

# PUBLIC HEALTH MANUAL Standard Operating Procedure

TITLE:	Recording and Managing Reports of Adverse Events Following Immunization (AEFI)	NUMBER: Revised-2018-02-07
Sponsor:	Senior Director; Population and Public Health	Page: 1 of 21
Approved by:		Approval Date:
		Effective Date:
Applies To:	All Staff working in Public Health, Public Health Managers, Public Health Directors, Medical Officers of Health for Nova Scotia	

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## PREAMBLE

Effective immunization programs are essential to the prevention and control of many infectious diseases (Public Health Agency of Canada, 2016) and immunization safety plays an integral role in the uptake and success of these programs. Surveillance of Adverse Events Following Immunization (AEFI) is in place to monitor risk, ensure safety and maintain public confidence. AEFIs are notifiable by law under the Nova Scotia <u>Health Protection Act (HPA)</u> [hyperlink] and must be reported to Public Health as outlined in the poster titled <u>It's the Law: Reporting Adverse Events Following Immunization function function http://www.phac-aspc.gc.ca/im/pdf/raefi- dmcisi-eng.pdf</u> and the <u>Nova Scotia Immunization Manual [hyperlink]</u>. Adverse events defined as serious must be reported to PH within one business day and all other events must be reported within five business days [hyperlink to AEFI definition].

The purpose of this Standard Operating Procedure (SOP) is to outline the process for recording and managing a report of an AEFI. Panorama software will be used to document all reports of AEFI and any action taken by Public Health.

# STANDARD OPERATING PROCEDURE

### PART 1-REPORTING AND FOLLOW-UP OF AN AEFI

An AEFI may typically be reported in the following ways:

- By a client to their Health Care Provider (HCP)
- By a client to Public Health
- By a HCP to Public Health
- By Public Health Staff who are present during an AEFI

#### Role of the HCP:

• When a HCP is made aware of an AEFI it must be reported to Public Health as required by law. Serious events must be reported within one business day and all others within five business days.

• Reports or inquiries received by administrative Staff regarding an AEFI are to be forwarded to the appropriate Public Health Nurse (PHN) for Panorama entry, investigation and follow-up.

#### Role of the PHN:

- Receive and review the AEFI report. Ensure all required information is collected.
  - If the report is from a HCP ensure that all information on the Public Health Agency of Canada (PHAC) <u>Adverse Events Following Immunization Reporting</u> <u>Form http://www.phac-aspc.gc.ca/im/pdf/raefi- dmcisi-eng.pdf</u> complete and accurate. If the HCP requires assistance offer information on how to access the PHAC <u>User Guide to Completion and Submission of the AEFI Reports</u> <u>http://www.phac-aspc.gc.ca/im/pdf/AEFI-ug- gu-eng.pdf</u>
  - Search for the client in Panorama. [User Guide]
  - If a client profile exists, review and update the profile.
  - o If a client profile does not exist, create a new profile.
    - In order to ensure the accuracy of data for reporting purposes and to minimize duplicate profile entries, it is extremely important that a careful and extensive client search is completed prior to creating a new profile.
    - Always search first using a Nova Scotia HCN as the only criteria
      - If no HCN, the first search may be done using an alternate client number from the drop down list.
    - If a HCN or other client number is unknown, not applicable, or the client is not found in a search using this criteria; clear the HCN field and search using the following criteria in any combination available:
      - Name (first and last); gender; date of birth
    - If still no results; search only the client first and last name using a wildcard symbol AND/OR a phonetic match
    - A minimum of three searches must be attempted prior to the creation of any new client profile.

#### Recording and Managing Reports of Adverse Events Following Immunization Page 4 of 21

- If duplicate profiles are found for the same client, follow the process for reporting duplicates. [hyperlink to Part 4-Other Documentation Considerations]
- Set the client profile in context for recording an AEFI. [User Guide]
- Determine whether the AEFI had been previously reported.
  - If the AEFI was previously reported, ensure Public Health follow-up had been completed.
  - If the AEFI was not previously reported, determine if the associated immunization is recorded in Panorama.
    - If the associated immunization is not recorded, add the immunization information to the client profile. [User Guide]
- Once it has been determined that an AEFI has not been previously reported and the associated immunization information is added to the client profile, the Nurse creates a new AEFI in Panorama [User Guide]
  - All reported AEFIs should be entered as soon as the investigation starts.
  - Cases that do not meet the PHAC reporting requirements (i.e. local skin reactions) for AEFI can be closed with the disposition of "does not meet temporal criteria". This will ensure that an accurate count of investigations is captured.
  - Historical reports of AEFI (i.e. verbal accounts given by a client on a past event): Only AEFIs with supporting documentation should be entered into Panorama.
    - If a verbal report is given of a historical event without documentation a note may be added to the client profile.

# \*Determine how supporting documents (i.e. ER reports, EHS reports, and discharge reports) will be managed and stored.

- Submit the AEFI to the zone MOH for review via Panorama [User Guide]
  - For **serious AEFIs**: Submit to the MOH for review **immediately**.
  - For **other AEFIs:** Submit to the MOH for review within **two weeks.**
- Send an email to the zone MOH to advise that a new AEFI has been submitted for review in Panorama.
  - Include the Panorama client ID as the identifier. Do not send health card numbers as the client identifier.
  - Copy the zone Health Protection manager and/or designate on the email.

#### Recording and Managing Reports of Adverse Events Following Immunization Page 5 of 21

 For serious AEFIs: send an email or phone notification to the Department of Health and Wellness (DHW) surveillance advising of the AEFI and provide the client ID#.

#### Role of the Medical Officer of Health (MOH)

- Review all AEFI reports submitted by the PHN and document recommendations for follow-up in Panorama. [User Guide]
  - For **serious AEFIs:** review, classify, provide recommendations and return to the Nurse who is managing the case within **one weeks**.
  - For **other AEFIs:** review, classify, provide recommendations and return to the Nurse who is managing the case within **two weeks**.
- Send an email to the assigned PHN to advise that recommendations have been added to the Panorama profile.
- Where the MOH is unable to enter recommendations directly into Panorama, the PHN may document the recommendations.
  - The Nurse will have access to the MOH role in Panorama in order to enter recommendations on their behalf.
    - Select "reviewer on behalf of health service provider"; then add the name of the MOH who provided the recommendation.

#### Role of the PHN:

- Review the MOH comments and complete follow-up of any recommendations provided [User Guide]
- Ensure a letter is sent to the HCP who provided the AEFI report (in addition to the family physician where applicable) and to the client outlining the MOH recommendations [hyperlink to Appendix F].
  - This should occur within **two weeks**.
- If required as per MOH recommendations, ensure a referral letter is sent to an allergist/specialist for client follow-up [hyperlink to Appendix G].

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- Ensure all documentation is complete under the client profile in Panorama including follow-up actions taken.
  - It is up to the PHN to close the case in Panorama. DHW will not be accountable to close the case.
- Notify DHW surveillance by email when an AEFI report has been completed.
- Ensure DHW is sent a copy of the completed AEFI report.
  - $\circ$  All cases of AEFI that meet criteria are forwarded to PHAC through DHW.

### PART 2-PANORAMA USE FOR NON-REGULAR STAFF

- It is expected that all Staff (PHNs) involved in case investigation and follow-up of AEFIs will utilize Panorama regardless of employment status.
- All Non-Regular Staff who provide case investigation and follow-up of AEFIs will require an Active Directory account in order to access and record information in Panorama.
  - Active Directory accounts are set up through the User Access Process with NSHA Information Technology Services.
  - The manager or delegate must be made aware of new users as soon as possible to ensure timely system access prior to scheduled immunization clinic(s).
  - Requests for Active Directory accounts can be made through SharePoint at: <u>http://intra.nshealth.ca/it-self-</u> <u>service/SitePages/User%20Access%20%e2%80%93%20Bulk%20Users.aspx</u>
- Hardware (i.e. laptops) will be made available within the zones to any staff who do not already have dedicated equipment assigned.
- All Non-Regular Staff will confirm they can access the Panorama immunization module prior to scheduled shifts that may involve case investigation and follow-up of an AEFI. Any issues with software/hardware access are to be identified with sufficient time for rectification prior to the scheduled date.

#### Nursing Students

• Nursing students who are completing a practicum placement with NSHA Public Health will not be assigned to complete cases of AEFI. They may observe or play a role in follow-up with an assigned nurse preceptor/mentor.

#### Part 3-CONSENT DIRECTIVES

#### **Consent for Disclosure:**

- Consent for Disclosure related to Panorama **must** be granted and put into effect by the DHW Privacy and Access Office.
  - Staff will advise clients who want to exercise this right to visit <u>https://novascotia.ca/dhw/phia/your-privacy.asp</u> for more information or consult the Privacy and Access Office at 1-855-640-4765 or <u>phia@gov.ns.ca</u>
  - Once a request goes through the formal process the client file will not appear in a search. Nurses must obtain client consent to override this directive. <u>[User</u> <u>Guide]</u>Only Nurse Immunizers and Medical Officers of Health (MOHs) are given permission in Panorama to complete a consent override.

#### Process as Part of AEFI Reporting and Follow-Up:

- AEFIs are reportable by law to Public Health under the Nova Scotia HPA and as such must be followed up.
- Client consent is **not** required to override this directive in Panorama for the purposes of reporting and gathering information related to an AEFI.
- The PHN will choose "Professional Judgement" in the Panorama dropdown list as the reason for the override and add a note in the comment box to indicate that the AEFI follow-up must be completed by law.

### Part 4-OTHER DOCUMENTATION CONSIDERATIONS

#### **Deletion of Errors**

- If information is entered accidentally on a client file (i.e. an allergy, address, consent typo, etc.) it should be deleted, not invalidated.
  - Deletions are only invisible to the end user; this information is still retrievable and auditable. In contrast, invalidated information can still be seen by the end user but is greyed-out.

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- In some cases visibility of incorrect information may cause user confusion and more risk of harm to a client where the information was never relevant to them in the first place.
- Users are **NEVER** to delete clinical notes, another user's entry, or a past entry. In all of these cases the information would be updated so that all previous information is fully accessible and visible to the end user.
- Immunization administration errors entered by a nurse would be invalidated (not deleted) and correct information entered.
- Any amendment made to a client file that falls outside client demographic data must include a clinical note to indicate which fields have been changed and the reason for the change.
- Note: Panorama Immunization users are not granted system permissions to delete within the AEFI module. Therefore users should indicate "disregard" rather than "delete" and enter a note on the client profile to indicate the reason for disregard status. [User Guide]

#### **Duplicate Client Profiles**

- If a duplicate client profile is found, an online ticket will be submitted to the Help Desk at <a href="https://ictservices.nshealth.ca/assystnet/application/assystNET.jsp">https://ictservices.nshealth.ca/assystnet/application/assystNET.jsp</a>
  - o The subject line should indicate "Panorama-possible duplicate client".
  - Include the client ID# for each possible duplicate file; do not include client names, health card numbers or other identifying information in the ticket.
  - Tickets for Panorama will be forwarded to the appropriate support Staff for resolution.

#### Immunization Deferral

- Immunization Deferral occurs in cases where a client is expected to receive the immunization in future but could not receive it on the day of the scheduled appointment (i.e. they are sick, more information is required from the HCP, etc.).
- The Nurse Immunizer assesses the client and uses clinical judgement as to the necessity for deferring an immunization.

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- Deferrals are documented on the deferral page in Panorama and should always include a comment in the comments section to indicate the reason for deferral.
   [User Guide]
  - The comments section is preferable over a clinical note as the clinical notes are not attached to a specific event and are more time consuming to locate. The end user must also know to search for a clinical note whereas comments are available to any user on the same page that indicates the deferral was made. If necessary a clinical note may also be included.
- Whenever possible, a deferral should indicate both the start and end date (i.e. the date the deferral was put in place and the date it is expected to end in immunization).
  - If an end date is unknown it may be left blank.

#### Special Considerations [Special Conditions]

### \*confirm & include definition chart from training material

- Special considerations are updated in the client profile where factors that may impact immunization exist.
  - If a consideration exists that is applicable to ALL immunization (i.e. a needle phobia) then a warning should be added rather than a precaution[User Guide]
  - Warnings will appear for any vaccine given whereas precautions appear for specific agents.
- Allergies recorded in Panorama will not affect the forecaster function. A contraindication (found under special considerations) should also be added to the client profile when a vaccine should not be administered again. Contraindications will adjust the forecaster[User Guide]
  - If subsequent doses are being recommended, do not use contraindications; instead add a precaution (i.e. longer post-immunization observation period).
     [User Guide]
- Allergies being captured that are unrelated to immunization may all be listed together under "other" in the comments section. [User Guide]

#### Part 5-CONTINGENCY (PANORAMA INACCESSIBLE)

This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against the electronic file version prior to use.

- Should Panorama access be interrupted or unavailable during the AEFI reporting and follow-up process, the PHN will proceed with paper documentation and information will be entered into Panorama as soon as possible.
  - The PHAC reporting form will be completed and submitted to the zone MOH and DHW within the same follow-up timeframe required electronically.
     [Hyperlink] to Adverse Events Following Immunization Reporting Form and User Guide to Completion and Submission of the AEFI Reports.
  - All hardcopy reports sent to the MOH and DHW during contingency follow-up will be scanned and emailed via secure file transfer.
  - As soon as Panorama software becomes accessible the case follow-up information will be entered.

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### REFERENCES

Nova Scotia Health Authority. (2015a). *Immunization toolkit for family practice*. Retrieved from <u>http://www.cdha.nshealth.ca/public-health/immunization-public-health/immunization-toolkit-family-practice</u>

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Public Health Agency of Canada. (2011). User Guide: Report of Adverse Events Following Immunization (AEFI). Retrieved from <u>http://www.phac-</u> aspc.gc.ca/im/aefi\_guide/index-eng.php

## **RELATED DOCUMENTS**

#### Policies

Reference and link to the new NSHA Immunization Policy [Public Health MM-IM-001] once approved (will supersede all former DHA immunization-related policies)

Reference and link to the new NSHA Anaphylaxis Policy once approved (will supersede all former related DHA policies)

#### Appendices

**Appendix A-Definitions** 

Appendix B-Nova Scotia Immunization Schedule for Children

https://novascotia.ca/dhw/cdpc/documents/13078\_NsChildhoodImmPoster\_En.pdf

Appendix C-Nova Scotia Immunization Schedule for Adults

https://novascotia.ca/dhw/cdpc/documents/13155\_AdultImmunizationSchedule\_En.pdf

Appendix D-Nova Scotia School Immunization Schedule

https://novascotia.ca/dhw/cdpc/documents/13153\_SchoolImmunizationSchedule\_En.pdf

Appendix E-"It's the Law: Reporting Adverse Events Following Immunization"

Appendix F-Sample AEFI Recommendation Follow-Up Letter

Appendix G-Sample AEFI Referral Letter

#### **Appendix A-Definitions**

AEFI	Adverse event following immunization is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the vaccine.
	A <b>serious</b> AEFI is one that is life threatening or results in death, requires hospitalization for more than 24 hours or prolongation of an existing hospitalization, results in residual disability or congenital malformation.
Consent for Disclosure	Consent granted by a client to a Nurse or MOH to view a file that has been masked by the DHW Privacy and Access Office. Masking is a process that limits the disclosure of specific portions of that client's personal health information.
Deferral	A postponement status assigned where a student is expected to have an eligible immunization at a date in the foreseeable future but could not receive it on the day originally scheduled.
Health Care Professional (HCP)	All persons employed by NSHA facilities, or NSHA funded facilities, as well as members of the medical staff, volunteers, board members, students, and others associated through contracts.
Immunization	The process by which immunity is conferred, either by injection of antigens (active Immunization) or by injection of serum containing specific antibodies (passive immunization).
Non-Regular Staff	Refers to all learners, temporary and casual Staff who provide services to clients as part of assigned work activities within Public Health at the NSHA. This may include both administrative and nursing related functions.
Notifiable Diseases	Communicable diseases identified by federal and provincial governments as priorities for monitoring and control efforts.
Health Protection Act (HPA)	Provincial legislation in Nova Scotia that provides a framework to enable public health officials to protect the public while preventing, detecting, and containing health threats.
Nurse	Refers to all permanent status registered nurses and licensed practical nurses who provide services to clients as part of assigned work activities within Public Health at the NSHA.
Panorama	An electronic public health surveillance system designed to increase efficiency in tracking vaccine usage, immunization coverage rates, and control of infectious notifiable diseases including outbreaks.

Publicly Funded Immunization Program	A provincially determined list of publicly funded vaccine which falls under various routine and non-routine eligibility criteria including childhood, school, adult and high risk categories.
Public Health Nurse (PHN)	A Registered Nurse (RN) employed by the NSHA with the specific title and role of PHN. This position is defined in the HPA with accountabilities for notifiable disease and health hazard reporting and follow-up under the guidance and authority of the Regional/Deputy/ and Chief Medical Officers of Health (MOH).
Staff	Unless specifically limited by a certain policy, refers to all employees, physicians, learners, volunteers, board members, contractors, contract workers, franchise employees, and other individuals performing work activities within NSHA.

# Routine Childhood Immunization Schedule

Childhood immunizations have changed in the past few years. This schedule reflects these changes and may be different from what you or your children may have received in the past.

The immunizations shown on this schedule are those that are given free of charge.

High-risk children may be eligible for additional vaccines. For more information, talk to your health care provider or call your local Public Health Services office.

		SCHEDULE					
		2 months	4 months	6 months	12 months	18 months	4-6 years
VACCINES	DTaP-IPV-Hib Diphtheria, tetanus, acellular pertussis (whooping cough), polio, and Haemophilus influenzae type b vaccine	✓	✓	✓		✓	
	Pneumo Conj. Pneumococcal conjugate vaccine	$\checkmark$	$\checkmark$		$\checkmark$		
	Men C Conj. Meningococcal group C conjugate vaccine				$\checkmark$		
	MMRV* Measles, mumps, rubella and varicella vaccine				$\checkmark$	<	$\checkmark$
	Tdap-IPV Tetanus, diphtheria, acellular pertussis (whooping cough), and polio vaccine						~

\*The second dose of MMRV can be given only once between 18 months and 6 years of age.

#### Seasonal Flu Vaccines

- Seasonal flu vaccines are free for all Nova Scotians. They are recommended for all adults and children EXCEPT for babies under 6 months.
- Seasonal flu vaccines are strongly recommended for anyone who lives with or takes care of a child under 5 years, and for anyone living in a home where a newborn is expected during influenza season (October to April). This includes both adults and older children.
- Seasonal flu vaccines are also strongly recommended for children with a health condition that
  places them at high risk and for anyone who lives with or takes care of these children.

REV15-16

Children under 9 years old getting their first flu vaccine need 2 doses.

For more information about seasonal flu vaccines, see: novascotia.ca/DHW/CDPC/flu.asp

Aussi disponible en français

# Immunization Schedule for Adults

The immunizations shown here are given free of charge.

Adults at high risk may be eligible for additional vaccines. For more information, talk to your health care provider or call your local Public Health office.

		SCHEDULE	
		Adults to age 64	Adults 65 and older
INES	<mark>Seasonal Flu<sup>1</sup></mark> Influenza vacctne (every flu season)	1	1
VACC	Td Tetanus, diphtheria vaccine. (Every 10 years. 1 dose should be given as Tdap <sup>2</sup> if not previously given in adulthood.)	<ul> <li>Image: A second s</li></ul>	<ul> <li>Image: A second s</li></ul>
	Pneumococcal polysaccharide Pneumococcal polysaccharide vaccine (1 dose) <sup>3</sup>	(high risk only)	<b>√</b>
	MMR Measles, mumps and rubella vaccine (2 doses)	(Adults born in 1970 or later)	

1 For more information about flu vaccine, see novascotia.ca/flu

2 Tdap (tetanus and diphtheria toxoid combined with acellular pertussis vaccine)

- All adults who have not received a dose of pertussis vaccine in adulthood should receive a single dose of Tdap for the prevention of pertussis (whooping cough), particularly if they are in regular contact with infants.
- 3 In most cases, pneumococcal polysaccharide vaccine should be given only once. More than one dose decreases the effectiveness of the vaccine. For some people, re-vaccination may be required. For more information on re-vaccination,
  - talk to your health care provider or
  - visit www.phac-aspc.gc.ca/publicat/cig-gci/p04-pneu-eng.php

# School Immunization Schedule

The immunizations shown on this schedule are those that are given free of charge.

Children at high risk may be eligible for additional vaccines. For more information, talk to your health care provider or talk to your local Public Health Office.

		School Year
		Grade 7
INES	HPV (for both boys and girls) Human papillomavirus vaccine (2 doses)	✓
VACO	Hepatitis B (HB) Hepatitis B vaccine (2 doses)	~
	Tdap Tetanus, diphtheria, and acellular pertussis (whooping cough) vaccine	~
	Meningococcal Quadrivalent Meningococcal Quadrivalent vaccine (Groups A, C, Y and W 135)	✓

13153/APR15 REV15-16

Recording and Managing Reports of Adverse Events Following Immunization Page 18 of 21 Appendix E-"It's the Law: Reporting Adverse Events Following Immunization"

# It's the Law: Reporting Adverse Events Following Immunization (AEFI)

# What to Report

You are required **BY LAW** to report to Public Health the following adverse events that may occur following immunization.

#### Serious Adverse Events

#### Report within 1 working day Any serious reaction that:

- Is life-threatening e.g., anaphylaxis, Guillain-Barré Syndrome
- Causes or prolongs hospitalization ≥ 24 hours
- Results in permanent disability or congenital malformation
- Is fatal

#### Other Adverse Events

#### Report within 5 working days

- Neurological events including febrile and afebrile convulsions
- Associated events where medical attention is required
- Events where consideration must be given to postpone or contraindicate future immunizations
- Unexpected events with no alternative explanation

# What NOT to Report

Do not report minor expected reactions such as localized tenderness, as outlined in the product monograph, unless they are more severe or more frequent than expected.

# How to Report

- 1. Consult your local Public Health office to determine if an AEFI form should be completed.
- 2. If required, download and complete the AEFI form: www.phac-aspc.gc.ca/im/aefi-form-eng.php
- 3. Send the completed form to your local Public Health office.

South Shore Health Public Health Services Tel: 543-0850 Fax: 527-4208

South West Health Public Health Services Tel: 742-7141 Fax: 742-6062

Annapolis Valley Health Public Health Services Tel: 542-6310 Fax: 542-6333 Colchester East Hants Health Authority Public Health Services Tel: 893-5820 Fax: 893-2614

Cumberland Health Authority Public Health Services Tel: 667-3319 Fax: 893-2614

Pictou County Health Authority Public Health Services Tel: 752-5151 Fax: 893-2614 Guysborough Antigonish Strait Health Authority Public Health Services Tel: 867-4500 ext. 4800 Fax: 863-5111

Cape Breton District Health Authority Public Health Services Tel: 563-2400 Fax: 563-2005

Capital Health Public Health Services Tel: 481-5800 Fax: 481-5889



Public Health Services

NOVA SCOTIA

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3087/AUG14 REV11-1

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PH Office Addres PH Office Addres PH Office Phon PH Office Fa Website: www.nshealth.c

DATE

FAMILY PHYSICIAN (NAME & ADDRESS)

Dear Dr.\_\_\_\_,

Re: Patient -DOB -

Please be advised that I've reviewed the attached "Report of Adverse Events Following Immunization" recently received on this patient.

Based on this information, I recommend\_\_\_\_\_

If you have any questions, please don't hesitate to contact me.

Sincerely,

Medical Officer of Health

#### Appendix G-Sample AEFI Referral Letter



PH Office Addres PH Office Addres PH Office Phon PH Office Fa Website: www.nshealth.c

DATE

Dear Dr.

#### Re: Patient: DOB:

As per the attached "Adverse Event Following Immunization" form regarding the above noted client, I have recommended that this client be evaluated by an allergy specialist.

As per my recommendation, can you please arrange for this client to be evaluated in your clinic? If you have any questions please contact my office at XXX-XXX-XXXX.

Sincerely,

Medical Officer of Health

CC:

#### **CURRENT VERSION**

- 1. Prepared by: Catharine Langlois (Consultant-Health Protection)
- **2. Reviewed by**: Panorama Immunization working group members as part of User Acceptance Testing January 22-26, 2018
- 3. Version #: February 1, 2018

# **Version History**

(To Be Completed by the Policy Office)

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)