Management of Vaccine Administration Errors or Deviation for all Immunizers

Purpose: The purpose of this policy is to provide standards of practice to all immunizers that provide publicly funded vaccines in New-Brunswick (NB) on management of errors or deviation in administration of vaccines. This policy is *not* for Adverse Events Following Immunizations (AEFI). For reporting AEFI's, refer to the New Brunswick Immunization Program Guide (NBIPG) document: Reporting of Adverse Events Following immunization.

Preamble: Immunization has become increasingly complex. It is crucial that vaccines are safely and effectively administered to as many eligible recipients as possible. Immunization errors include deviations in recommended vaccine type, reconstitution volume, dose, site, route, person, time or schedule. Immunization related incidents include a range of events, such as a needle injury caused by failed positioning of a child, immunization without consent, or fainting with a fall resulting in injury.

Methods to detect immunization errors or incidents may include vaccine provider self-reporting, direct observation or record audits. Clinical judgment is necessary for making appropriate decisions regarding vaccine administration errors and deviations.

Policy: All employers of immunizers who provide publicly funded vaccine and biologics through the New Brunswick Immunization Program must have an internal process in place on how to manage/ report vaccination administration errors and deviations.

In addition to reporting administration errors and deviations, incidents and near misses are tracked in order to offer support, recognize trends and/or identify professional development/competency shortcomings and implement strategies to prevent it from happening again.

Standards:

- All errors, deviations, incident or near miss must be reported immediately by the immunizer to the direct person in charge/supervisor or authorized prescriber[1] in order to assess direct impact to the client. A process will be in place for clients needing immediate intervention measures and determine if further recommendations should be made (i.e., give another dose, re-assess in 24 hours, etc.).
- All immunizers who do not have direct access to enter or correct vaccines in the Public Health Information Solution (PHIS) will need to follow the procedures in **Appendix A**-Standard Operating Procedure for external PHIS users of this policy (depending on their immunizer category) to ensure that any errors or deviations in vaccine administration are captured in the PHIS.
- Inform the client, parent or legal guardian of the error/incident as soon as possible after it is identified. The client should be informed of any implications/recommendations for future doses, possibility for local or systemic reaction and impact on the effectiveness of the vaccine (if applicable and as known).
- Report all errors, deviations or near miss incidents in accordance with the employers' policy and/or professional regulatory body's required quality management system.
- Determine how the vaccine administration error, deviation or near miss occurred and implement strategies to prevent it from happening again.

Note: Guidance documents exists for managing vaccine administration errors or deviations for certain vaccines programs (i.e., COVID-19 vaccines). All immunizers providing vaccines in these specific programs must be familiar with the resource documents as well as the management of these vaccine administration errors or deviations.

[1] *In NB current authorized prescribers include physicians, nurse practitioners, optometrists, dentists, pharmacists and midwives.*

APPENDIX A- STANDARD OPERATING PROCEDURE FOR EXTERNAL PHIS USERS

Subject: External PHIS Immunizers reporting immunization errors in vaccine documentation and administration or clients' choices to deviate from New Brunswick immunization recommendations to PHIS support.	
Approved by: Shelley Landsburg	**Approval Date:** February 2023
Applies To: All external immunizers who administer vaccines in which their immunization information is transferred to PHIS through integrations of systems (i.e. physicians/Nurse Practitioners via Medicare; Pharmacists/Pharmacy technicians via Drug Information System). Also, PHIS users with view only access.	

Introduction

External PHIS immunizers provide vaccine administration support to the New Brunswick Public Health Immunization Program. All immunizers will provide immunization services in alignment with the legislation, policies, and standards as outlined in the New Brunswick Immunization Program Guide (NBIPG) to ensure the provision of safe, effective, and competent immunization.
Public Health Information Solution (PHIS) receives immunization data through multiple means which includes integration with the following systems:

- The Pharmacy Drug Information System (DIS) for Pharmacists' and Pharmacy Technicians' administered vaccines
- Medicare for Physicians', Nurse Practitioners' (NPs) and Midwives' administered vaccines

Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the key processes required to ensure accurate documentation is contained in PHIS client records pertaining to errors in documentation and administration of vaccines or when a client chooses to deviate from New Brunswick (NB) immunization recommendation that has been entered via other electronic systems. This SOP is to be used in conjunction with the NBIPG.

For errors documented manually, please refer to the following PHIS documents:

- PHIS DO AND DO NOT- Invalid Doses vs Doses Recorded in Error
- Documentation and Review of Immunization Information in PHIS

Responsibilities

Immunization providers administering vaccines, whose immunization data is integrated into PHIS through other systems, are accountable to ensure accurate information is updated in PHIS such as when an error has occurred, or a client chooses to deviate from NB recommendation. In addition, all those who have been provided PHIS view only access for the purpose of providing immunization services, are responsible to notify PHIS support if an error in documentation is noted on a client's record.

Process for Vaccine Documentation and Administration Errors

Documentation:

<u>Vaccine documentation error is detected in a community pharmacy</u>-

- Immunizer should follow internal and professional processes for reporting and correcting vaccine documentation errors.
- The error should be corrected in DIS by immunizer which will correct the vaccine

documentation in PHIS through integration of systems.

- If the correction cannot be made in DIS, then the pharmacist or pharmacy technician will contact PHNB via the PHIS support email Phisisp@gnb.ca. PHIS support will notify the PHIS clinical corrections team, and they will contact the pharmacist to obtain the applicable information and make the correction in PHIS.

Vaccine documentation error is detected by a physician/NP or a midwife-

- The immunizer should follow internal and professional processes for reporting and correcting vaccine documentation errors.
- Contact PHNB via the PHIS support email Phisisp@gnb.ca to report error. PHIS support will notify the PHIS clinical corrections team, and they will contact the physician/NP or midwife to obtain the applicable information and make the correction in PHIS.

Vaccine documentation errors detected by PHIS Audits-

- The PHIS clinical correction team will contact the applicable immunizer or manual data entry person to investigate and confirm that it is a vaccine documentation error.
- If the error occurred in a community pharmacy, the error should be corrected in DIS by immunizer which will correct the vaccine documentation in PHIS through integration of systems.
- If the error occurred by a physician/NP or a midwife, the clinical corrections team will obtain the applicable information and will make the correction in PHIS.
- If the error was made by manual data entry, the correction should be made by the person who entered the data. If that person is no longer available, the clinical corrections team will require the paper consent/admin form to make the correction in PHIS.
- The immunizer should follow organization's internal and professional processes for reporting and correcting vaccine documentation errors.

Administration Error:

Vaccine administration errors detected in a community pharmacy-

- The immunizer should follow internal and professional processes for reporting and correcting vaccine administration errors including notifying the client.
  Refer to the NB Immunization Program Guide-Policy 2.15 to the required follow-up for this type of vaccine administration error. Consult with Regional Medical Officer of Health if needed.
- The pharmacist or pharmacy technician will contact PHNB via the PHIS support email Phisisp@gnb.ca. PHIS support will notify the PHIS clinical corrections team, and they will contact the vaccine administer to obtain the applicable information and make the appropriate note in PHIS.

Vaccine administration errors detected by a physician/ nurse practitioner or a midwife-

- Immunizer should follow internal and professional processes for reporting and correcting vaccine administration errors including notifying the client.
- Refer to the NBIPG Policy - Management of Vaccine Administration Errors or Deviation for all Immunizers for the required follow-up for this type of vaccine administration error. Consult with Regional Medical Officer of Health if needed.
- The physician, NP or midwife will contact PHNB via the PHIS support email Phisisp@gnb.ca. PHIS support will notify the PHIS clinical corrections team, and they will contact the vaccine administer to obtain the applicable information and make the appropriate note in PHIS.

Vaccine administration errors detected by PHIS Audits-

- The PHIS clinical correction team will contact the applicable immunizer or manual data entry person to investigate and confirm that it is a vaccine administration error.

- The PHIS clinical correction team will obtain the applicable information and make the appropriate note in PHIS.
- If not already completed, immunizer should follow internal process for vaccine administration errors.
- Refer to the NBIPG Policy - Management of Vaccine Administration Errors or Deviation for all Immunizers for the required follow-up for this type of vaccine administration error. Consult with Regional Medical Officer of Health if needed.

Process when a client chooses to deviate from New Brunswick (NB) recommendation:
In rare instances, a client may refuse the vaccine that is recommended by NB immunization program and request another publicly funded vaccine they are **eligible to receive**. For example, an individual 65 years of age may refuse High Dose influenza vaccine but accept standard dose. Reminder, a client should not be given a publicly funded vaccine that they are not eligible to receive.

- The immunizer will contact PHNB via the PHIS support email Phisisp@gnb.ca. PHIS support will notify the PHIS clinical corrections team, and they will contact the immunizer to obtain the applicable information and make the appropriate note in PHIS.

History

Date	Version	Revised By	Approved By	Revision
15-02-2023	V 1.0	Suzann Feggos	Shelley Landsburg	Initial Version