the AEFI investigation and reporting process

• Understand how to translate AEFI case information into high quality provincial AEFI surveillance data
Assumptions

• Use of Appendix B guidelines to classify AEFI for provincial reporting is required

• Use of the Ontario AEFI reporting form is highly recommended for initial reporting of AEFI

• Case studies are designed to highlight how provincial surveillance documents can
  • support the AEFI investigation and reporting process; and
  • promote high quality provincial surveillance information.

• Health units will continue to have additional documentation and processes in place to support local AEFI investigation and management
How the case studies work

• Background information is provided on each case to assist with the case study questions
  • Appendix 1 - Initial AEFI reporting form. Completed / faxed in by health care provider or completed based on initial telephone report)
  • Appendix 2 – Case information. Additional case information from public health follow-up (e.g. nursing notes, ER / hospital records, MOH recommendations)

• A series of case study exercise questions will guide you through completion of the AEFI form, classification of the case (confirmed / DNM / PUI) and the event (reaction) classification

• An answer key is available and will be distributed in a separate document

• 6 case studies in total – 1 example, 2 small group work, 3 homework
**Background:** Assume it is December 12th, 2012 and you are a case manager working in a local health unit in Ontario. The admin clerk brings you an AEFI reporting form (Appendix 1) that has just been faxed in.

**Task:** Complete question Q1 and Q2 based on information in the AEFI reporting form only.
Case study #1

Q1. Is the AEFI reporting form complete? *(Pick one of the two options below)*

[ ] Yes, it is complete

[ ] No, there is missing / incomplete information.

If no, list the missing / incomplete information.

**Missing information (list the main pieces of missing information, there can be more or less than 3)**

<p>| | |</p>
<table>
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<td>2.</td>
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<td>3.</td>
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<tr>
<td>Other:</td>
<td></td>
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</table>
Q1. Is the AEFI reporting form complete? *(Pick one of the two options below)*

[ ] Yes, it is complete

[✓] No, there is missing / incomplete information.

If no, list the missing / incomplete information.

**Missing information (list the main pieces of missing information, there can be more or less than 3)**

1. **Section 2** - lot #, exp. date, dose number, dosage / unit, immunization error, previous history of AEFI

2. **Section 3** – duration of event

3. **Section 4** – medical history, concomitant medications, description of previous AEFI history / immunization error (if any)

**Other:** **Section 5 & 6** – It is not expected these sections to be completed in the initial report; to be completed upon completion of case investigation

Finish this section before turning over the page
Q2. Assuming that the AEFI reporting form is incomplete, what is your plan for obtaining this additional information required to support the reporting / management of this AEFI?

<table>
<thead>
<tr>
<th>Plan (list as many steps as you think are necessary)</th>
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<tbody>
<tr>
<td>Step 1:</td>
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<tr>
<td>Step 2:</td>
</tr>
<tr>
<td>Step 3:</td>
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Case study #1

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<table>
<thead>
<tr>
<th>Plan (list as many steps as you think are necessary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1: Contact client to obtain a more complete description of signs and symptoms, treatment effect, progression / outcome of the event, medical history, concomitant medications, previous history of AEFI</td>
</tr>
<tr>
<td>Step 2: Contact physician’s office to obtain lot # / exp. date</td>
</tr>
<tr>
<td>Step 3:</td>
</tr>
<tr>
<td>Other steps:</td>
</tr>
</tbody>
</table>
Background: On December 19th, you receive a copy of the nursing notes from the nurse who did the follow-up and a copy of the recommendations from the AMOH. Both are attached as Appendix 2 (Case information).

Task: Based on this additional information, complete questions Q3 –Q6 below.
Q3. Using the information in the nursing note and AMOH recommendations, complete sections 5 and 6 of the AEFI reporting form and update sections 1 to 4.

See attached completed AEFI reporting form.
Q4. Is there any other information not documented in the AEFI form or nursing notes that is required to support the assessment / reporting of this AEFI?

<table>
<thead>
<tr>
<th>Additional information (list the additional pieces of information that you think will be required to assess / report this AEFI)</th>
</tr>
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<tbody>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
<tr>
<td>Other:</td>
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Q4. Is there any other information not documented in the AEFI form or nursing notes that is required to support the assessment / reporting of this AEFI?

<table>
<thead>
<tr>
<th>Additional information (list the additional pieces of information that you think will be required to assess / report this AEFI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Dosage / unit</strong> may be obtained from the product monograph or HU distribution management system if available.</td>
</tr>
<tr>
<td>2. Information in the report supports no previous history of Pneu-P-23 immunization however if there had been previous immunization with Pneu-P-23 in this case, this would be important information to document. Previous history of Pneu-P-23 vaccination can provide important context as re-immunization of healthy adults is not recommended and has been associated with increased local injection site and systemic reaction when administered less than 2 years after the initial dose. Studies have suggested that re-vaccination after an interval of at least 4 years is not associated with an increased incidence of adverse side effects. (1)</td>
</tr>
<tr>
<td>3. Severe local reactions including reports of injection site cellulitis and peripheral edema in the injected extremity have been documented rarely with Pneu-P-23 vaccine in post-marketing surveillance, even with the first dose. (1)</td>
</tr>
<tr>
<td>Other:</td>
</tr>
</tbody>
</table>
Q5. Based on the information that you have now, does this event meet the definition of a **confirmed** AEFI described in Section 3.0 (Case Classification) of the *AEFI Appendix B (Infectious Diseases Protocol, 2013)*? Please describe what information in the AEFI report supports your assessment in the “details” column. Provide any additional rationale below.

<table>
<thead>
<tr>
<th>Options (Pick one)</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes</td>
<td>Justify why it is a confirmed AEFI:</td>
</tr>
<tr>
<td>[ ] No</td>
<td>Justify why it is not a confirmed AEFI:</td>
</tr>
<tr>
<td>[ ] Not sure</td>
<td>Indicate the reason for your uncertainty:</td>
</tr>
<tr>
<td>[ ] Need more information</td>
<td>Indicate what additional information is needed:</td>
</tr>
</tbody>
</table>
Q5. Based on the information that you have now, does this event meet the definition of a confirmed AEFI described in Section 3.0 (Case Classification) of the *AEFI Appendix B (Infectious Diseases Protocol, 2013)*? Please describe what information in the AEFI report supports your assessment in the “details” column. Provide any additional rationale below.

<table>
<thead>
<tr>
<th>Options (Pick one)</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>[✔] Yes</td>
<td>Justify why it is a confirmed AEFI:</td>
</tr>
<tr>
<td></td>
<td>The event meets the definition of a confirmed AEFI according to the following rationale:</td>
</tr>
<tr>
<td></td>
<td>• The event is temporally associated with immunization (occurred after immunization)</td>
</tr>
<tr>
<td></td>
<td>• The event cannot be clearly attributed to any other cause. (There is no information in the report to suggest that there may be an alternative cause for the event that occurred.)</td>
</tr>
</tbody>
</table>
Q6. Does this event meet any of the specific AEFI case definitions described in Section 5.0 (Clinical Evidence) of the [AEFI Appendix B (Infectious Diseases Protocol, 2013)](https://example.com)? Please describe what information in the AEFI report supports your assessment in the “details” column. Provide any additional rationale below.

<table>
<thead>
<tr>
<th>Options (Pick one)</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes</td>
<td>Indicate the AEFI definition(s) that you would use:</td>
</tr>
<tr>
<td>[ ] No</td>
<td>Justify why it does not meet any of the definitions:</td>
</tr>
<tr>
<td>[ ] Not sure</td>
<td>Indicate the reason for your uncertainty:</td>
</tr>
<tr>
<td>[ ] Need more information</td>
<td>Indicate what additional information is needed:</td>
</tr>
</tbody>
</table>
Case study #1

Q6. Does this event meet any of the specific AEFI case definitions described in Section 5.0 (Clinical Evidence) of the [AEFI Appendix B (Infectious Diseases Protocol, 2013)]? Please describe what information in the AEFI report supports your assessment in the “details” column. Provide any additional rationale below.

<table>
<thead>
<tr>
<th>Options (Pick one)</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>[✓] Yes</td>
<td>Indicate the AEFI definition(s) that you would use:</td>
</tr>
<tr>
<td></td>
<td>The event meets the definition “Pain, redness and swelling at the injection site” in Section 5.0 (Clinical Evidence), A. Local reactions at the injection site as per the following criteria:</td>
</tr>
<tr>
<td></td>
<td>• The event occurred at the injection site (Pneu-P-23 vaccine administered intramuscularly in the left arm) AND</td>
</tr>
<tr>
<td></td>
<td>• Redness, swelling and pain extended beyond the nearest joint (elbow) AND</td>
</tr>
<tr>
<td></td>
<td>• The event persisted for longer than 4 days (event was not yet resolved when follow-up information was obtained from the client on day 7)</td>
</tr>
</tbody>
</table>
Small group work

• Case study exercises included in PHO folder; use hard copy to complete answers
• Each table will complete either case study exercise #2 or #3
• IVPD team members available for consultation
• Report back responses / discussion with larger group

Webinar participants
• Case study exercises and answer keys (#1-3) have been sent via email
• Complete case studies independently

All participants
• 3 additional case studies with answer keys (#4-6) will be sent via email following the workshop to complete independently
Public Health Physicians and Vaccine Safety

PHO Rounds
January 21, 2013

Shelley Deeks, Medical Director
Tara Harris, Nurse Consultant
Immunization and Vaccine Preventable Diseases
Outline and objectives

• Review vaccine safety surveillance objectives
• Identify why safety surveillance is important
• Understand why changes were needed
• Review changes in Adverse Events Following Immunization (AEFI) Surveillance and the new Ontario AEFI Surveillance form
• Discuss challenging issues related to safety
Objectives of provincial AEFI surveillance

• To identify and investigate serious or unexpected occurrences of AEFI
• To detect and investigate safety signals
• To estimate provincial rates of reported AEFI by vaccine
• To report to stakeholders on the safety of publicly funded vaccines in Ontario
• To maintain public confidence in vaccine programs
What do Canadian parents think?

- Concerned that newer vaccines are not safe as older vaccines: 25% Disagree (1-3), 22% Neither (4), 51% Agree (5-7)
- More concerned about safety of vaccines now than five years ago: 38% Disagree (1-3), 19% Neither (4), 43% Agree (5-7)
- Adverse reactions to vaccines don’t get enough attention in the media: 30% Disagree (1-3), 28% Neither (4), 40% Agree (5-7)
- Children today receive too many vaccines: 51% Disagree (1-3), 18% Neither (4), 31% Agree (5-7)
- Don’t think that vaccines are safe: 71% Disagree (1-3), 13% Neither (4), 16% Agree (5-7)
- Use of alternative practices: 63% Disagree (1-3), 19% Neither (4), 14% Agree (5-7)

n=1247-1285
Vaccine Safety Survey, 2011

Available at: http://resources.cpha.ca/immunize.ca/data/1792e.pdf
Where do Canadian parents go for information?

“If you were looking for the most reliable and trustworthy information on vaccines, where would you look or who would you talk to?”

Physician: 68%
Internet: 27%
Public health nurse: 13%
Local public health authority: 7%
Family member/friend: 5%
Other health care worker: 5%
CLSC: 4%
Health Canada: 4%
Pharmacist: 3%
Government (general): 2%
Scientific sources, research studies: 2%
Other: 10%
DK/NR: 2%

[IF INTERNET]
“Where on the Internet would you usually go?”

Google search: 49%
Health Canada: 15%
Government websites: 6%
Provincial sources: 6%
Health-related sites: 3%
Mayo clinic: 3%
Multiple/other search engines: 2%
Medical journals: 2%
Family/parenting sites: 2%
Other online sources: 17%
DK/NR: 13%

n=453
Vaccine Safety Survey, 2011

Available at: http://resources.cpha.ca/immunize.ca/data/1792e.pdf
Vaccine safety

• Decrease in disease risks and increased attention on vaccine risks

• Vaccination universally recommended and subject to “mandatory choice”

• Public confidence in vaccine safety is critical and key to success of programs
  • Higher standard of safety is expected of vaccines
  • Lower risk tolerance = need to search for rare reactions
  • Vaccinees generally healthy (vs. ill for drugs)
Keeping public and providers well informed may help avoid misconceptions

Supported by:

• Understanding that rate of adverse vaccine reactions is considerably lower than the rate of disease complications
• Being aware of benefits and risks of vaccines
Is there a perfect vaccine? No

Vaccines should cause no adverse reactions and completely prevent the infection that they target.

Current technology does not allow for such perfection.

Key is to minimize adverse events and ensure safe use of vaccines.

AEFI surveillance monitors adverse events and follows up on severe events that may result from the vaccine.

Therefore essential to monitor vaccine safety.
Monitoring vaccine safety: Pre-licensure

• Clinical trials

• Vaccines are tested in thousands of persons before being licensed

• Common reactions are identified pre-licensure
Monitoring vaccine safety: Post licensure

- Identify rare reactions not detected during pre-licensure studies;
- Monitor increases in known reactions;
- Identify risk factors or pre-existing conditions that may promote reactions;
- Identify whether there are particular vaccine lots with unusually high rates or certain types of events;
- Identify signals of possible adverse reactions that may warrant further study or affect current immunization recommendations.
Post-licensure Vaccine Safety Activities

• Phase IV Trials
  • about 10,000 participants
  • better but still limited

• Regulatory oversight

• Passive surveillance

• Active surveillance

• Observational Studies
Health Canada: Post Marketing Oversight

• Lot release program:
  • Upon approval vaccines are placed on Evaluation Group 2 (strictest oversight including sample testing, protocol review and issuance of lot release letter for each lot)
  • Manufacturer may request reclassification (e.g. from Group 2 to Group 3)
• Any change to vaccine manufacturing and control must be approved before implemented
• Review Yearly Biologic Product Report
• Post-marketing surveillance of efficacy and adverse events
Health Canada: What happens when a vaccine quality issue arises?

• Issue brought to attention of senior management
• Issue analysis summary (IAS) prepared using a prescribed template:
  • Description of issue, context, previous discussions, considerations, options, recommended strategy and implementation plan, list of other organisations involved and/or consulted
• IAS presented at Risk Management Committee regular or ad hoc meeting
• Decision made, documented and communicated
• Issue lead is expected to report back regularly to the RMC on the implementation of strategy and outcomes
Health Canada’s Risk Management Committee

• Mandate to provides oversight for identification, analysis and decision making around health risk issues falling within the BGTD mandate
• Chaired by BGTD’s Director General, all BGTD directors are members + representatives from:
  • HPFB Inspectorate
  • Marketed Health Product Directorate
  • PHAC
  • Medical Devices Bureau
  • Legal
  • Communications
Post marketing surveillance

• Surveillance is meant to generate signals
  • It is a starting point; not a stopping point
  • Subsequent investigation may often be required

• Investigation
  • Begin with better understanding of reported cases
  • More extensive understanding:
    • Identify risk factors
    • Identify mechanism (Clinical studies)
    • Management / Reimmunization?
# Players involved in AEFI surveillance

<table>
<thead>
<tr>
<th>Immunization provider</th>
<th>Public health units</th>
<th>Public Health Ontario / MOHLTC</th>
<th>Public Health Agency of Canada</th>
<th>WHO/ Uppsala Monitoring Centre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inform and counsel re: risks/benefits</td>
<td>Case assessment &amp; management</td>
<td>Provincial surveillance &amp; legislation</td>
<td>National AEFI database</td>
<td>Global AEFI database</td>
</tr>
<tr>
<td>Recognize and report AEFIs</td>
<td>Reporting of AEFIs (iPHIS)</td>
<td>Case / cluster management advice</td>
<td>Signal detection</td>
<td>Signal detection</td>
</tr>
<tr>
<td>Manage AEFIs</td>
<td>Advice re: future immunization</td>
<td>Public health action</td>
<td>Causality assessment</td>
<td>Expert advisory Group</td>
</tr>
</tbody>
</table>

© iStock Photo (Microsoft Images), 2012. Reproduced with permission.
AEFI Reporting Process Flow in Ontario

**Reporting sources**
- Vaccinees / parents
- Physicians
- Nurses
- Pharmacists
- IMPACT

**Health units**
- Case assessment & management
- Reporting of AEFIs (iPHIS)
- Advice re: future immunization

**Public Health Ontario**
- Provincial surveillance
- Case management advice

**MOHLTC**
- Provincial legislation
- Standards and protocols
- Vaccine supply

**Vaccine manufacturers**

**Health Canada**
- Canada Vigilance Adverse Reaction Database

**Public Health Agency of Canada (PHAC)**
- Canada Adverse Event Following Immunization Surveillance System (CAEFISS)
- National standards & collaboration
- Causality assessment

**WHO**
- Global AEFI surveillance
- Global standards & collaboration
Assessment of AEFI surveillance: Key observations

Challenges

• Inconsistency across key AEFI surveillance documents (e.g. Appendix B, iPHIS User Guide, AEFI reporting form)

• Data quality issues

• Limited configuration possible in iPHIS

• Limited analysis and reporting of AEFI data
Assessment of AEFI surveillance: Key observations

Opportunities

• Committed network of staff across HUs
• Established collaboration with other P/Ts, PHAC
• Broad support for system improvements
• Timely opportunity to implement changes due to planned ID protocol revisions
Provincial AEFI Surveillance Enhancements (2012-2013)

- Ontario AEFI Reporting Form *(New)*
- AEFI Appendix B *(Revised)*
- Vaccine Safety Surveillance Working Group (VSSWG) Education and training
- Periodic data quality reviews
- Enhanced signal detection
- Annual Provincial AEFI Surveillance Report
- iPHIS application *(Updated)*
- iPHIS User Guide *(Revised)*
AEFI reporting in Ontario: Guiding documents

• Health Protection and Promotion Act
• Ontario Public Health Standards
  • outlines responsibility of health units in promoting reporting, investigating and documenting AEFI
• Infectious Disease Protocol, Appendix B
• iPHIS AEFI User Guide

Health Protection and Promotion Act, Reg. 38

- Mandates duty to inform and the duty to report

- Duty to inform: responsibility of providers to inform vaccine recipients (or their parents) of importance of reporting an adverse event

- Duty to report: responsibility of physicians, pharmacists and nurses to report adverse events to public health within 7 days

- Also outlines immunizing agents and types of events which are reportable
Revised AEFI Appendix B

- Implemented January 2013
- Complete re-write of 2009 AEFI Appendix B
- Review of evidence and environmental scan of AEFI guidance documents from other jurisdictions
- Input from stakeholders sought via Vaccine Safety Surveillance Working Group (VSSWG)

Key components include:
- Definition of a confirmed case /event
- New / revised definitions of specific AEFI
- Temporal criteria for specific AEFI
- Additional supporting information for each specific AEFI
Case classification

Confirmed case
- Any reported event listed in sections 5.0 in a vaccine recipient which follows immunization which cannot be clearly attributed to other causes. A causal relationship with the administration of the vaccine does not need to be proven.

Does not meet
- Any reported event in a vaccine recipient which follows immunization which has been clearly attributed to other causes.

- Classification is for surveillance purposes only
- Classifying a case as confirmed does not imply the vaccine caused the event nor is it a diagnosis of causation
- Most reported AEFI will meet definition of confirmed unless a clear alternative cause is established
  - eg. Report of GBS with laboratory-confirmed campylobacter
AEFI Appendix B revisions: Highlights

• Local injection site reactions \textit{lasting longer than 4 days} or extending \textit{beyond the nearest joint}

• Fever of $\geq 38^\circ C$ \textit{in conjunction} with another reportable event

• Severe vomiting / diarrhea \hspace{1cm} \textit{New}

• Allergic reactions, Event \textit{managed as anaphylaxis}

• Anaesthesia / paraesthesia \hspace{1cm} \textit{New}

• Syncope \textit{with injury} \hspace{1cm} \textit{New}

• Other severe / unusual events
An Example: AEFI Appendix B - Definition of specific AEFI: Nodule

2009

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.

2013

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 (8) and is:

- ≥ 2.5 cm in diameter; and
- Persists for more than one month.

**Temporal criteria:**
A nodule is generally seen within 7 days of vaccine receipt

**Discussion:**
Nodules are mainly associated with aluminum-adsorbed vaccines, particularly if the dose is deposited subcutaneously rather than intramuscularly. Sterile nodules can take up to 1 year or more to resolve, but most commonly resolve within 2 to 3 months.

Nodules are not a contraindication to further doses of vaccine.
Ontario AEFI Reporting Form

- Ontario-specific form based on
  - Input from individual HUs & consultation with VSSWG
  - Environmental scan of AEFI reporting forms used in other Canadian jurisdictions
  - Identification of specific data quality issues occurring as a result of misalignment between PHAC AEFI reporting form and iPHIS

- Format adapted from BC-CDC AEFI reporting form
- Most fields map directly to iPHIS data entry fields
- Aligned with PHAC AEFI reporting form where possible (where iPHIS data entry fields exist)
Ontario AEFI Reporting Form (cont.)

• Can be completed in electronic (but not saved) or hard copy format

• Q & A document accompanies the form to address questions about reporting of AEFI to public health and completion of the form

• Form is intended for use by
  • Health care providers reporting an AEFI to the HU (either spontaneously or upon request by the HU e.g. following a telephone report)
  • HU staff to assist with collection of case details required for provincial reporting via iPHIS

• Use of the form is recommended but not required
Implications for Local Public Health

• Improved support for AEFI investigation and reporting
  • Clear reporting and documentation criteria
  • Evidence-based guidelines
  • AEFI reporting form aligned with provincial AEFI reporting process

• Reduced reporting of mild injection site reactions

• Reduction in requests from PHO to amend AEFI reports in iPHIS

• Improved AEFI data quality
  • Enhanced ability to detect and investigate vaccine safety signals
  • More robust and timely AEFI reports to inform immunization program decision-making and vaccine safety communication strategies
Additional implications

- Improved quality, validity and timeliness of provincial AEFI surveillance data
- Better alignment with national vaccine safety reporting
- Greater ability to report on the safety of publicly-funded vaccines
- Contribute towards maintaining public confidence in vaccines
Vaccine Safety Surveillance Working Groups

• Jill Fediurek* (Chair)
• Tara Harris
• Dr. Shelley Deeks
• Dawn Williams
• Marlon Drayton
• Tsui Scott
• Ruth Gratton
• Joanne Orr
• Christina Taylor
• Lois Lacroix
• Katie Souliere

• Joanne Vieira
• Mary Ann Holmes
• Karen Dowsett
• Susan O’Gorman
• Julie Lafleche
• Dr. Vinita Dubey
• Dr. Ian Gemmill
Acknowledgements

• Tara Harris, PHO
• Jill Fediurek, PHO
• Patrick Zuber, WHO
• Natasha Crowcroft, PHO
• Barbara Law, PHAC
Challenging AEFI Issues?
Vaccine Safety Resources

General vaccine safety resources

- Definitions and Applications of Terms for Vaccine Pharmacovigilance (WHO / CIOMS)

- Adverse Effects of Vaccines: Evidence and Causality (IOM)
  [Link](http://www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx)

- Brighton Collaboration
  [Link](https://brightoncollaboration.org/public.html)
Vaccine Safety Resources

International
- Global Advisory Committee on Vaccine Safety (GACVS)
  http://www.who.int/vaccine_safety/committee/en/
- WHO vaccine reaction rates information sheets
- WHO Vaccine Safety e-Training Course
  https://extranet.who.int/vaccsafety/

National
- Health Canada Drug Product Database (vaccine product monographs)
  http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp
- NACI statements
- Evergreen CIG
Vaccine Safety Resources

Ontario-specific AEFI surveillance resources

- AEFI Appendix B (Infectious Diseases Protocol, 2013)

- Ontario AEFI Reporting Form
  [Link](http://www.oahpp.ca/resources/documents/2013Jan2_ON%20AEFI%20Form_final%20draft.pdf)

- AEFI Reporting Questions and Answers for Healthcare Providers
  [Link](http://www.oahpp.ca/resources/documents/2012Dec21_AEFI%20Form%20QsAs_final%20draft.pdf)
Vaccine Safety Surveillance Workshop
January 21, 2013

Agenda item #9

Overview of changes to iPHIS and AEFI

iPHIS User Guide
Provincial AEFI Surveillance Changes (2012-2013)

- Ontario AEFI Reporting Form *(New)*
- AEFI Appendix B *(Revised)*
- Vaccine Safety Surveillance Working Group (VSSWG)
  - Education and training
- iPHIS application *(Updated)*
- iPHIS User Guide *(Revised)*
- Periodic data quality reviews
- Enhanced signal detection
- Annual Provincial AEFI Surveillance Report
Provincial AEFI Surveillance Outcomes (2012-2013)

- Greater alignment with National Vaccine Safety reporting
- Improved quality, validity and timeliness of provincial AEFI surveillance data
- Greater ability to detect and investigate vaccine safety signals
- Ability to report on the safety of publicly-funded vaccines
- Contribute towards maintaining public confidence in vaccines
Components of an AEFI report

Case Details
- Reported Date
- Health Unit Responsible
- Assigned date
- Branch Office
- Disease
- Aetiologic Agent
- Classification
- Classification Date
- Outbreak Case Classification
- Outbreak Classification Date
- Disease
- Aetiologic Agent
- Classification
- Classification Date
- Outbreak Case Classification
- Outbreak Classification Date
- Disposition
- Disposition Date
- Status
- Status Date
- Priority

Reporting Information
- Other reporting source type
- Other reporting source name
- Diagnosing HU

Assignment History
- Investigator

Immunizations
- Administration Date/Time
- HU Branch
- Provider/Personnel
- Agent
- Lot Number (Expiry Date)
- Site
- Route
- Dose #
- Dosage / unit
- Informed Consent
- Comments

Risks
- Chronic illness / underlying medical condition
- Immunocompromised
- Immunocompromised (notes)
- Immunization program error
- Immunization program error (notes)

Outcome (if fatal)
- Outcome
- Outcome Date
- Accurate
- Cause of Death
- Type of Death
- Source

Adverse Event Reaction
- Onset Date/Time
- Interval to onset Days
- Interval to onset Hours
- Interval to onset Minutes
- Treatment received
- Treatment type
- Duration Days
- Duration Hours
- Duration Minutes

Adverse Event Agent

Case Notes
- Note Date and Time
- Note
- Provider
- Closing a Case
- Classification
- Classification Date
- Outbreak Case Classification
- Outbreak Classification Date
- Disposition
- Disposition Date
- Status
- Status Date

Adverse Event Recommendation
- Recommendations
- MOH/Physician Name
- Comments

Adverse Event List Details
- Branch
- Reported Date
- FOI Discussed
- Administration Date/Time
- Medical Consultation Sought
- Consultation date
- Hospitalized
- Hospital name
- Seen in ER
- Date Seen in ER
- Admit Date
- Discharge Date
- Outcome Code

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AEFI data quality: 7 deadly sins

1. Immunization not linked the adverse event
2. Case classified as “DNM” or “PUI” when it should be “Confirmed”
3. Missing adverse event reaction / time to onset / duration
4. Missing case notes or notes completed in wrong field
5. Incomplete hospitalization dates
6. Classifying a reaction as “Other severe / unusual event” when it meets another specific AEFI case definition
7. Lot # missing or completed in wrong field
iPHIS application update

• “Adverse event reaction” drop-down list condensed from 69 to 31 values

• Mapped to 2013 Infectious Diseases Protocol AEFI Appendix B Case Definitions

Additional updates to be completed
• Update of agent list to correct Rota-4 (should be Rota-5)
• Revise list to include immunizing agents only (remove anti-virals, anti-venom, Tuberculin, etc.)
iPHIS User Guide Revisions

• Improved readability & navigation throughout document
  • Linked table of contents, screen shots moved to appendix, hyperlinks to key surveillance documents (Appendix B, AEFI Reporting Form)

• Explanation of how Appendix B and the AEFI Reporting Form relate to iPHIS data entry

• Revised list of **mandatory** and **required** fields

• Clarification of fields required for provincial surveillance

• Description of **every** field that is designated as **mandatory** or **required** including expectations / rationale for data entry and drop-down values (if applicable)
iPHIS User Guide Revisions (cont.)

• Clear explanation of how to classify cases that is consistent with guidance provided in Appendix B
• Reinforcement throughout the document about where to enter case notes
• AEFI Reporting Form mapped to iPHIS data entry fields

• Under review until April 1, 2013
• Comments / suggestions welcome: ivpd@oahpp.ca
Tour of AEFI iPHIS User Guide
Introduction to iPHIS data entry of case study

- Case study #1 - completed AEFI reporting form
- Follow along in iPHIS user guide
- Opportunity for in-depth questions / discussion during independent data entry and Q & A session