Ontario

Ministry of Health

COVID-19 Vaccine Administration Errors and Deviations Guidance

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This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

In the event of any conflict between this guidance document and any applicable emergency orders, or directives issued by the Minister of Health, Minister of Long-Term Care, or the Chief Medical Officer of Health (CMOH), the order or directive prevails.

- Please check the Ministry of Health (MOH) COVID-19 website regularly for updates to this document, list of symptoms, other guidance documents, Directives and other information.

Background

This guidance document is intended to assist healthcare providers by providing them with suggested actions to take after an inadvertent immunization error has occurred to support consistent and optimal management of these incidents. A vaccine administration error is any preventable event that may cause or lead to incorrect use of a vaccine and/or patient harm. This guidance also addresses scenarios that deviate from other recommended practices (e.g., vaccine use outside of recommendations made by Canada's National Advisory Committee on Immunization (NACI), but are not vaccine administration errors). These are referred to as "deviations" below.

One of the challenges in the management of inadvertent vaccine administration errors is that there is often limited evidence regarding the potential impact of the error and the appropriate response to mitigate any potential harm or impacts on immune response (protection) as a result of the error.

The following guidance is based on expert opinion from Canada, including published guidance from NACI, the Public Health Agency of Canada (PHAC) as well as the Australian Technical Advisory Group on Immunisation (ATAGI), the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and Public Health England.[1-9] It is intended for reference purposes to support the decision-making of healthcare providers. The table below has been adapted from the CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States to the Canadian context based on expert opinion. This guidance will be updated as additional information becomes available and should only be considered current as of [June 23].

For inadvertent immunization errors and deviations that are not addressed in the table and/or that involve multiple errors or have additional complexity, healthcare providers are encouraged to contact their local Public Health Unit (PHU) for further advice. Local PHUs can contact Public Health Ontario (PHO) at ivpd@oahpp.ca for additional support.

Key steps for healthcare providers:

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

- Inform the recipient of the vaccine administration error or deviation as soon as possible after it has been identified.
- Inform the recipient of any implications/recommendations for future doses, and the possibility for local or systemic adverse events (if applicable and as known).
- Complete Ontario's AEFI reporting form, including details of the error or deviation, if an inadvertent vaccine administration error or deviation results in an adverse event following immunization (AEFI). The completed AEFI form should be submitted to your local PHU.
- Determine how the vaccine administration error or deviation occurred and promptly implement strategies to prevent it from happening again.
- Serologic testing to assess vaccine-induced immunity following COVID-19 vaccine errors or deviations to guide management decisions is generally not recommended. Healthcare providers are encouraged to contact their local PHU or PHO for advice if they are considering using serology to investigate an error or deviation.

- Report all errors, deviations or near miss incidents, in accordance with the institutional medication error and/or professional body's reporting process. Errors can also be reported to the Canadian Medication Incident Reporting and Prevention System (CMIRPS).
- The local PHU should be notified and vaccine administration errors or deviations should be handled and reported in accordance with both the site (if non-PHU) and PHU procedures.
    - Vaccine administration errors and deviations that should be escalated to the Ministry of Health include those that may result in public safety concerns, cause misinformation, serious adverse events or death to any person, or where large volumes of vaccine doses have been impacted or wasted. When in doubt, err on the side of caution and notify the Ministry of Health. For all issues that are escalated to the Ministry of Health, please report these per the following protocol:
        - Email the Ministry of Health Comms team (media.moh@ontario.ca), the EOC (eocoperation.moh@ontario.ca), and the Implementation team (covid.immunization@ontario.ca) with the following header:

Incident Report for [PHU/Site] on [Date]: Description of Incident

- Date of Incident:
- Location of Incident:
- Type of Incident:
    - Administration error or deviation:
- Description of Incident:
- Summary of action steps taken to-date:
- Next steps:

Additional resources on vaccine administration practices can be found in the Canadian Immunization Guide. See the COVID-19 Guidance for Individuals Vaccinated outside of Ontario/Canada for vaccine administration recommendations for non-Health Canada approved vaccines.

Guidance for COVID-19 Vaccine Administration Errors and Deviations

Site / route:

Administration error/deviation	Guidance
• Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site])	• Consider this a valid dose, do **not** repeat this dose. • Inform the recipient of the potential for local and systemic adverse events. • If this was the first dose, the second dose should be given at the Ontario recommended interval.* • Document in the clinical notes field in COVaxON.
• Incorrect route (e.g., subcutaneous)	• Consider this a valid dose, do **not** repeat this dose. • Inform the recipient of the potential for local and systemic adverse events. • If this was the first dose, the second dose should be given at the Ontario recommended interval.* • Document in the clinical notes field in COVaxON.

Age:

Administration error/deviation	Guidance
• Use at a younger age than authorized by Health Canada and/or recommended by NACI	**Pfizer-BioNTech vaccine:** • Consider this a valid dose. • If received first dose at age less than 12 years, do not give a second dose at this time. Offer second dose at 12 years of age or when the vaccine is authorized for their age group. • Document in clinical notes field in COVaxON. **Moderna vaccine:** • Consider this a valid dose. • If received first dose at 12 to < 18 years, individual can be offered a second dose of Pfizer-BioNTech at the Ontario recommended interval.*2 • If received first dose at age less than 12 years, do not give a second dose at this time. Offer second dose of Pfizer-BioNTech at 12 years of age or when the vaccine is authorized for their age group. • Document in clinical notes field in COVaxON. **AstraZeneca, COVISHIELD vaccines:** • Consider this a valid dose. • If received first dose at 12 to < 18 years, individual can be offered a second dose of Pfizer-BioNTech at the Ontario recommended interval.*7 • Document in clinical notes field in COVaxON. **Janssen vaccine:** • Consider this a valid dose. • If received dose at < 18 years, do not give a second dose as the vaccine series is considered complete. • Document in clinical notes field in COVaxON.

Co-administration

Administration error/deviation	Guidance
• COVID-19 vaccine dose administered on the same day, or less than 14 days after another vaccine (e.g., a non-COVID-19 vaccine) OR another non-COVID-19 vaccine administered less than 28 days after a COVID-19 vaccine	• Consider this dose of COVID-19 vaccine and the other vaccine(s) valid. • Do not repeat this dose of the COVID-19 vaccine and do not repeat the dose(s) of other vaccine(s) given. • If this was the first dose, the second dose should be given at the Ontario recommended interval.* • Document in clinical notes field in COVaxON.

Intervals:

Administration error/deviation	Guidance
• Two doses of a COVID-19 vaccine administered on the same day	• Inform the recipient of the potential for local and systemic adverse events. • If one of these doses was the first dose of the series, the second dose given on the same day should be discounted and a third dose given at the Ontario recommended interval.* • Document in clinical notes field in COVaxON and "Discounted" administered dose should be updated to "Status – Invalid" by using the "Review Dose Administered" functionality.[6]
• Second dose administered earlier than the NACI minimum interval (i.e., fewer than 19 days (Pfizer-BioNTech) or fewer than 21 days (Moderna), or fewer than 28 days (AstraZeneca or COVISHIELD) after the first dose	• If a second dose was given less than the minimum recommended interval, the second dose should be considered invalid. Administer a third dose at least 60 days after the invalid dose (i.e., the second dose that was given too early). Inform the recipient of the potential for local and systemic adverse events. • Document in clinical notes field in COVaxON. To invalidate a documented administered dose in COVaxON use the "Review Dose Administered" functionality and update "Status to Invalid." [6]

Administration error/deviation	Guidance
• Second dose administered later than the NACI extended interval (i.e., more than 4 months after the first dose)	• If administration of the second dose of a vaccine is delayed beyond 4 months, it should be provided as soon as possible. No further doses are required. Do not restart the series. • Document in clinical notes field in COVaxON.

Dosage:

Administration error/deviation	Guidance
• Higher-than-authorized dose volume administered (Per Product Monograph)	• Consider this dose valid. Do **not** repeat this dose. Inform the recipient of the potential for local and systemic adverse events. • If this was the first dose, the second dose should be given at the Ontario recommended interval.*3 • Document in clinical notes field in COVaxON.
• Lower-than-authorized dose volume administered (e.g., leaked out, equipment failure, recipient pulled away)	• If more than half of the dose was administered, consider this a valid dose and do not repeat this dose. If this was the first dose, the second dose should be given according to the authorized interval in the product monograph (21 days Pfizer-BioNTech, and 28 days for Moderna and AstraZeneca).* • Document in clinical notes field in COVaxON. • If less than half of the dose was administered or the proportion of the dose administered cannot be estimated, administer the full dose volume as soon as possible, in the opposite arm. [4] Inform the recipient of the potential for local and systemic adverse events. • Document in clinical notes field in COVaxON. To invalidate a documented administered dose in COVaxON use the "Review Dose Administered" functionality and update "Status to Invalid" [6]

Storage and Handling

Administration error/deviation	Guidance
• Dose administered after improper storage and handling (e.g., temperature excursion)	• Contact your local PHU for guidance. Local PHUs will formulate an assessment in consultation with the manufacturer. In the event that it is determined that the dose should be repeated, the repeated dose may be given as soon as possible upon identification of the error, in the opposite arm.[5] • Inform the recipient of the potential for local and systemic adverse events. • If this was the first dose, the second dose should be given at the Ontario recommended interval.*[3] • Document in clinical notes field in COVaxON. To invalidate a documented administered dose in COVaxON use the "Review Dose Administered" functionality and update "Status to Invalid." [6]
• Dose administered past the expiration/beyond use date (e.g., more than 6 hours after first vial puncture)	• Contact your local PHU for guidance. Local PHUs will formulate an assessment in consultation with the manufacturer. In the event that it is determined that the dose should be repeated, the repeated dose may be given as soon as possible upon identification of the error, in the opposite arm.[5] • Inform the recipient of the potential for local and systemic adverse events. • If this was the first dose, the second dose should be given at the Ontario recommended interval.*[3] • Document in clinical notes field in COVaxON. To invalidate a documented administered dose in COVaxON use the "Review Dose Administered" functionality and update "Status to Invalid." [6]

Diluent (Pfizer-BioNTech only)

Administration error/deviation	Guidance
• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)	• Contact your local PHU for guidance. Local PHUs will formulate an assessment in consultation with the manufacturer. In the event that it is determined that the dose should be repeated, the 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. • If this was the first dose, the second dose should be given at the Ontario recommended interval.* • Document in clinical notes field in COVaxON. To invalidate a documented administered dose in COVaxON use the "Review Dose Administered" functionality and update "Status to Invalid" [6]
• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	• Inform the recipient that no vaccine was administered. Administer a valid (appropriately diluted) dose as soon as possible in the opposite arm.5 • Document in clinical notes field in COVaxON. To invalidate a documented administered dose in COVaxON use the "Review Dose Administered" functionality and update "Status to Invalid." [6]
• No diluent, resulting in higher than the authorized dose (i.e., 0.3 ml of undiluted vaccine administered, more concentrated dose)	• Consider this a valid dose. Do not repeat this dose.[3] Inform the recipient of the potential for local and systemic adverse events. • If this was the first dose, then the second dose should be given at the Ontario recommended interval.* • Document in clinical notes field in COVaxON.

Administration error/deviation	Guidance
• Incorrect diluent volume (i.e., the vial contents were diluted with a diluent volume other than 1.8 ml, but a 0.3 ml dose was still administered)	• Inadvertent dilutions with volumes other than 1.8 ml, but between 1.5 ml and 2.0 ml are considered a valid dose. Do not repeat dose. If this was the first dose, the second dose should be given at the Ontario recommended interval.* Document in clinical notes field in COVaxON. • Under-diluted vaccine (more concentrated dose): For doses administered with vial diluent volume less than 1.5 mL (i.e., higher than authorized dosage administered). Consider this a valid dose. Do not repeat dose. Inform the recipient of the potential for local and systemic adverse events. If this was the first dose, the second dose should be given at the Ontario recommended interval.*[3] • Document in clinical notes field in COVaxON. • Over-diluted vaccine (less concentrated dose): Dilution with a volume greater than 2.0 mL: Repeat (correctly diluted) authorized dose as soon as possible in the opposite arm. • Document in clinical notes field in COVaxON. To invalidate a documented administered dose in COVaxON use the "Review Dose Administered" functionality and update "Status to Invalid." [6]

*See the COVID-19 Vaccine Series Second Dose Eligibility Quick Reference for more information on the Ontario recommended interval.

1. National Advisory Committee on Immunization (NACI) Recommendations on the use of COVID-19 vaccines.

2. See NACI's recommendations on interchangeability of authorized COVID-19 vaccines.
3. If the administration error resulted in a higher-than-authorized vaccine dose (more concentrated dose), in general the second dose may still be administered at the Ontario recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the second dose, the decision to administer the second dose and its most appropriate timing should be assessed on a case-by-case basis in consultation with an expert (e.g., allergist, immunologist).

4. PHE and the US Advisory Committee on Immunization Practices (ACIP) recommend administering another full dose of vaccine, if less than a standard recommended dose of vaccine is administered (e.g., due to leakage, spill during administration) with the repeat dose being provided on the same day or as soon as possible, thereafter.

5. If the dose was given in error, the second dose should be administered at the Ontario recommended interval from the date of receipt of the valid dose and not the date of receipt of the invalid dose (i.e., the vaccine dose subject to a vaccine storage or handling issue).

6. In order to use the "Review Dose Administered" functionality the COVaxON user must have the "Site Superuser" role and the client must be in the checked-out status.

7. See NACI's recommendations on interchangeability of authorized COVID-19 vaccines.

References

1. 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

2. 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

3. Public Health England. COVID-19 vaccination programme Information for healthcare practitioners Republished 26 February 2021 Version 3.4. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/965177/COVID-19_vaccination_programme_guidance_for_healthcare_workers_26_February_2021_v3.4.pdf

4. Australian Technical Advisory Group on Immunisation (ATAGI) Clinical guidance on use of COVID-19 vaccine in Australia in 2021. Version 1.0 5 February 2021. Available from: https://www.health.gov.au/sites/default/files/documents/2021/02/covid-19-vaccination-atagi-clinical-guidance-on-covid-19-vaccine-in-australia-in-2021.pdf

5. World Health Organization (WHO). Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing. January 8, 2021. Available from: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendationBNT162b2-2021.1

6. World Health Organization (WHO). Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19. January 25, 2021. Available from: https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-1273-vaccine-against-covid-19

7. World Health Organization (WHO). Interim recommendations for use of the AZD1222 (ChAdOx1-S (recombinant)) vaccine against COVID-19 developed by Oxford University and AstraZeneca. February 10, 2021. Available from: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1

8. Public Health England- Vaccine Incident Guidance: Responding to Errors in Vaccine Administration Storage and Handling. 2020. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/859773/PHE_vaccine_incident_guidance_January_2020.pdf

9. Advisory Committee on Immunization Practices (ACIP). General Best Practices Guidelines for Immunization: Best Practice Guidance of the Advisory Committee on Immunization Practices (ACIP). Available from: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html.