Vaccine Safety: Overview of Session & Passive Surveillance

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Faculty/Presenter Disclosure

Relationships with financial sponsors:
- Any direct financial relationships including receipt of honoraria: None
- Memberships on advisory boards or speakers’ bureau: None
- Patents for drugs or devices: None
- Other: financial relationships/investments: None

Disclosure of financial support:
- Monika Naus is a grant tenure UBC faculty member whose position is entirely funded by BCCDC/ Provincial Health Services Authority
- This presentation has not received financial support from any other organization
Mitigating Potential Bias

- I have disclosed my professional training and background as a public health physician. As such, my perspective is strongly focused on primary prevention.
- Perspectives of public health take into account health of populations. Because vaccines are administered at an individual level, both individual and population considerations are taken into account in planning and assessment of immunization programs.
Evolution of immunization program and concern about vaccine safety
Sources of information about vaccine safety
### Limitations of passive or active AEFI surveillance

<table>
<thead>
<tr>
<th>Immunized</th>
<th>Adverse event</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>a</td>
<td>b</td>
</tr>
<tr>
<td>No</td>
<td>c</td>
<td>d</td>
</tr>
</tbody>
</table>

**Value of background rates**

**Large linked data bases can be useful**

**Analytic studies are needed to verify association**
AEFI reporting process in BC

- Canadian AEFI Surveillance System
- BC Centre for Disease Control
- Medical Health Officer
- Health care professional
- AEFI case

Reporting under regulatory framework since 2019

Entered into PIR

Electronic extract
In October 2009, we removed: Redness/Swelling/Pain lasting 4-9 days (B01) and redness/swelling 5cm (2”) or more in diameter (B03)
**Report of Adverse Event Following Immunization**

**Dear Doctor / Pharmacist / Health Care Provider:**

Complete this report if a person who has received immunization and experienced an event that required medical attention, was unvaccinated, was uninsured, had an adverse event associated with the vaccine.

**ADVERSE EVENT**

<table>
<thead>
<tr>
<th>Time to Onset in Minutes</th>
<th>Duration in Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>60</td>
</tr>
</tbody>
</table>

**PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Date of Birth</th>
<th>Gender</th>
<th>Race</th>
<th>Age</th>
<th>Dose</th>
<th>Health Care Card Number</th>
<th>Add. Address</th>
<th>Phone Number</th>
<th>Relationship to Patient</th>
<th>Date of Birth</th>
<th>Immunization</th>
<th>Immunization Site</th>
<th>Time to Onset</th>
<th>Time to Onset</th>
<th>Duration in Minutes</th>
<th>Immunization Site Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith</td>
<td>John</td>
<td>1990-01-01</td>
<td>Male</td>
<td>Caucasian</td>
<td>30</td>
<td>1</td>
<td>1234567890</td>
<td>123 Main St</td>
<td>555-123456</td>
<td>Father</td>
<td>1990-01-01</td>
<td>1</td>
<td>Smith Health Centre</td>
<td>30</td>
<td>60</td>
<td>1234567890</td>
<td>Smith Health Centre</td>
</tr>
</tbody>
</table>

**MEDICAL HISTORY**

- Current medications (Yes/No)
- Eye problems (Yes/No)
- Headache (Yes/No)
- History of cancer (Yes/No)
- Asthma (Yes/No)
- Allergies (Yes/No)
- History of diabetes (Yes/No)

**VACCINATION DATA**

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Date of Administration</th>
<th>Date of Next Dose</th>
<th>Route of Administration</th>
<th>Site of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19</td>
<td>2021-03-15</td>
<td>2021-06-15</td>
<td>Intramuscular</td>
<td>Smith Health Centre</td>
</tr>
</tbody>
</table>

**IMPACT OF AE:**

- Select impact of AE:
  - Limited daily activities
  - Participated in activities (Yes/No)
  - Hospitalized
  - Death (Yes/No)

**ADVERSE EVENT**

- Local reactions at injection site:
  - Pain
  - Redness
  - Swelling

- Systemic reactions:
  - Headache
  - Fever
  - Fatigue

**COMMENTS**

- Additional comments:
  - Patient was discharged from hospital on 2021-03-19.

**REPORTER INFORMATION**

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Relationship to Patient</th>
<th>Date of Birth</th>
<th>Phone Number</th>
<th>Immunization Site</th>
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**BC Centre for Disease Control**

*July 28, 2021*

Page 1 of 2
Percent of Vaccinated Children Reporting Specific Events Following Infant/Toddler Immunizations, BC
Alerting on potential signals

Ed Napke’s ‘pigeon-hole’ system for AR reports
Blue/Red: serious
Green: unexpected
Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jan. 28, 2023 (N=6,131)

http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccine-safety
WHO Causality Assessment Algorithm:

I. Is there strong evidence for other causes?
   - Yes
   - No

IA. Inconsistent causal association to immunization

II. Is there a known causal association with the vaccine/vaccination?
   - Yes
   - No

IIA. Consistent causal association to immunization

II (Time). Was the event within the time window of increased risk?
   - Yes
   - No

III. Is there a strong evidence against a causal association?
   - Yes
   - No

IIIA. Inconsistent causal association to immunization

IV. Review other qualifying factors
   - Yes
   - No

IVA. Consistent causal association to immunization

IVB. Indeterminate

IVC. Inconsistent causal association to immunization

IVD. Unclassifiable

Is the event classifiable?

Mandatory path
Nevertheless, passive surveillance identified:

- Narcolepsy in association with the 2009 H1N1 pandemic vaccine
- Thrombosis and thrombocytopenia syndrome with adenovirus vector COVID-19 vaccine
- Myocarditis with mRNA COVID-19 vaccines
- …and other events
- Best at identification of unusual / unexpected events as a ‘potential signal’ for verification using additional types of investigations
Vaccine safety is a shared responsibility internationally

Global Advisory Committee on Vaccine Safety
www.who.int/vaccine_safety/en/

USA:
IOM: Institute of Medicine
VAERS
Vaccine Safety Datalink
Clinical Immunization Safety Assessment (CISA)

US/Europe:
Brighton Collaboration

‘Vigibase’
www.who-umc.org