# Guidance Document on the Management of Inadvertent Vaccine Errors

**February 4, 2022**

## 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.

There is limited evidence to guide the management of these situations. This document provides guidance only. Health authority protocols may differ from this guidance document and clinical judgement in particular situations may also result in different management decisions than outlined below.

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

## Steps to be taken after an error is recognized

Following the identification of an inadvertent vaccine administration error, healthcare providers should:

- Inform the recipient of the vaccine administration error as soon as possible after it is identified. The recipient should be informed 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).
- Report all errors or near miss incidents in accordance with the institutional medication error or professional body's reporting process, including the BC Patient Safety Learning System (PSLS).
- If an inadvertent vaccine administration error results in an adverse event following immunization (AEFI), complete the AEFI Case Report Form and submit it to the local public health authority. Information on AEFI reporting can be found in the BC Immunization Manual, Part 5: Adverse events Following Immunization.
- Determine how the vaccine administration error occurred and implement strategies to prevent it from happening again.
- 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 local public health authority for advice if considering using serology to investigate an error.
- Additional resources on vaccine administration practices can be found in the BC Immunization Manual, Appendix B: Administration of Biological Products.

| Type | Administration error | Interim guidance on how to consider the dose and recommended action |
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| **Site/route** | Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site]) | Consider this a valid dose.<br><br>Inform the recipient of the error and the potential for local and systemic adverse events and that the dose is considered acceptable. |
| | Incorrect route (e.g., subcutaneous) | Consider this a valid dose.<br><br>Inform the recipient of the error and potential for local and systemic adverse events and that the dose is considered acceptable. |
| **Age** | Use at a younger age than authorized by Health Canada and/or recommended by NACI | Pfizer-BioNTech vaccine:<br>Consider this a valid dose.<br><br>Give the second dose at the recommended interval using the product formulation that is authorized for the client's age (if the client is at least 5 years of age).<br><br>Moderna vaccine:<br>Consider this a valid dose.<br><br>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).<br><br>AstraZeneca/COVISHIELD vaccines:<br>Consider this a valid dose.<br><br>Give the second dose as an mRNA vaccine authorized for the client's age at the recommended interval. |

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| | | Janssen vaccine:<br>Consider this a valid dose.<br><br>The vaccine series is considered complete. |
| | Receipt of a WHO EUA qualified COVID-19 vaccine not authorized in Canada (e.g., Sinovac, Sinopharm, Covaxin) at < 18 years of age | Consider this a valid dose.<br><br>Give the second dose as an mRNA vaccine authorized for the client's age at the recommended interval. |
| **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.<br><br>Consider both doses valid, and the series complete if the second dose was administered:<br>• 18 or more days after the first for Pfizer-BioNTech COVID-19 Vaccine adult / adolescent formulation (30 mcg)<br>• 19 days or more after the first for Pfizer-BioNTech Vaccine pediatric formulation (10 mcg)<br>• 21 or more days after the first for Moderna<br>• 4 or more weeks after the first for AstraZeneca<br><br>If the second dose was administered less than minimum interval indicated above for the respective vaccine, consider the second dose invalid and repeat at the recommended interval between first and second dose (counting from the date of the invalid dose).[1] If a significant local or systemic reaction from the invalid dose occurs, consult an allergist/immunologist before repeating. When repeating the dose, inform the |

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| | | recipient of the potential for local and systemic adverse events. |
| | Second dose administered later than the recommended interval | If administration of the second dose of a COVID-19 vaccine is delayed beyond the recommended interval, the second dose should be provided as soon as possible. No further doses are required. |
| **Dosage** (see Diluent section below for specific information regarding Pfizer-BioNTech and the diluent) | Higher-than-authorized dose volume administered | Consider this dose valid.<br><br>Inform the recipient of the potential for local and systemic adverse events.[2] |
| | 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.<br><br>Administer a full repeat dose immediately in the opposite arm. Inform the recipient of the potential for local and systemic adverse events.[2]<br><br>**Note:**<br>• When Moderna is being used as a 3rd dose in primary series for a moderately to severely immunocompromised individual (for whom the 0.5 mL [100 mcg] dose is recommended) and 0.25 mL (50 mcg) was inadvertently administered:<br>○ If the error is discovered on the same clinic day, another 0.25 mL (50 mcg) dose of Moderna vaccine can be administered on the same day, and the two doses can be counted as one full dose.<br>○ If the error is discovered after the clinic day, consider the dose valid and **do not repeat.** |

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| | **Booster dose**: 0.25 mL (50 mcg) dose of Moderna COVID-19 vaccine given for booster indication to a client for whom a 0.5 mL (100 mcg) dose is recommended (e.g., client ≥ 70 years of age). | Consider this a valid dose. Although NACI recommends a 0.5 mL (100 mcg) booster dose for certain populations, Health Canada has authorized the 0.25 mL (50 mcg) dose for all booster dose indications. |
| | Client aged 12–17 years administered the Pfizer-BioNTech Vaccine pediatric formulation (10 mcg), resulting in a lower-than-authorized dose. | In general, consider this a valid dose and do not repeat dose.<br>• If the dose given in error is the first dose, administer the Pfizer-BioNTech COVID-19 Vaccine adult/adolescent formulation (30 mcg) dose at 8 weeks after the last dose in order to complete the primary series.<br>• If the dose given in error is the second dose, consider valid and the series complete.<br>• However, based on clinical judgement (e.g., the adolescent received two doses of incorrect formulation), a repeat dose of Pfizer- BioNTech COVID-19 Vaccine adult/adolescent formulation (30 mcg) may be administered at an interval of 8 weeks after the dose given in error. |
| | Client ≥18 years of age administered the Pfizer-BioNTech Vaccine pediatric formulation (10 mcg), resulting in a lower-than-authorized dose. | Considered invalid. Repeat dose immediately (no minimum interval) with the age-appropriate dose and formulation. If the dose given in error is the first dose, administer the second dose at the recommended interval after the repeat dose (i.e., 8 weeks after repeat dose) with the age-appropriate formulation. |
| | 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. |

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| **Storage and Handling** | Dose administered after improper storage and handling (e.g., temperature excursion) | Contact BCCDC Pharmacy for guidance. If BCCDC provides information suggesting the dose should be considered invalid and if that seems appropriate based on clinical judgement, a repeated dose may be given as soon as possible in the opposite arm. Inform the recipient of the potential for local and systemic adverse events.[2] |
| | Dose administered past the expiration/beyond use date | Contact BCCDC Pharmacy for guidance. If BCCDC provides information suggesting that the dose should be considered invalid and if that seems appropriate based on clinical judgement, a repeated dose may be given as soon as possible in the opposite arm. 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 BCCDC Pharmacy for guidance. If BCCDC provides information suggesting that the dose be considered invalid and if that seems appropriate based on clinical judgement, a repeated dose may be given as soon as possible in the opposite arm. 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 (Note: For the adult/adolescent formulation, this would be more than 2.0 mL of diluent) | 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] |
| | No diluent or less than the recommended diluent, resulting in higher than the authorized dose | Consider this dose valid.<br>Inform the recipient of the potential for local and systemic adverse events.[2] |

[1] When reviewing immunization records retrospectively, a '4-day grace period' may be applied to doses given ≤ 4 days prior to the recommended minimum interval, allowing such doses to be counted as valid. However, an additional dose may be offered, preferably with an mRNA vaccine, at an interval of 8 weeks after the last dose, as optimal protection is attained when longer intervals are observed. If this additional dose is given at least 8 weeks after the last dose, it will be considered as a valid booster dose. For more information, go to the BC Immunization Manual, Part 1: Immunization Schedules, 4.5.4 Grace Period. **NOTE**: The exception to this is the pediatric formulation of the Pfizer-BioNTech COVID-19 Vaccine for which there is no 4-day grace period allowance to the minimum interval.

[2] If the client requires a final dose to complete the series, an interval of 8 weeks should be used. 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 by the Medical Health Officer and/or 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

Public Health England. COVID-19 vaccination programme: Information for healthcare practitioners Republished 20 May 2021 Version 3.7. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/988091/COVID-19_vaccination_programme_guidance_for_healthcare_workers_20_May_2021_v3.7.pdf