Guidance on the Management of Inadvertent COVID-19 Vaccine Errors

April 2024

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 BC Immunization Manual guidelines (referred to as vaccine administration errors). This document builds on guidance developed by the Public Health Agency of Canada's Managing COVID-19 vaccine administration errors or deviations and the CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.

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 guidelines within the BC Immunization Manual should be followed when administering COVID-19 vaccines to prevent errors or deviations from occurring. The following will be addressed in this document:

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 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 appropriate AEFI Case Report Form found on the Adverse Events Following Immunization page 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.
- As with usual practice, when managing errors and deviations, inquire about the client's history of adverse events following vaccination. If they experienced a significant local or systemic reaction, base your decision to offer subsequent doses on a case-by-case basis in consultation with the Medical Health Officer and/or in consultation with an allergist/immunologist.
- If the client who had a repeat dose following an invalid dose requires a subsequent dose, give it with a recommended age-appropriate dosage and product. Count the interval from the repeat dose.
- 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
Site/route	**Guiding Principle:** COVID-19 vaccines should be administered intramuscularly. The vastus lateralis (anterolateral thigh) is recommended for children less than 1 year of age. The vastus lateralis or the deltoid muscle can be used for toddlers and older children. The deltoid is often selected as the injection site in these age groups as temporary muscle pain in the vastus lateralis muscle post-vaccination may affect ambulation. The deltoid muscle of the arm is the preferred injection site in adolescents and adults. When selecting a site, it is important to consider available muscle mass. Clients administered a vaccine in an incorrect site or by an incorrect route should be informed of the potential for local and systemic adverse events.	
	Incorrect site (i.e., site other than the deltoid muscle or vastus lateralis as appropriate for age)	Consider the dose **valid**.
	Incorrect route (e.g., subcutaneous)	Consider the dose **valid**.
Age	Use at a younger age than authorized by Health Canada and/or recommended by NACI	Consider the dose **valid**.
	Receipt of a WHO EUA qualified COVID-19 vaccine not authorized in Canada (e.g., Sinovac, Sinopharm, Covaxin) at < 18 years of age for one or more doses.	Consider the dose **valid**.
Intervals	**Guiding Principle:** Doses given longer than the recommended interval: While recommended intervals are optimal, doses delayed beyond the recommended interval are considered **valid**. Doses given earlier than the minimum interval: Doses given too close together may result in a suboptimal immune response due to: (1) Less than optimal time to allow for the immune response to mature between doses; and (2) Antibodies produced to the early dose may interfere with the antibody response to the later dose. For information on recommended and minimum intervals for products that are currently available, refer to the respective product pages in the BC Immunization Manual, Part 4-Biological Products, COVID-19 Vaccines.	

<table>
<tr><th>Type</th><th>Administration error</th><th>Interim guidance on how to consider the dose and recommended action</th></tr>
<tr><td rowspan="3"></td><td colspan="2">For review of historical records only - Minimum intervals between doses within the primary series for products no longer available for use:
<table>
<tr><th>Vaccine Product</th><th>Minimum interval between the initial doses of a primary series</th></tr>
<tr><td>Pfizer-BioNTech Adult/Adolescent (original monovalent and bivalent)</td><td>18 days</td></tr>
<tr><td>Pfizer-BioNTech 5-11 years of age (original monovalent and bivalent)</td><td>19 days</td></tr>
<tr><td>Pfizer-BioNTech 6 months to 4 years of age (original monovalent)</td><td>21 days</td></tr>
<tr><td>Moderna 6 years of age and older (original monovalent and bivalent)</td><td>21 days</td></tr>
<tr><td>Moderna 6 months to 5 years of age (original monovalent and bivalent)</td><td>28 days</td></tr>
</table>
Individuals who are moderately to severely immunosuppressed receive an additional dose in the primary series at least 28 days following the previous dose.</td></tr>
<tr><td>Individuals recommended to receive 2 or more doses that receive a subsequent dose prior to the minimum interval indicated between doses.</td><td>If the dose was administered at less than the minimum interval, consider the dose invalid and repeat at the recommended interval (counting from the date of the invalid dose).[1]</td></tr>
<tr><td>An individual received a COVID-19 booster prior to the minimum interval from the last dose of COVID-19 vaccine.</td><td>If 8 weeks has passed since the last dose (i.e., primary series or preceding dose) and the COVID-19 booster dose, consider the current dose valid.

If less than 8 weeks has passed since the last dose (i.e., primary series or preceding dose) and the booster dose, consider the current dose invalid and repeat the dose 6 months from the invalid dose.</td></tr>
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Higher than authorized dose administered	**Guiding Principle:** Doses that are higher than authorized are considered **valid**. The client should be advised of the potential for local and systemic adverse events.	
	Adult dose provided to a child resulting in a higher than authorized dose. This includes a partial adult dose provided to a child resulting in an equivalent or higher than authorized mcg dose for client's age.	Consider this dose **valid**.
Less than authorized dose, product or schedule error based on age (see Diluent section below for specific information regarding Pfizer-BioNTech and the diluent)	**Guiding Principle:** Client should be immunized with the age-appropriate product based on age at presentation. When a client requires more than 1 dose for their age/vaccine history and they transition to a different age prior to all doses given, the age-appropriate product based on age at presentation is given. Lower than the authorized doses may result in a sub-optimal response and are generally considered **invalid**, see exception below. For complete information on authorized doses per product by age, see the respective product pages, within the BC Immunization Manual, Part 4-Biological Products, COVID-19 Vaccines. If a repeat dose is indicated, inform the client of the potential for local and systemic adverse events with the repeat dose.	
	Less than a full dose (dose unknown) was administered (for example, leaked out, equipment failure, client pulled away)	If less than a full dose is administered or the proportion of the dose administered cannot be estimated, consider the dose **invalid**. Administer a full repeat dose as soon as the error is recognized. If this is the same clinic day as the invalid dose, use a separate anatomic injection site whenever possible (e.g., different limb).
	Pfizer-BioNTech Comirnaty 3 mcg dose administered to a child 5 to 11 years (rather than the recommended 10 mcg dose)	Consider this dose **invalid**. Administer a full repeat dose as soon as the error is recognized. If this is the same clinic day as the invalid dose, use a separate

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		anatomic injection site whenever possible (e.g., different limb). [2]
	Exception:	
	Moderna Spikevax 25 mcg dose administered to an individual 12 years of age and older (rather than the recommended 50 mcg dose)	Consider the dose **invalid**. *However*, if the error is discovered in time, offer a 25 mcg dose of Moderna Spikevax vaccine, on the same clinic day in a separate anatomic injection site whenever possible (e.g., different limb) If the dose cannot be given on the same clinic day, offer a full age-appropriate dose as soon as the error is identified.[2]
Storage and handling	**Guiding Principle:** Storage and handling errors or deviations require individual consideration based on the particular circumstances, in consultation with the BCCDC Pharmacy and based on clinical judgement. If deemed to be invalid, a repeat dose may be given as soon as possible at a different site. Inform the recipient of the potential for local and systemic adverse events. For information on Storage and Handling refer to the respective product pages in the BC Immunization Manual, Part 4-Biological Products, COVID-19 Vaccines.	
	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 repeat dose may be given as soon as possible in a separate anatomic injection site whenever possible (e.g., different limb).
	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 repeat dose may be given as

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		soon as possible in a separate anatomic injection site whenever possible (e.g., different limb).
Reconstitution error (some formulations of Pfizer-BioNTech only)	**Guiding Principle:** Reconstitution errors may require individual consideration based on the particular circumstances, in consultation with the BCCDC Pharmacy and based on clinical judgement. If deemed to be invalid a repeat dose may be given as soon as possible at a different site. Inform the recipient of the potential for local and systemic adverse events. For information on diluent volume per product, refer to the respective product pages in the BC Immunization Manual, Part 4-Biological Products, COVID-19 Vaccines.	
	Incorrect diluent type (e.g., sterile water instead of 0.9% sodium chloride for Pfizer dilution)	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 repeat dose may be given as soon as possible in a separate anatomic injection site whenever possible (e.g., different limb).
	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 a separate anatomic injection site whenever possible (e.g., different limb).
	Too much diluent administered resulting in a lower than authorized dose.	Consider this an **invalid** dose. Administer a full repeat dose immediately in a separate anatomic injection site whenever possible (e.g., different limb).
	No diluent or less than the recommended diluent, resulting in higher than the authorized dose.	Consider this dose **valid**. Inform the recipient of the potential for local and systemic adverse events.

Type	Administration error	Interim guidance on how to consider the dose and recommended action
More or less than authorized number of doses obtained from vial	**Guiding Principle:** Depending on the type of supplies used (e.g., low dead volume syringe) the number of doses obtained from vials may vary. As long as the correct volume was drawn up per dose (and the correct amount of diluent was used, if applicable), the doses are **valid**.	

[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. For more information, go to the BC Immunization Manual, Part 1: Immunization Schedules, 4.5.4 Grace Period.

[2] Some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis and pericarditis from mRNA COVID-19 vaccines, particularly in groups at increased risk for myocarditis and pericarditis (e.g., males ages 12–39 years). Individual risk for COVID-19 and the likelihood for an adverse event following vaccination should be taken into consideration when recommending a longer interval.

References

Centres for Disease Control and Prevention (CDC). Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates. Available from: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-d

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 Agency of Canada. Type of administration errors or deviations: Guiding principles and recommended actions. Available from: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/quick-reference-guide-covid-19-vaccines/managing-administration-errors-deviations.html