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Keeping it Safe.
2015 Annual Report on Vaccine Safety in Ontario

PHO Grand Rounds - Nov. 22, 2016
Presented by Tara Harris and Shelley Deeks
Immunization & Vaccine Preventable Diseases
Learning objectives

1. To summarize adverse events reported in Ontario following administration of vaccines in 2015.
2. To describe the importance of AEFI surveillance in Ontario.
3. To improve health professional communication about vaccine safety.
Background

• Annual assessment of all adverse events following immunization (AEFIs) reported in Ontario following vaccines administered in the previous year

• Objectives: contribute to provincial vaccine safety surveillance, provide information to stakeholders and support communication about vaccine safety

• 2012-14 reports
  • Two different versions: one for public health units (PHU-specific estimates), one public-facing (provincial-estimates only)
  • Dissemination via email (PHU version), PHO website (public-facing version)
  • Full-length technical report and one-page summary for healthcare providers (“Immunizer Overview”)

Annual Report on Vaccine Safety in Ontario
Annual Report on Vaccine Safety

One-page summary “Immunizer Overview”

Vaccine safety webpage
Evaluation of the Annual Report on Vaccine Safety

**Objective:** To assess whether the report helps public health professionals improve their knowledge and communication about vaccine safety

**Target audience:** Public health unit (PHU) stakeholders including MOH/AMOHs, VPD managers and program staff

**Methods:**
- Website and email metrics
- Online survey of PHU stakeholders
  - Survey questions on satisfaction and use of the (1) report; (2) Immunizer Overview; and (3) vaccine safety webpage
  - Recruitment via email using existing contact lists

Evaluation results: Online survey

- 31 participants, representing 58% (21/36) PHUs
- 97% had read the Annual Report; 65% read the Immunizer Overview, 66% accessed the webpage in the last year
- 100% agreed or strongly agreed on overall satisfaction with the report and overview; easy to find information and understand key messages
The email open rate for PHU recipients of the report was 45.2% (75/166)

Of those that opened the email, 66.7% (50/75) accessed the full report using the direct link provided

Vaccine safety webpage views have increased over time, peaks coincide with release of annual reports; the most frequently viewed product was the Ontario AEFI reporting form
**New for 2015 report**

Modifications based on stakeholder feedback

- Shorter report
  - detailed methods published separately (Technical Annex)
- One-page summary of key messages
- Expanded dissemination
- Interactive report under development

One version of report for all

- Provincial and PHU-specific estimates
- PHU preview prior to public release
Vaccine Safety

Public Health Ontario analyzes adverse events following immunization (AEFI) that are reported in Ontario to monitor the safety of administered vaccines and contribute to national and international vaccine safety surveillance systems. An AEFI is an unwanted or unexpected health effect that happens after someone receives a vaccine, which may or may not be caused by the vaccine.

In Ontario, health professionals are required to report adverse events following immunization (AEFIs) to their local public health unit. Public health units investigate adverse events and provide support to immunizers, individuals, and their families. If you have an AEFI, contact your health care provider.

For health professionals

How to report an AEFI:
1. Complete an AEFI reporting form
2. Send it to your local public health unit

New!
See our AEFI reporting fact sheet for more information.

Reports

2015
The Annual Report on Vaccine Safety in Ontario, 2015 is a comprehensive annual provincial assessment of vaccine safety, and includes a summary of adverse events following immunization (AEFI) reported in Ontario in 2015.

- Immunizer Overview
- Technical Annex
- PHO in Action: Highlighting the safety and effectiveness of vaccines

Surveillance forms
- AEFI reporting form | Large print version
- Anaphylaxis reporting form
- Intussusception investigation form | How to guide

Guidance documents
- For a copy of the IPHIS User Guide for AEFI, please contact lvpd@oahpp.ca.
- AEFI reporting factsheet for healthcare providers (new)
- Provincial Case Definitions for AEFIs

For public health units

Presentations

- PHO Rounds - Vaccine Safety: Strength in numbers (November 24, 2015)
- PHO Rounds - Vaccine Safety in 2013: It’s everyone’s business (November 25, 2014)
- PHO Rounds - Vaccine Safety: It’s everyone’s business! (November 19, 2013)
- PHO Rounds - Not a shot in the dark: Restoring confidence in vaccine safety (October 9, 2012)

www.publichealthonline.ca/vaccinesafety

Methods

• Data extracted from the integrated Public Health Information System (iPHIS) on May 1, 2016

• Active immunizing agents only; publicly funded and non-publicly funded vaccines

• Descriptive analysis limited to “confirmed” AEFIs

• Reporting rates calculated based on population estimates/projections for overall rates and doses distributed for vaccine-specific rates

• Serious AEFIs defined using standard WHO definition adapted for use in Ontario
• 678 AEFIs reported following vaccines administered in 2015; population-based reporting rate of 4.9 per 100,000
Age distribution

- Age range: one month to ninety-three years of age
- Proportion of reports evenly divided between children and adolescents and adults >18 years (49.5% vs. 50.5%, respectively)
- The highest age-specific reporting rates in the youngest age groups
Age and sex distribution

- Overall, 66.0% of AEFI reports were female
The majority of AEFIs are reported by physicians and other health care professionals (69.3%)
Reporting rates of all AEFIs by public health unit, 2015
Reporting rates of AEFIs among adolescents following school-based vaccines* by public health unit, 2015

*11-17 year olds following adolescent meningococcal, hepatitis B and HPV vaccines
## Reporting rates and number of AEFIs by vaccine, 2015

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Number of AEFI reports by vaccine</th>
<th>Vaccine-specific reporting rate</th>
<th>Number of serious reports</th>
<th>Vaccine-specific serious reporting rate</th>
<th>Doses distributed</th>
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</thead>
<tbody>
<tr>
<td><strong>Infant and childhood vaccines</strong></td>
<td></td>
<td></td>
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<tr>
<td>DTaP-IPV-Hib</td>
<td>50</td>
<td>8.7</td>
<td>5</td>
<td>0.9</td>
<td>572,930</td>
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<td>Pneu-C-13</td>
<td>58</td>
<td>12.4</td>
<td>7</td>
<td>1.5</td>
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<tr>
<td>Rot-1</td>
<td>17</td>
<td>6.4</td>
<td>5</td>
<td>1.9</td>
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<tr>
<td>Men-C-C</td>
<td>39</td>
<td>19.5</td>
<td>3</td>
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<td>MMR</td>
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<td>Var</td>
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<td>11.9</td>
<td>1</td>
<td>0.4</td>
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<td><strong>Adolescent vaccines</strong></td>
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<tr>
<td>Men-C-ACWY</td>
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<td>34.7</td>
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<td>19.8</td>
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<td>HPV4</td>
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<td>Tdap</td>
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<td>10.6</td>
<td>1</td>
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<td><strong>Routine adult vaccines</strong></td>
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<tr>
<td>Pneu-P-23</td>
<td>63</td>
<td>23.1</td>
<td>2</td>
<td>0.7</td>
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<td>Td</td>
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<td>0.0</td>
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<tr>
<td>Td-IPV</td>
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<td>5.1</td>
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<td>0.0</td>
<td>19,501</td>
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<td><strong>Universal Influenza Immunization Program (UIIP)</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inf</td>
<td>157</td>
<td>3.5</td>
<td>12</td>
<td>0.3</td>
<td>4,549,459</td>
</tr>
</tbody>
</table>
Number of serious and non-serious AEFI reports by adverse event category, 2015

- Pain/redness/swelling
- Cellulitis
- Nodule
- Infected abscess
- Sterile abscess
- Rash
- Fever ≥ 38 °C
- Severe vomiting/diarrhea
- Arthritis/arthralgia
- Syncope with injury
- Adenopathy/lymphadenopathy
- Intussusception
- Hypotonic-hyposensitive episode
- Persistent crying/screaming
- Parotitis
- Thrombocytopenia
- Allergic reaction - skin
- Event Managed as Anaphylaxis
- Oculo-respiratory Syndrome
- Anaesthesia/paraesthesia
- Convulsions/seizures
- Bell’s palsy
- Guillain-Barre Syndrome
- Meningitis
- Myelitis
- Encephalopathy/Encephalitis
- Other severe/unusual events

Number of reports
Specific adverse events

• Injection site reactions
  • The most frequently reported event (43.0% of all AEFIs)
  • Most frequently associated vaccines: Pneu-P-23, Var, Tdap

• Rash
  • Second most frequent reported event (24.7% of reports), nearly half of these were associated with live virus vaccines
  • 10 confirmed vaccine-strain virus by genotyping (9 measles, 1 varicella)

• Anaphylaxis
  • 15 reports; 1.6 per million doses distributed
  • 9 (60%) met Brighton definition (four level I, five level II diagnostic certainty)
• 34 serious AEFIs (5.0% of reports); reporting rate of 2.5 per million population or 3.7 per million doses distributed

• 67.6% (n=23) < 18 years, with most < 4 years (n=16)

• All hospitalized, mean length of stay of 3.0 days; 11 documented as reported by IMPACT¹

• Most frequent types of events: febrile illness (n=10) including 4 with rash and 2 Kawasaki disease; GBS (n=4), ataxia (n=3), intussusception (n=3)

• There were 2 reports of death, both subject to additional investigation and assessment, and no link to vaccine was made

¹. Immunization Monitoring Program ACTive
Discussion: What does it all mean?

By the numbers: 2015

9 million

Approximate number of publicly funded vaccine doses distributed in Ontario

678 adverse events following immunizations reported

Most reported events were mild
- 231 sore arms
- 167 rashes
- 117 allergic skin reactions

Serious events after vaccines are very rare
- 34 serious events were reported, which represents:
  - 4 in every 1 million doses distributed
Under-reporting in Ontario

- Ontario low AEFI reporting rate (4.9 per 100 000)
  - Canada 10.1 per 100 000 (2012)
  - Australia 13.2 per 100 000 (2014)*

- PHU variability in reporting rates identified

- Primary Care Reporting
  - Reporting rate for public health administered programs is higher than primary care delivered programs

- PHU Reporting
  - Variation in program delivery, consent process, interpretation of requirements for AEFI reporting and provincial case definitions

Barriers and Facilitators to reporting

• Barriers to AEFI reporting:
  • Lack of awareness of reporting requirement
  • Confusion about what to report, how to report, who is responsible for reporting
  • Assumptions that equates to causal assessments
  • Time constraints / human resource requirements

• Facilitators to AEFI reporting
  • AEFI Fact Sheets for providers
    • Required to be shared during cold chain inspection since July 2016
  • Immunizer Overview to PHUs
  • Information on reporting included on consent forms and fact sheets
  • PHU in-service to providers including within their PHU
# AEFI Reporting Fact Sheet

## Adverse Event Following Immunization Reporting for Healthcare Providers in Ontario

### Do Your Part to Monitor Adverse Events!

1. Advise patients to contact you or your team if they experience an adverse event after vaccination.
2. Report adverse events to your local public health unit using Public Health Ontario's Report of Adverse Event Following Immunization Reporting Form.
3. Contact your local public health unit if you have any questions about AEFI reporting.

### Questions & Answers

- **What is an AEFI?**
  - An adverse event following immunization (AEFI) is an unwanted or unexpected health effect that happens after someone receives a vaccine which may or may not be caused by the vaccine.

- **Who should report an AEFI?**
  - Health care providers (i.e., physicians, nurses, and pharmacists) are required by law to report AEFI. Reports should be made using the Ontario AEFI Reporting Form and sent to the local public health unit. Vaccine recipients or their caregivers may also voluntarily report AEFI to public health.

- **What types of adverse events should be reported?**
  - You should report any event which may be related to receipt of a vaccine, as outlined on the next page. Of particular importance are events which require medical consultation, or unusual or unexpected events. Submitting a report does not mean that the vaccine caused the event.

- **What does NOT need to be reported?**
  - Some common or mild events do not need to be reported. These include:
    - fever that is not accompanied by any other symptoms
    - injection site reactions that last less than 4 days
    - vasovagal syncope (without injury)
    - events that are clearly attributed to other causes.

### Types of Adverse Events to Report

<table>
<thead>
<tr>
<th>AEFI Type</th>
<th>Temporal Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site reactions</td>
<td>0 to 48 hours</td>
</tr>
<tr>
<td>Pain, swelling, or redness lasting 4 days or more</td>
<td>0 to 48 hours</td>
</tr>
<tr>
<td>Infection</td>
<td>0 to 7 days</td>
</tr>
<tr>
<td>Sore throat</td>
<td>0 to 7 days</td>
</tr>
<tr>
<td>Nausea</td>
<td>0 to 7 days</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>0 to 7 days</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>0 to 7 days</td>
</tr>
</tbody>
</table>

### Systemic Reactions

- Rash
- Arthralgia/myalgia
- Severe vomiting/diarrhea
- Parotitis
- Hypertensive-hypotensive episode (H-H)
- Persistent crying/reclining, under 2 years of age
- 8 hours
- 3 days
- 3 days
- N/A
- 0 to 48 hours
- 72 hours

### Allergic Reactions

- Event managed as anaphylaxis (e.g., epinephrine administered)
- Gastroenteritis/Syndrome of Ors
- Allergic skin reaction (e.g., hives)

### Neurologic Events

- Convulsion/seizure
- Encephalopathy/post-vaccination
- Guillain-Barré Syndrome (GBS)
- Bell's palsy

### Other Events of Interest

- Arthritis/arthralgia
- Influenza infection
- Other serous/serosanguinous
- 30 minutes
- 30 minutes
- 30 minutes

For questions about AEFI reporting, contact your local public health unit. Public Health Ontario.ca/VaccineSafety
AEFI REPORTING IN 3 STEPS

1. Advise patients to contact you or your team if they experience an adverse event after vaccination.

2. Report adverse events to your local public health unit, using Public Health Ontario’s Report of Adverse Event Following Immunization Reporting Form.

3. Contact your local public health unit if you have any questions about AEFI reporting.

DO YOUR PART TO MONITOR ADVERSE EVENTS!
Factors influencing the risk of AEFIs*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Issue</th>
<th>Local AE</th>
<th>Systemic AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle length</td>
<td>Too short for IM</td>
<td>↑↑</td>
<td>↑</td>
</tr>
<tr>
<td>Depth of injection</td>
<td>Too superficial for IM</td>
<td>↑</td>
<td>(↑↑)</td>
</tr>
<tr>
<td>Admin route</td>
<td>ID compared to SC or IM</td>
<td>↑</td>
<td>(↑)</td>
</tr>
<tr>
<td></td>
<td>SC compared to IM</td>
<td>↑</td>
<td>(↑)</td>
</tr>
<tr>
<td>Adjuvants</td>
<td>Immunostimulant</td>
<td>↑↑</td>
<td>↑</td>
</tr>
<tr>
<td>Age</td>
<td>Increasing age</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Type of antigen</td>
<td>Increasing purity</td>
<td>↓</td>
<td>(↓↓)</td>
</tr>
<tr>
<td>Sex</td>
<td>Females vs males</td>
<td>↑</td>
<td>↑</td>
</tr>
<tr>
<td>Admin site</td>
<td>Improper landmarking</td>
<td>↑</td>
<td>↑</td>
</tr>
</tbody>
</table>

*Adapted from Herzog C. Influence of parenteral administration routes and additional factors on vaccine safety and immunogenicity: a review of recent literature. Expert review of vaccines 2014;13:399-415
Sex-specific differences in AEFI reporting

• Further analysis of 2012-15 Ontario data
  • Female predominance concentrated in adults (18-64 years of age) whereas no differences observed for children ≤10 years old
  • For routine vaccines, greatest sex differences were for Td, Tdap and influenza vaccines and by event-type within injection site reactions and allergic events
  • 81% of self-reported AEFIs were female
  • Serious events were more evenly distributed between females and males

• Female predominance in AEFI reporting consistently observed in passive vaccine safety surveillance systems and studies

• Both biological and behavioural factors may play a role
Sex-specific differences in AEFI reporting

• **Biological Factors**
  1-4
  • More fever, injection site pain and inflammation among females, across a range of vaccines and ages
  • Immunological, hormonal, genetic and microbiome differences may play role
  • Body mass, muscle volume/distribution, subcutaneous fat
  • Females tends to have higher immune and inflammatory responses

• **Behavioural Factors**
  1-4
  • Sex differences in vaccine uptake
  • Health seeking behavior differences
  • Females may be more likely to report an AEFI if one occurs

What is not a contraindication?

- Local reactions: Recurrence risk tends to be moderate and declines with the length of interval between doses. Patients should be aware of potential for recurrence.

- Sterile abscess: Can occur if vaccine given SC in error rather than IM. No deferral of subsequent vaccines is necessary. Use alternate site for the next dose and ensure proper technique.

- Arthralgia: Has been associated with rubella vaccine but also linked with others; females > males.
• Fever: Risk of recurrence varies in studies. Parents should be aware of potential for recurrence

• Hypotonic hyporesponsive episode (HHE): sudden onset of reduced muscle tone, hyporesponsiveness, and pallor or cyanosis. Usually benign and does not recur

• Persistent crying: Consider pain management prior to next immunization

• Seizures: Febrile seizure more common in children 12-23 months. Limited data about recurrence however no need to defer subsequent immunizations
Kawasaki Disease

- Two reports of Kawasaki disease (KD) in 2015 (3 in 2014)
- Self-limited febrile vasculitis which primarily affects young children (6 mo to 4 yrs) of unknown etiology
  - High-grade fever (often >5 days), bilateral conjunctivitis, rash, swelling of extremities, swollen cervical LNs, and inflammation of the lips and tongue; cardiac complications
- In US: estimates approx 20 cases/100,000 children <5 years hospitalized; higher among male and Asian/Pacific Islanders
- Abrams et al, followed 1.7 million children <7 years for 4.4 million person-years in US and found no causal link between KD and immunizations*

Intussusception

- 3 reports following RV vaccine; rate 1.1 per 100,000 doses distributed
- Usually occurs in infants between 5 and 10 months; more common in boys; incidence varies by geography
- Baseline intussusception hospitalization rate in Canada estimated to be 20-30 /100,000 infants <1yr\(^1\)
- Epidemiologic studies using different methods from different countries estimate risk of between 1 and 7 excess cases /100,000 doses in 7 days following the first and second dose of RV vaccine
- Advisory committees throughout world (NACI, ACIP, GACVS) continue to emphasize that benefits outweighs risk
- Parents should be informed of the low risk of intussusception following RV vaccine, as well as the signs and symptoms of intussusception and the importance of seeking medical care should symptoms develop

Limitations of passive surveillance

- Data quality and completeness
- Reporting bias
- Lack of a population-based provincial immunization registry to estimate the number of individuals immunized/doses administered
- Changes in surveillance definitions over time
- Limited analysis of trends
Conclusions

• Overall low rate of AEFI reporting in Ontario continues
• Most reported events were mild and individuals recovered completely
• No unexpected signals were identified and serious events were very rare
• Continued surveillance of AEFDs in Ontario is needed to monitor vaccine safety and to further understand geographic variations and under-reporting within the surveillance system
Next steps

• Further collaboration with PHUs and MOHLTC to develop strategies to address underreporting of AEFIs

• Development of an online, interactive report vaccine safety report
  • Increase accessibility and transparency of AEFI surveillance data
  • Enable greater visual representation of data and in-depth exploration to meet specific stakeholder needs

• Engage system stakeholders and encourage continued AEFI reporting
Acknowledgements

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www.publichealthonotario.ca/vaccinesafety