



BC Centre for Disease Control
Provincial Health Services Authority

BC Immunization Forum
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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

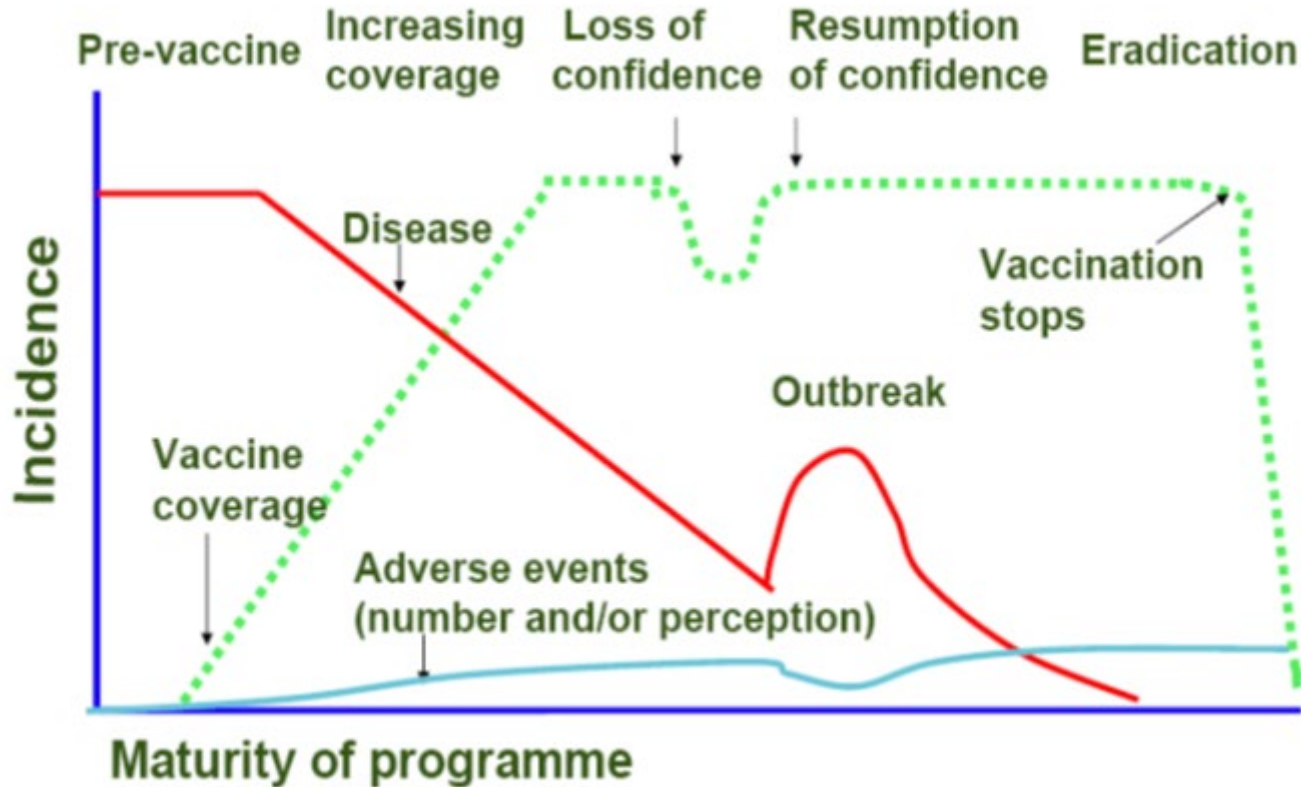
Disclosure of financial support:

- 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

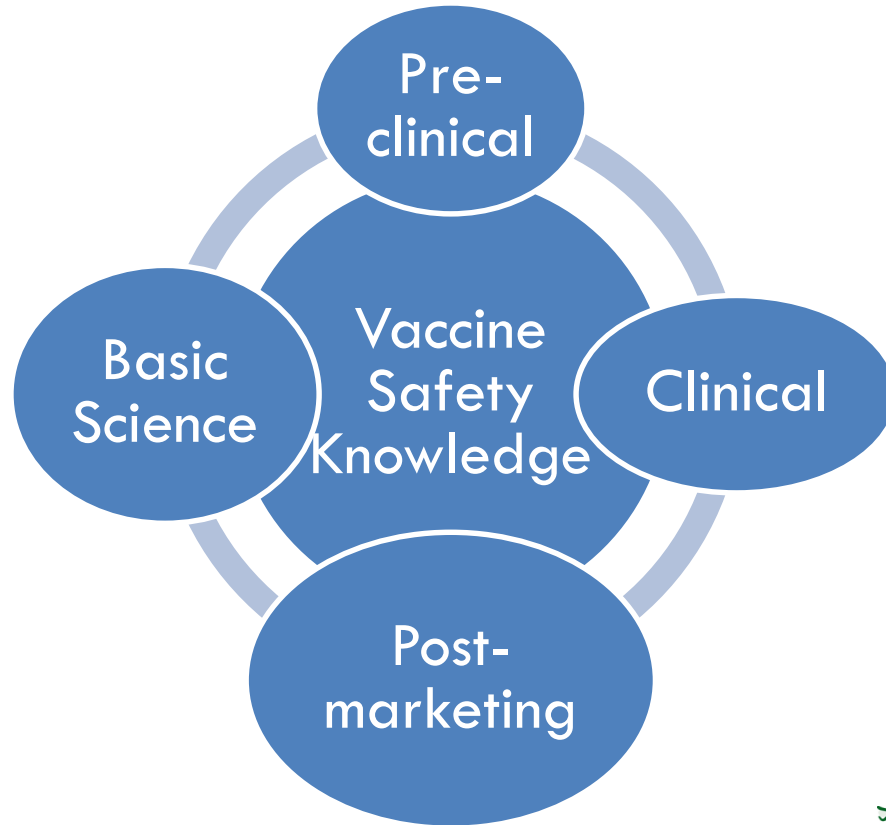
Mitigating Potential Bias

- 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

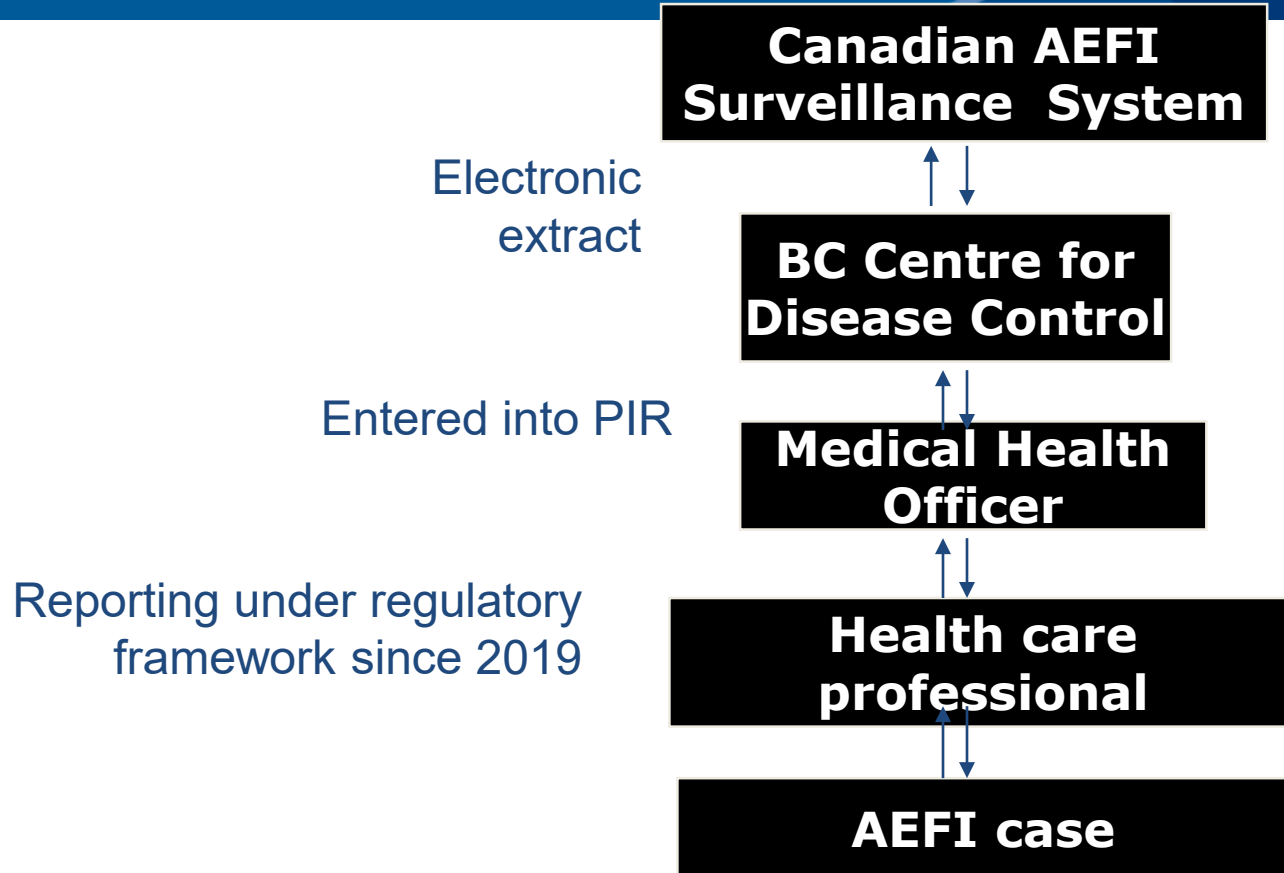
	Adverse event	
Immunized	Yes	No
Yes	a	b
No	c	d

Value of background rates

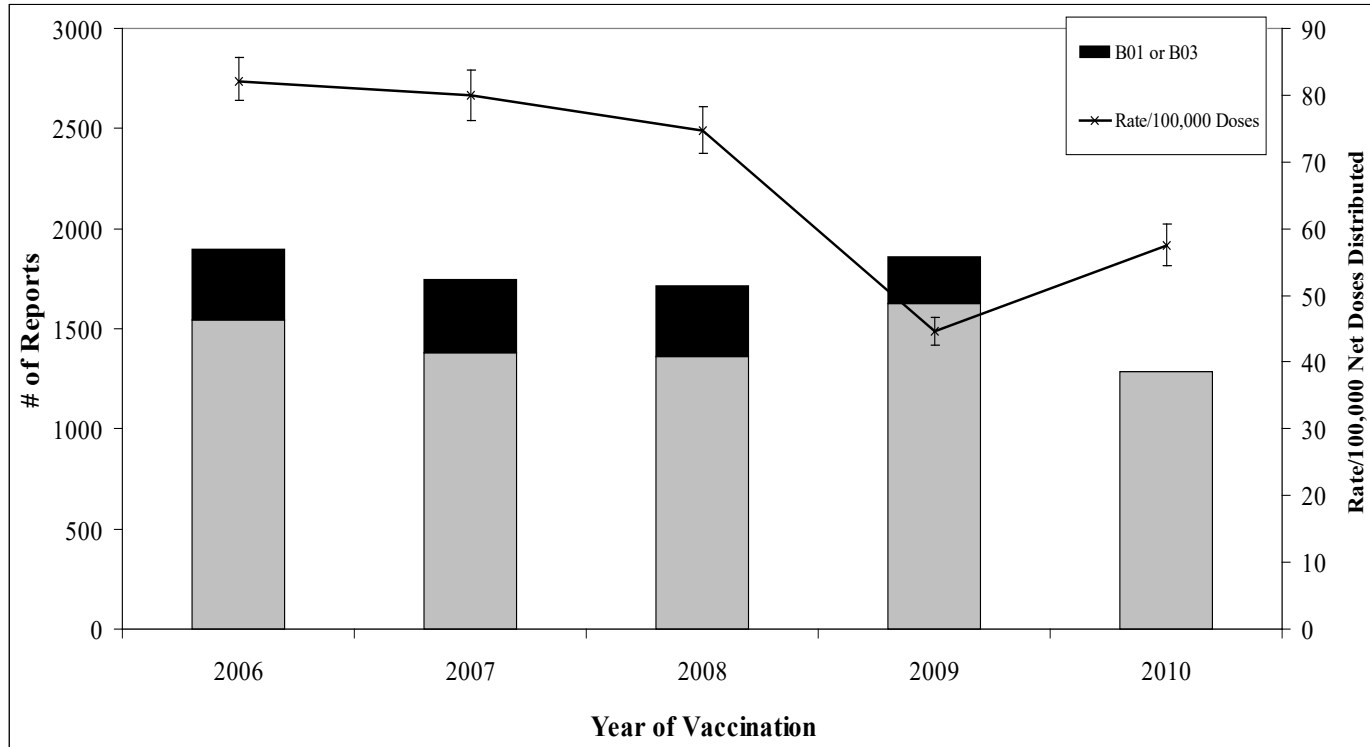
Large linked data bases can be useful

Analytic studies are needed to verify association

AEFI reporting process in BC



Removing 'noise' from AEFI reporting



In October 2009, we removed: Redness/Swelling/Pain lasting 4-9 days (B01) and redness/swelling 5cm (2") or more in diameter (B03)

Two page reporting form during COVID campaign



Report of Adverse Event Following Immunization

Dear Doctor / Pharmacist / Health Care Provider:

Complete this report on a person who has received immunization and experiences an event that required medical attention, was unvaccinated, unexpected, was serious (hospitalization, residual disability, life threatening, fatal outcome) and was suspected to be related to the vaccine. Unusual clusters or high frequency of events should also be reported to your medical health officer / local health unit (by phone / fax / email). For details, see CD Manual: Chapter 2: Immunization, Part 5: Adverse Events Following Immunization. Save and email or print and fax the completed report to your local or regional health unit as listed here: <https://bit.ly/3qbbn72>. Email completed form from a regional health authority account. Emailing from other accounts (e.g., yahoo, gmail, etc.) is not secure.

PATIENT INFORMATION

Last Name		First Name		Middle Name(s)	
Date of birth YYYY	MM	DD	Health Card Number (PHN)	Gender <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Undifferentiated <input type="checkbox"/> Unknown	
Phone No.	Alt. Phone Number		Email		
Address: Unit #	Street #	Street Name		City	
Postal Code	Province	County of Residence (if outside of Canada)			

MEDICAL HISTORY

Current medications if yes, specify:	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Known medical conditions if yes, specify:	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
Known allergies if yes, specify:	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

IMMUNIZATION DATA

Vaccine name	Date vaccine administered YYYY	MM	DD	Lot#	Dosage (mL)	Route	Site

IMPACT OF AEFI OUTCOME, AND LEVEL OF CARE OBTAINED

Highest impact of AEFI (Choose one of the following):

Did not interfere with daily activities Interfered but did not prevent daily activities Prevented daily activities

Outcome at time of report (Choose one of the following):

Permanent disability/incapacity Fully recovered Not yet recovered

Unknown Death, specify date: YYYY MM DD

Highest level of care obtained (Choose one of the following):

Emergency visit Non-urgent visit Telephone advice from a health professional None Unknown

Admitted to hospital (days) OR Resulted in prolongation of existing hospitalization (by days)

Hospital Name: _____ Hospital Admission Date: YYYY MM DD Hospital Discharge Date: YYYY MM DD

Treatment received:
 No Unknown Yes

Provide details of treatment, including self-treatment:



Report of Adverse Event Following Immunization

ADVERSE EVENT
Time to Onset must be recorded as number of minutes, hours or days / Duration of event must be recorded as number of minutes, hours, days or unresolved

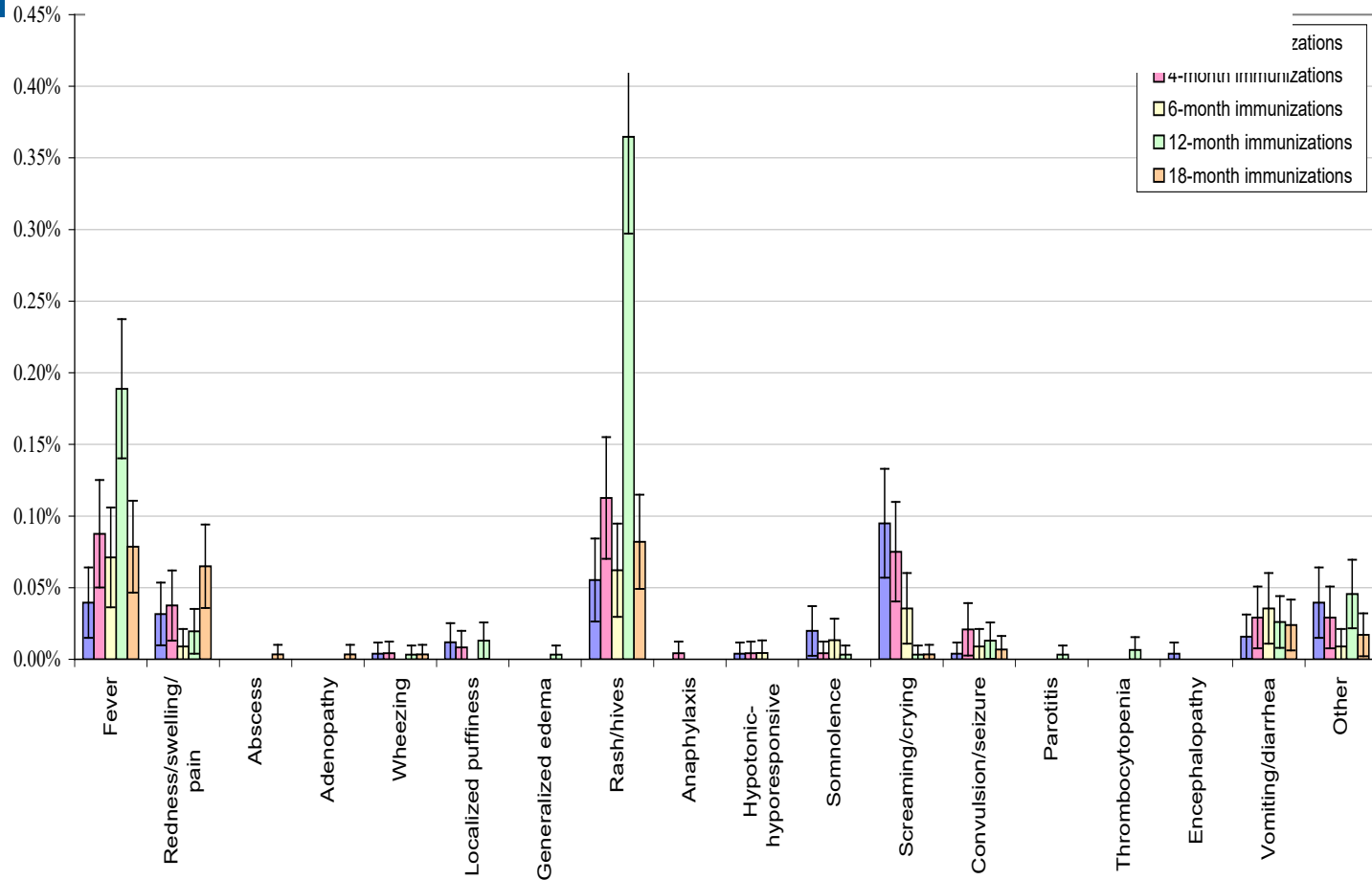
	Time to Onset in Number			Duration in number				Neurological events cont'd	Time to Onset in Number			Duration in Number			
	Minutes	Hours	Days	Minutes	Hours	Days	Unresolved		Minutes	Hours	Days	Minutes	Hours	Days	Unresolved
Local reactions at or near injection site								Myalgia / Pain Myelitis / Transverse Myelitis Other paralysis Other Neurological - specify: Other events of interest Ataxia Persistent Crying (>3 hours) Hypotonic-Hyporeactive Episode (>2 years old) Thrombocytopenia (pH<150x10 ⁹ /L) Syncope with injury Myocarditis/Pericarditis Rash (non-injection site) requiring MD Vomiting/diarrhea (>2 in 24 hours) Other serious or unusual - specify:							
Infected Abscess															
Sterile Abscess															
Celulitis															
Nodule															
Pain/redness/swelling past joint															
Pain/redness/swelling <10 days															
Adenopathy/Lymphadenitis															
Rash at Injection Site															
Allergic reactions															
Anaphylaxis															
Allergic reaction (non-anaphylaxis)															
Oculo-Respiratory Syndrome (ORS)															
Neurological events															
Seizures															
Anesthesia/Painesthesia															
Meningitis															
Encephalopathy/Encephalitis															
Gullain-Barre Syndrome															

COMMENTS FURTHER DESCRIBING ADVERSE EVENT(S)

REPORTER INFORMATION

Last Name	First Name	<input type="checkbox"/> MD <input type="checkbox"/> Pharmacist <input type="checkbox"/> RN <input type="checkbox"/> NP <input type="checkbox"/> Other
Phone No.	Ext.	Fax No.
Email		Date reported to public health: YYYY MM DD
Setting:	<input type="checkbox"/> Physician office <input type="checkbox"/> Hospital <input type="checkbox"/> Pharmacy <input type="checkbox"/> Health Authority Workplace Health	
	<input type="checkbox"/> Other, specify:	

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

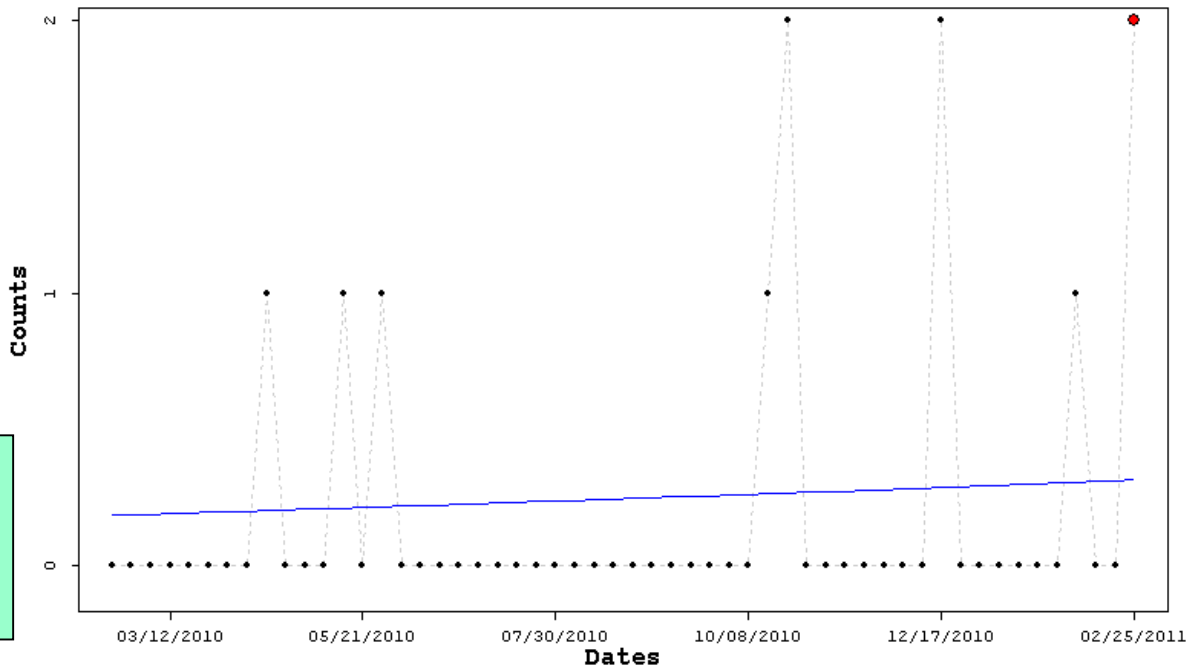
Faint
Warning

Sterile_Abscess

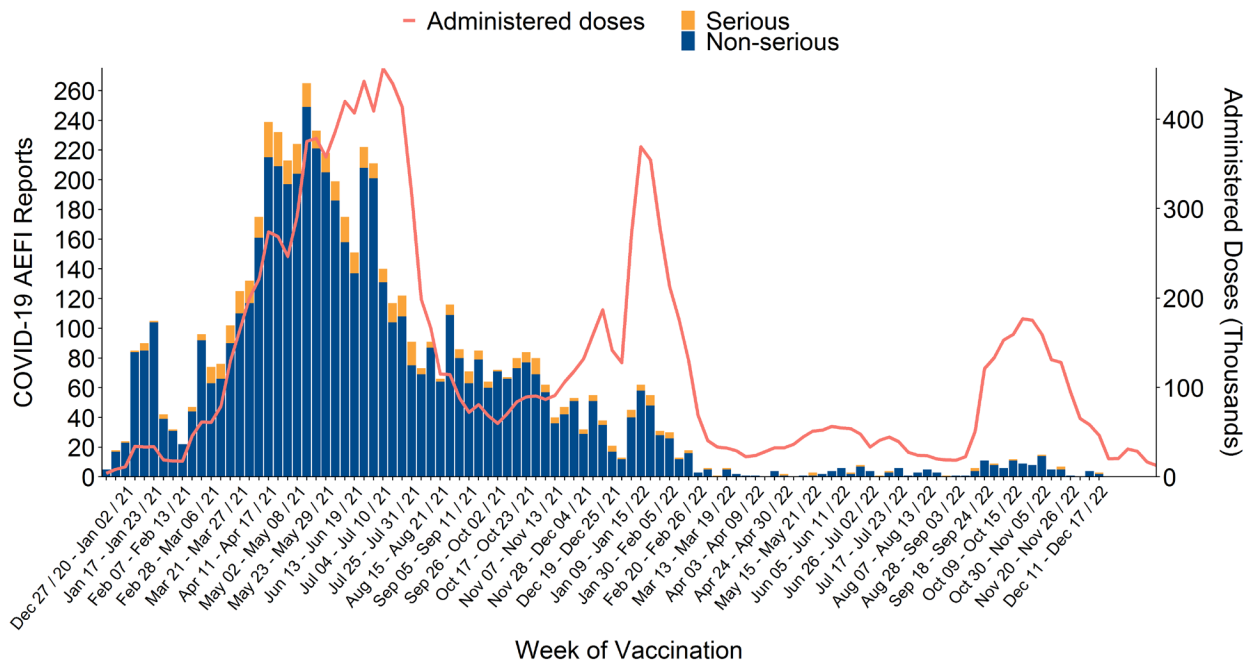
AEFI

Low Alert

Scale 1.07

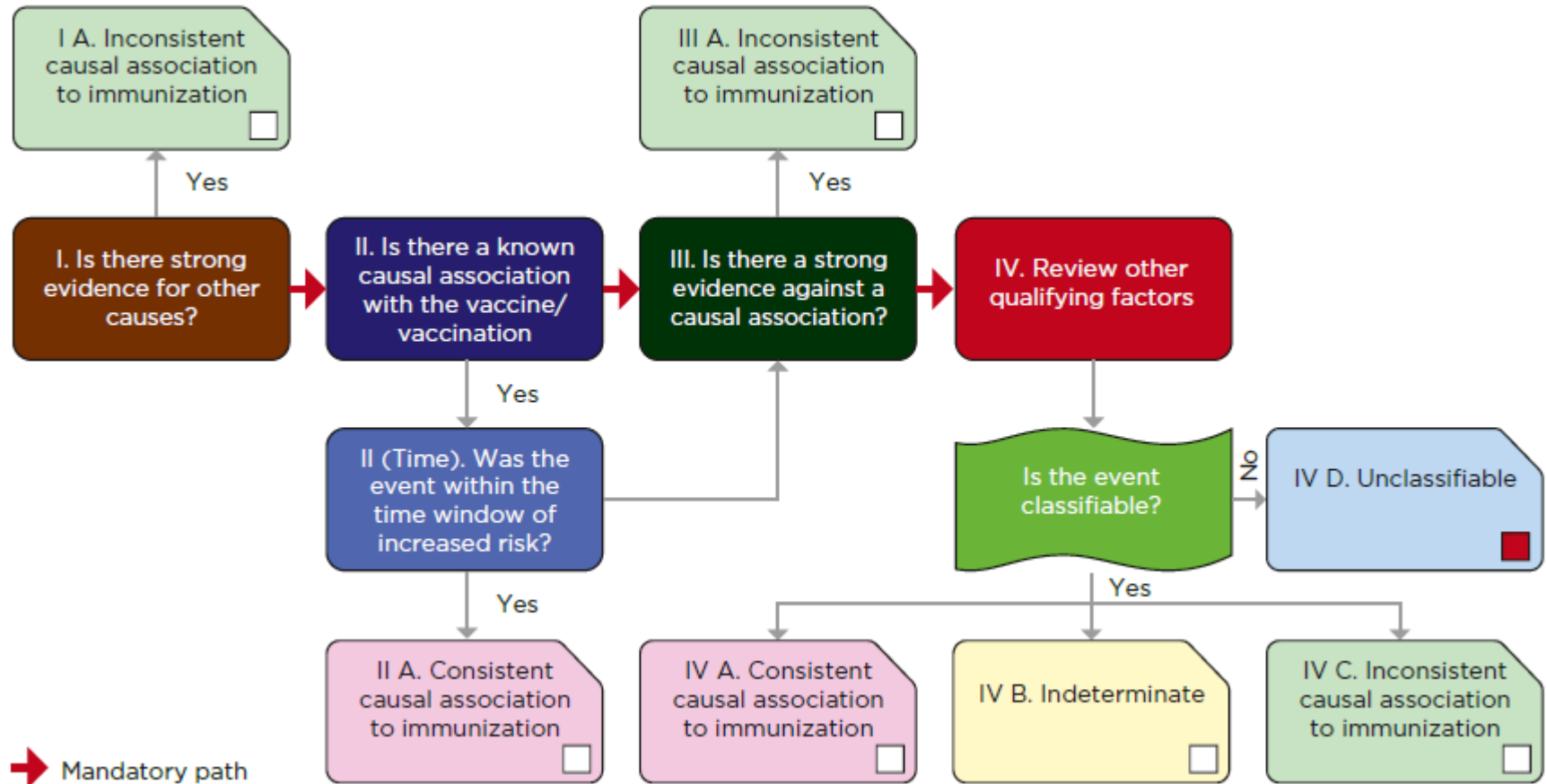


Adverse event reports following receipt of a COVID-19 vaccine by week of vaccination, BC, Dec. 13, 2020 - Jan. 28, 2023 (N=6,131)



<http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/vaccine-safety>

WHO Causality Assessment Algorithm:



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/



'Vigibase'
www.who-umc.org

USA:

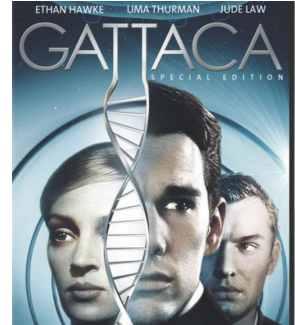
IOM: Institute of Medicine

VAERS

Vaccine Safety Datalink

Clinical Immunization Safety

Assessment (CISA)



US/Europe:

Brighton Collaboration



**Global Vaccine
Data Network®**