Guidance on the Management of Inadvertent COVID-19 Vaccine Errors

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Table of Contents

1.0 Introduction

The intent of this document is to provide guidance for healthcare providers in managing COVID-19 vaccines that are administered in a manner differing from the recommendations of the manufacturer as authorized by Health Canada and/or as recommended by the National Advisory Committee on Immunization (NACI) and/or as approved by the Chief Public Health Officer of Nunavut.

These are referred to as vaccine administration errors or deviations. This guidance relates more specifically to the Pfizer-BioNTech COMIRNATY® (5-11 and 12+ formulations) and the Moderna SPIKEVAX® (6+ formulation) COVID-19 vaccines. Please note that while the Moderna formulation is for ages 6+, two separate vaccine administration error reference guides were used to draft this document (one for ages 5 to 11 and one for ages 12+).

This document provides guidance only. Vaccine protocols may differ from the guidance in this document and clinical judgement in certain situations may also result in different management decisions than outlined below. Please always advise the Regional Communicable Disease Coordinator (RCDC) when an inadvertent error arises.

Note: this document is to be used only to manage errors that have already occurred. Please ensure to follow the product monograph and the Government of Nunavut COVID-19 immunization protocols when administering COVID-19 vaccines.

2.0 Steps to be taken after an error is recognized

If an inadvertent vaccine administration error or deviation is found, healthcare providers should:

1. Inform the client of the vaccine administration error or deviation as soon as possible
    - Explain the possibility for local and systemic reactions
    - Explain any recommendations for future doses (e.g., if the dose given is considered valid or invalid and when a repeat or next dose is recommended).
    - The occurrence and the respective action(s) should be documented in Meditech (e.g., patient was informed of the error, health teaching was provided, etc.).
2. Complete an incident report on Meditech and notify RCDC
3. Complete an Adverse Event Following Immunization (AEFI) form and submit to RCDC if the vaccine administration error or deviation results in an AEFI

4. Determine how the vaccine administration error occurred and implement strategies to prevent it from happening again.

Note: Serologic testing to assess vaccine-induced immunity following COVID-19 vaccine errors to guide management decisions is generally not recommended.

3.0 Types of administration errors and recommended actions for each error

Type	Administration Error or Deviation	Guidance/Recommended Action
Site/route	Incorrect site (other than deltoid muscle).	Consider this a valid dose. Inform the client of the error or deviation and the potential for local and systemic adverse events and that the dose is acceptable.
	Incorrect route (e.g., subcutaneous).	Consider this a valid dose. Inform the client of the error or deviation and the potential for local and systemic adverse events and that the dose is acceptable.
Age	Dose or product administered to a client younger than the minimum age authorized by Health Canada and/or recommended by NACI.	Consider this a valid dose. Give the subsequent dose with the recommended age-appropriate dosage and interval. Inform the client of the potential for local and systemic adverse events.
Dosage	Higher-than-authorized dose volume administered.	Consider this a valid dose. Inform the client of the potential for local and systemic adverse events.
	Lower-than-authorized dose volume administered (e.g., leaked out, equipment failure, recipient pulled away, paediatric dose administered to an adult 18 years or older).	If less than a full dose has been administered, consider this an **<u>invalid dose.</u>** If the error is discovered on the same clinic day, administer a full repeat dose immediately on the alternate deltoid muscle. If the error is discovered after the clinic day: • If the invalid dose was a 1st dose, administer a full repeat dose when the error is discovered. • If the invalid dose was not the 1st dose, wait 8 weeks to offer a repeat dose (unless the amount administered is likely to be very small, in which case repeat immediately). • Inform the client of the potential for local and systemic adverse events. **Exceptions**: • If an adolescent 12 to 17 years of age inadvertently received a Pfizer-BioNTech COMIRNATY® 0.2 mL (10 mcg) dose, consider the dose(s) valid and do not repeat (even if both doses were 0.2 mL). If this was their 1st dose, the 2nd dose should be a 0.3 mL (30 mcg) dose given 8 weeks later. • If Moderna SPIKEVAX® is being used as an additional dose for moderately to severely immunocompromised individuals (for whom a 0.5 mL (100 mcg) dose is recommended) and only 0.25 mL (50 mcg) dose was inadvertently administered, consider the dose valid and do not repeat. • If Moderna SPIKEVAX® is being used for a booster dose (for those with eligibility criteria for which a 0.5 mL (100 mcg) dose is recommended) and only 0.25 mL (50 mcg) dose was inadvertently administered, consider the dose valid and do not repeat.

	Pfizer-BioNTech COMIRNATY® pediatric dose, 0.2 mL (10 mcg) administered to an individual ≥ 18 years of age.	Consider this an **invalid dose.** Repeat dose immediately using the age-appropriate dose and formulation. If the dose given in error is the 1st dose, administer the 2nd dose at the recommended interval after the repeat dose (i.e., 8 weeks after repeat dose) using the age-appropriate formulation.
	More or less than the authorized number of doses obtained from the vial.	As long as the correct volume was drawn up per dose (and the correct amount of diluent was used if required), the doses are valid.
Intervals	1st and 2nd doses of the primary series given too close together.	Consider both doses valid if: • Using Pfizer-BioNTech COMIRNATY® (both paediatric and adolescent/adult formulations), the 2nd dose was administered ≥ 19 days after the 1st dose. • Using Moderna SPIKEVAX®, the 2nd dose was administered ≥ 21 days after the 1st dose. If the 2nd dose was administered less than minimum interval indicated above for the respective vaccine, consider the 2nd dose **invalid**. Repeat with at least an 8-week interval from the date of the invalid dose. Inform the client of the potential for local and systemic adverse events.
	2nd dose administered more than 8 weeks from the 1st dose.	No interval is too long, and all doses would be considered valid.
	3rd dose in the primary series administered less than 28 days from the 2nd dose for moderately to severely immunocompromised individuals.	Consider the dose valid. If eligible, offer a booster dose when recommended.
	Booster dose given less than 6 months from the last dose in the primary series for individuals 12 to 17 years of age, or less than 4.5 months from the last dose in the primary series for individuals ≥ 18 years of age.	If ≥ 8 weeks has passed since the last dose in the primary series, consider the booster dose valid. If < 8 weeks has passed between the last dose in the primary series and the booster dose, consider the booster dose **invalid** and repeat the booster dose at least 6 months from the invalid dose.
Mixed COVID-19 Vaccines	A different COVID-19 vaccine used for the 1st, 2nd, or additional/booster doses.	Consider all doses valid regardless of the vaccine type, unless non-Health Canada authorized vaccines.
COVID-19 vaccine administered within 14 days before or after a non-COVID-19 vaccine	COVID-19 vaccine dose administered on the same day, or up to 14 days before or after another vaccine (a non-COVID-19 vaccine).	Both the COVID-19 and the other vaccine are valid. *Note: Co-administration has been approved for ages 12+.
Storage and Handling	Dose administered after improper storage and handling.	Contact RCDC and the pharmacy for advice. If RCDC and pharmacy consider the dose invalid, a repeated dose may be given. Consider delaying the repeat dose 8 weeks from the invalid dose. Inform the client of the potential for local and systemic adverse events.
	Dose administered past the expiration/beyond use date.	Contact RCDC and pharmacy for advice. If RCDC and pharmacy consider the dose invalid, a repeated dose may be given. Consider delaying the repeat dose 8 weeks from the invalid dose. Inform the client of the potential for local and systemic adverse events.

Diluent (Pfizer-BioNTech COMIRNATY® only)	Incorrect diluent type.	Contact RCDC and pharmacy for advice as it is likely the manufacturer will need to be contacted for guidance. If RCDC and the pharmacy consider the dose invalid, a repeated dose may be given. Consider delaying the repeat dose 8 weeks from the invalid dose. Inform the client of the potential for local and systemic adverse events.
	ONLY diluent administered.	Inform the client that no vaccine was administered. Administer the authorized (appropriately diluted) dose as soon as possible on the alternate deltoid muscle.
	Too much diluent administered.	For Pfizer-BioNTech COMIRNATY® paediatric formulation, if > 1.3 mL of diluent was added to the vial, consider this an invalid dose. For Pfizer-BioNTech COMIRNATY® adolescent/adult formulation, if > 2 mL of diluent was added to the vial, consider this an invalid dose. If the error is discovered on the same clinic day, administer a full repeat dose immediately on the alternate deltoid muscle. If the error is discovered after the clinic day: • If the invalid dose was a 1st dose, administer a full repeat dose when the error is discovered. • If the invalid dose was not the 1st dose, wait 8 weeks to offer the repeat dose.
	No diluent or less than the recommended diluent, resulting in higher than the authorized dose.	Consider this a valid dose. Inform the client of the potential for local and systemic adverse events.

References

Government of Canada. Quick Reference Guide on Use of COVID-19 Vaccine for Children 5 to 11 Years of Age: Managing Vaccine Administration Errors or Deviations. Date modified 03 Feb 2022. Available from: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/quick-reference-guide-covid-19-vaccines-children/managing-administration-errors-deviations.html

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