

CIC 2014 CCI

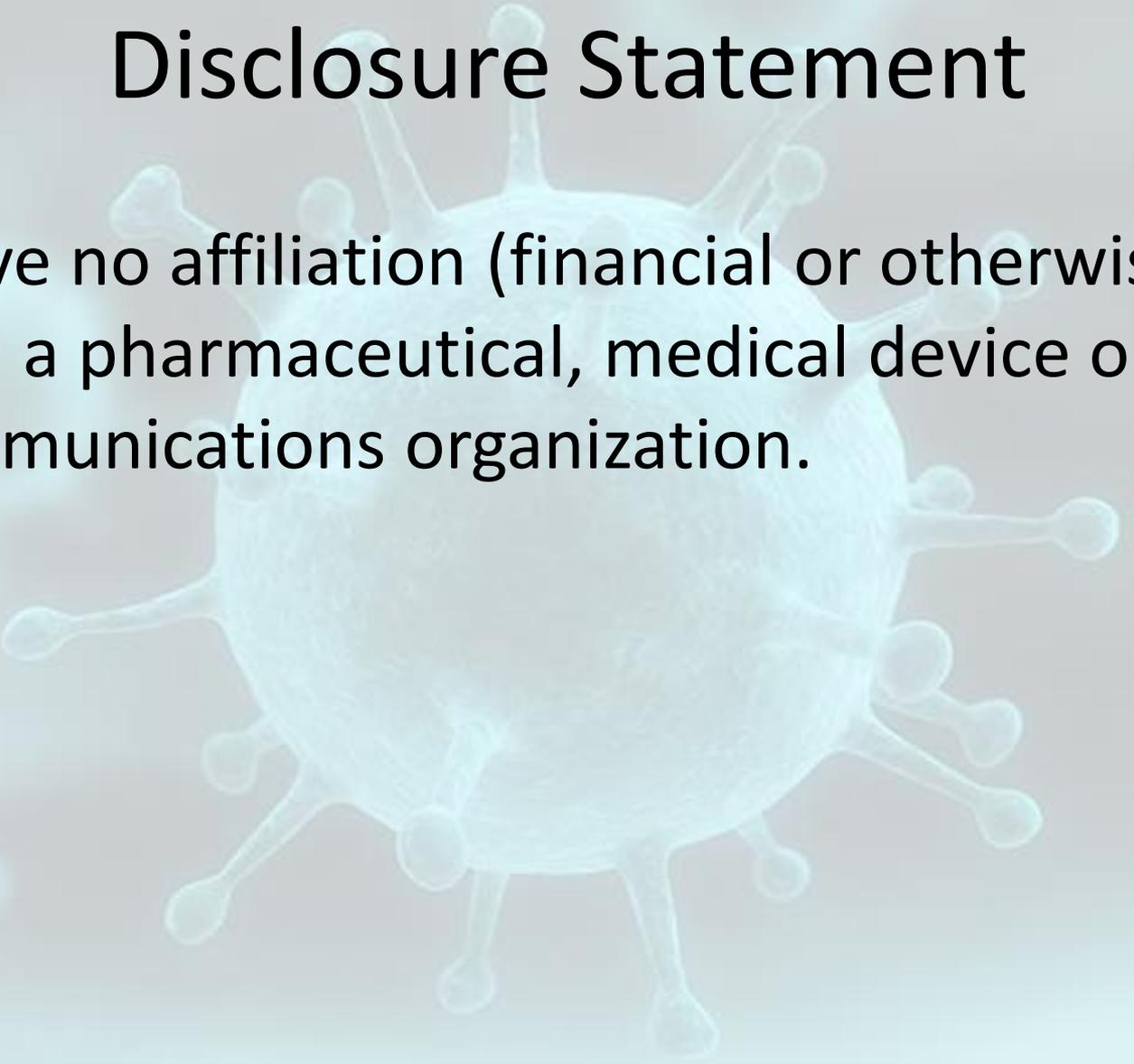
December 2-4
2 - 4 décembre
OTTAWA

**Canadian Immunization Conference
Conférence canadienne sur l'immunisation**

**Public Health Partnerships:
The Final Report on a Best Practice
Model for Vaccine Safety in British
Columbia**

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Disclosure Statement



- I have no affiliation (financial or otherwise) with a pharmaceutical, medical device or communications organization.

Vaccine Safety Pilot Project

- Post-pandemic evaluation of F/P/T AEFI surveillance response
- Pandemic challenges reflected inability to meet priorities elaborated for vaccine safety in NIS
- PHAC partnered with BC and Manitoba to develop a Best Practice Model for Vaccine Safety

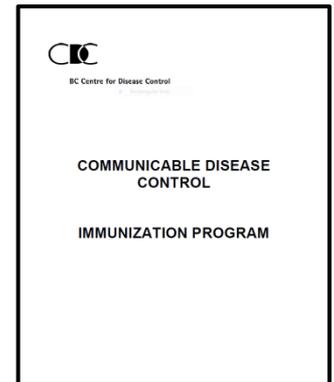


Receive Free Neurological Disorder with Your Swine Flu Vaccination

Two Project Phases

- **PHASE 1:** November 2011 – September 2012
 - BCCDC AEFI Annual Report
 - Anaphylaxis Worksheet
 - AEFI Alerts Protocol
 - Draft Protocol for Cluster Investigation
 - Section IX: AEFI in Immunization Program Manual

[Immunization Program Manual - Section IX - AEFI](#)



Two Project Phases

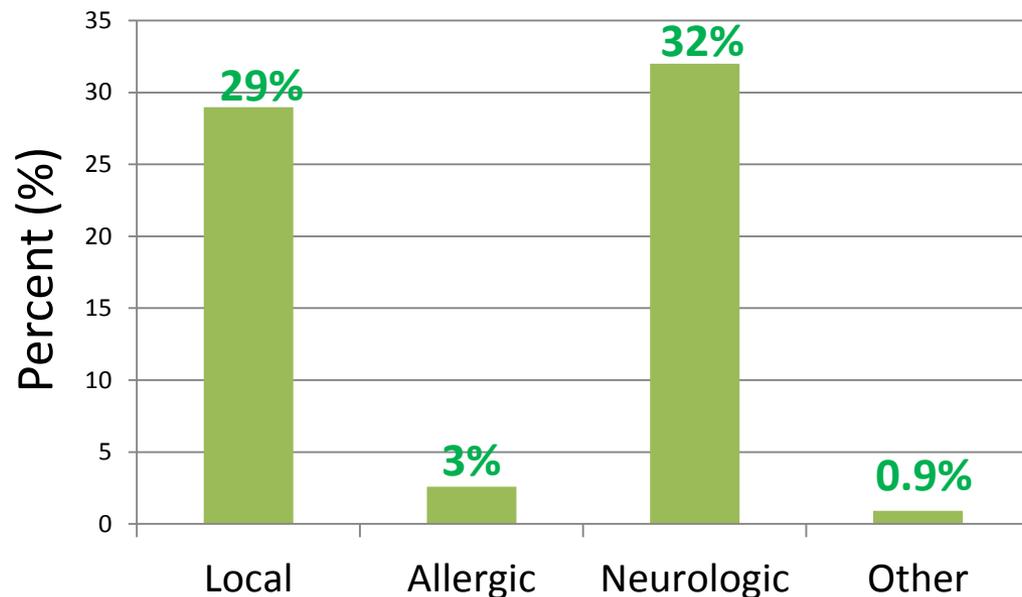
- **PHASE 2:** October 2012 – March 2014
 - Panorama training materials
 - Gap analysis: WHO causality assessment model
 - Causality assessment pilot project
 - Environmental scan of vaccine movement throughout BC
 - Signal Detection Evaluation
 - NIS 2002 Vaccine Safety Priority Review

Best Practice Model for Vaccine Safety in BC

Panorama Training Materials

1. Developed the Panorama AEFI Data Entry Guidelines
2. “AEFI Data Reporting Tips” 2-page briefing document developed

Percent of Records with Missing Event*



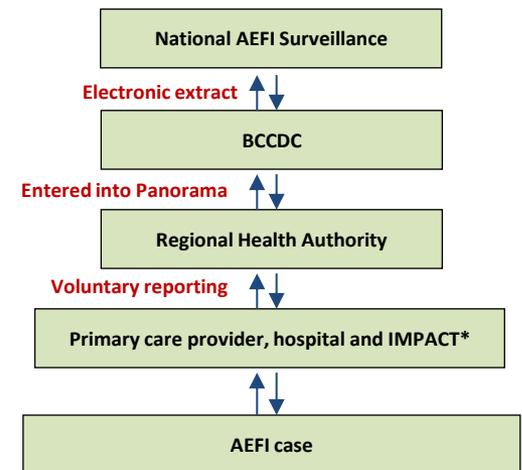
*If onset and duration were entered, but no specific adverse event was entered OR if details of event were selected without an event category selected.

AEFI Causality

- Comparison of ACCA, WHO and CISA models
 - Limitations in each model
 - WHO: focus on low income countries
 - CISA: assumes diagnostic certainty
 - ACCA: over-attribution based on temporal association
 - Analysis examined the resources required to operationalize such a model provincially
 - Informed the approach for development of provincial causality review
- BC Causality Pilot Project
 - Developed a provincial algorithm following review of the 3 key causality algorithms
 - Currently in pilot phase with intent of expansion to all Regional Health Authorities

BC Signal Detection Evaluation

- A review and evaluation of provincial AEFI reporting and surveillance practices
- SWOT analysis
- Evaluated current capacity against
 - 2002 NIS vaccine safety priorities
 - WHO core indicators
 - WHO immunization safety surveillance manual
 - Needs identified from Regional Health Authorities



BC Cluster Investigation Review

Year	Date	Alerting Mechanism	Time-to-Alert	Investigative Analysis	Results/Findings	Public Health Actions
		<i>How the alert was detected.</i>	<i>If available. For example: 4 hrs > 3 days</i>	<i>Who is involved? Type of analysis carried out?</i>	<i>General findings.</i>	<i>Dissemination of findings and to whom? CNPHI Posting? Lot recalls/lot discontinuation?</i>
2008	July 8	PHN contacted BCCDC to note that there were 2 “significant local reaction” AEFIs following immunization with same lot of Td.	n/a	Epidemiologist examined the reporting rate of local reaction AEFIs of the lot of interest compared against 3 other lots used previously in the province between 2007-2008. % doses with local reaction was calculated. Doses distributed was used as the denominator for these calculations .	The rate of local reactions following immunization with the lot of interest was lower compared to other lots recently distributed in the province.	An analysis report was sent via email to the Health Authority reporting the event by July 10 th , 2008. Recommendation was to continue immunization with the lot of interest.

NIS 2002 Vaccine Safety Priority Review

- A full-time vaccine safety epidemiologist at BCCDC
- Implementation of a comprehensive immunization registry
- Addition of AEFI as a notifiable event under the BC Public Health Act regulations
- Data linkage between adverse event data, immunization registry data and health care datasets such as medical records billings, hospital separations files and pharmacy billings data within BC
- Improvement of Panorama, including the adoption of data standards

BCCDC Sustainable Best Practice Logic Model for Vaccine Safety

Goal	To optimize post-marketing surveillance of AEFI to identify and respond to safety concerns in a timely manner						
Components	Immunization and Reporting Guidelines	Reporting	Alert and Investigation	Database and Analytical Capabilities	Research	Causality Assessment	Communication and Public Health Action
Activities	<ul style="list-style-type: none"> - Evidence-based and best practice Immunization and AEFI Reporting Guidelines which are regularly reviewed to ensure up-to-date. 	<ul style="list-style-type: none"> - BC AEFI Case Report Form - BC Anaphylaxis WS - Panorama AEFI DE Guidelines - Data clean-up reports 	<ul style="list-style-type: none"> - Weekly PHIDO alerts - Weekly SAEFI surveillance table - Weekly Influenza AEFI surveillance table - AEFI investigation analysis template -PHRDW development and maintenance 	<ul style="list-style-type: none"> -PHRDW development and maintenance 	<ul style="list-style-type: none"> - Literature review for data linkages, background rate calculations and attributable risk calculations (in process) 	<ul style="list-style-type: none"> - BC SAEFI Causality Pilot Project Guidelines - BC AEFI Causality Review Form - Stimulated quarterly list of SAEFIs for health region pilot sites to evaluate pilot 	<ul style="list-style-type: none"> - Respond to specific concerns at individual consultation level, to public health community and to community immunization service providers and the public - Use appropriate content or findings from any of these program components to communicate to appropriate stakeholders - Participation in VVWG

Opportunities for Program Enhancement

Reporting

- Surveillance for new vaccines
- Build enhancements into Panorama to improve data quality and meet Brighton case definitions

Alert and Investigation

- Background rates of selected conditions
- PHIDO AEFI Alert Evaluation

Research

- Data linkages to examine rare events, background rate calculations, attributable risk calculations

Communications and Public Health Actions

- BC Vaccine Safety Website



Questions?