Guidance Document on the Management of COVID-19 Vaccine Errors In Newfoundland and Labrador

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August 16, 2021

Overview

This document is intended to assist healthcare providers by providing an approach to managing COVID-19 vaccines that are administered in a manner that differs from the recommendations of the manufacturer and/or the National Advisory Committee on Immunization (NACI) (referred to as vaccine administration errors). This document builds on guidance developed by CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States and the guidance developed by Public Health Ontario, with input from the Canadian Immunization Committee and the National Advisory Committee on Immunization.

Currently, there is limited evidence to guide the management of these situations.

Note that this document is to be used to manage errors that have already occurred. Provincial policies and recommendations should be followed when administering all COVID-19 vaccines as well as the product monograph and recommendations from the National Advisory Committee on Immunization.

Key Steps for Health Care Providers following Identification of a COVID-19 Vaccine Administration Error

- Inform the recipient of the vaccine administration error as soon as possible after it has been identified.
- Advise the recipient of any implications/recommendations for future doses and possibility for local or systemic reactions and impact on the effectiveness of the vaccine (if applicable and as known).
- Determine how the vaccine administration error occurred and implement strategies to prevent it from happening again.
- Report all errors or near miss incidents to the Department of Health and Community Services.

If a vaccine administration error results in an adverse event following immunization (AEFI), complete the AEFI form and submit it to the regional Communicable Disease Control Department. Information on AEFI reporting is provided here.

Serologic testing to assess vaccine-induced immunity following COVID-19 vaccine errors to guide management decisions is generally not recommended. Providers are encouraged to contact their Regional Medical Officer of Health for advice if considering using serology to investigate an error.

Additional resources on vaccine administration practices can be found in the Canadian Immunization Guide.

Table 1: Guidance on Management of COVID-19 Vaccine Administration Errors in Newfoundland and Labrador

Type	Administration error	Interim guidance on how to consider the dose and recommended action
Site/route	• Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site])	• Consider this a valid dose. • Inform the recipient of the error and the potential for local and systemic adverse events.
	• Incorrect route (e.g., subcutaneous)	• Consider this a valid dose. • Inform the recipient of the error and potential for local and systemic adverse events.
Age	• Use at a younger age than authorized by Health Canada and/or recommended by NACI	**Pfizer-BioNTech** vaccine: • Consider this a valid dose. • Give the second dose at the recommended interval if the client is at least 12 years of age or when authorized for the client's age (if authorization is extended to below 12 years of age). **Moderna** vaccine: • Consider this a valid dose. • Give second dose at the recommended interval if the client is at least 16 years of age or when authorized for the client's age (if authorization extended to below 16 years of age). **AstraZeneca/COVISHIELD** vaccines: • Consider this a valid dose. • Do **not** give a second dose at this time. Await NACI recommendations. **Janssen** vaccine: • Consider this a valid dose. • The vaccine series is considered complete.
Co-administration	• COVID-19 vaccine dose administered on the same day, or 28 days before or 14 days after another vaccine (i.e., a non-COVID-19 vaccine)	• Both the COVID-19 and the other vaccine are considered valid.

Intervals	• Two doses of a COVID-19 given too close together in time (including on the same day)	• Inform the recipient of the potential for local and systemic adverse events. • If the second dose was administered 19 or more days after the first for Pfizer-BioNTech or 21 or more days after the first for Moderna or AstraZeneca, consider both doses valid, and the series complete. • If the second dose was administered less than 19 days after the first for Pfizer-BioNTech or less than 21 days after the first for Moderna or AstraZeneca, consider the second dose invalid and repeat at the recommended interval between first and second dose (counting from the date of the invalid dose).
	• Second dose administered later than the longest NACI extended interval (i.e. more than 4 months after the first dose)	• The second dose is valid. • No further doses are required.
Mixed vaccines for first and second doses	• A different vaccine used for the first and second dose	• Consider both doses valid regardless of the type of vaccine used for the first and second doses. • The vaccine series is considered complete.[1]
Dosage (see Diluent section below for specific information regarding Pfizer-BioNTech and the diluent)	• Higher-than-authorized dose volume administered	• Consider this dose valid. • Inform the recipient of the potential for local and systemic adverse events.[2] • Give second dose at the recommended interval.
	• Lower-than-authorized dose volume administered (e.g. leaked out, equipment failure, recipient pulled away)	• If less than a full dose is administered, consider it invalid. • Administer a full repeat dose immediately in the opposite arm. • Inform the recipient of the potential for local and systemic adverse events.[2]
	• More or less than the authorized number of doses obtained from the vial	• As long as the correct dosage were drawn up per dose (and the correct amount of diluent was used, if applicable) the doses are considered valid.
Storage and Handling	• Dose administered after improper storage and handling (e.g., temperature excursion)	• Contact the Department of Health and Community Services for guidance. • Inform the recipient of the potential for local and systemic adverse events.[2]

	• Dose administered past the expiration/beyond use date	• Contact the Department of Health and Community Services for guidance. • Inform the recipient of the potential for local and systemic adverse events. [2]
Diluent (Pfizer-BioNTech only)	• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)	• Contact the Department of Health and Community Services for guidance. • Inform the recipient of the potential for local and systemic adverse events.[2]
	• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	• Inform the recipient that no vaccine was administered. • Administer the authorized (appropriately diluted) dose as soon as possible in the opposite arm.
	• Too much diluent administered (more than 2.0 mls of diluent) (based on 0.3 ml dose administered)	• If more than 2.0 mls of diluent was added to the vial, consider this an invalid dose. • Administer a full repeat dose immediately in the opposite arm. • Inform the recipient of the potential for local and systemic adverse events.[2] • **Discard vial and contents, report remaining doses as wastage.**
	• No diluent or less than the recommended diluent, resulting in higher than the authorized dose (based on 0.3 ml dose administered)	• Consider this dose valid. • Inform the recipient of the potential for local and systemic adverse events.[2] • Administer second dose as per recommended interval.

[1] Note that this recommendation currently only applies to vaccines authorized for use in Canada. Guidance on vaccines not authorized for use in Canada is pending.

[2] If the client requires a final dose to complete the series, follow the recommendations for the timing of the final dose from the last dose (whether it was valid or not). The client should be advised regarding the potential for local and systemic adverse events following the final dose. If the client who requires a final dose has developed a significant local or systemic reaction from an earlier dose, the decision to administer the final dose should be assessed on a case-by-case basis and, if appropriate, in consultation with an allergist/immunologist

References

Centres for Disease Control and Prevention (CDC). Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States. Available from: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

National Advisory Committee on Immunization (NACI). Recommendations on the use of COVID-19 vaccines. Available from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html

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