Ministry of Health

COVID-19 Vaccine Administration Errors and Deviations Guidance

Version 2.0- December 30, 2021

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 vaccine administration error or deviation 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 the manufacturer and/or 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 was prepared in consultation with Public Health Ontario (PHO) and is based on expert opinion from Canada, including published guidance from NACI, the Public Health Agency of Canada (PHAC) as well as international guidance from the Centers for Disease Control and Prevention (CDC), the US Advisory Committee on Immunization Practices (ACIP) and Public Health England (PHE). It is intended for reference purposes to support the decision-making of healthcare providers to manage errors or deviations that have already occurred. This guidance will be updated as additional information becomes available and should only be considered current as of [December 30, 2021].

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 and the Ministry of Health at covid.immunization@ontario.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 and impact on effectiveness of the vaccine (if applicable and as known).
- If an inadvertent vaccine administration error or deviation results in an adverse event following immunization (AEFI), complete Ontario's AEFI reporting form, including details of the error or deviation. 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; where large volumes of vaccine doses have been impacted or wasted; or where there is inadvertent administration of exposed and/or expired vaccine to a large number of patients. 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 Communications team (media.moh@ontario.ca), the Implementation team (covid.immunization@ontario.ca) and the EOC (eocoperation.moh@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 and steps taken to-date:
- Next steps:

Additional resources on vaccine administration practices can be found in the Canadian Immunization Guide and MOH Vaccine Administration Guidance.

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. • Any subsequent dose(s) should be given at the Ontario recommended interval.[1] • Document in the clinical notes field in $COVax_{ON}$.
• 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. • Any subsequent dose(s) should be given at the Ontario recommended interval.[1] • Document in the clinical notes field in $COVax_{ON}$.

[1] The Ontario recommended interval between first and second doses is 8 weeks, see the MOH COVID-19 Vaccine Administration guidance for more information. See the MOH COVID-19 Vaccine Third Dose Recommendations for Ontario recommended intervals for third or booster doses.

Age:

Administration error/deviation	Guidance
• Use at a younger age than authorized by Health Canada and/or recommended by NACI	**Pfizer-BioNTech vaccine 5-11 years pediatric formulation (orange cap):** • Consider this a valid dose, do **not** repeat dose. • Inform the recipient of the potential for local and systemic adverse events. • If less than 5 years and the error involved the first dose, offer second dose at the Ontario recommended interval[1] when the individual is eligible and/or when a pediatric formulation of vaccine is authorized for their age group. • Document in clinical notes field in COVax$_{ON}$. **Pfizer-BioNTech vaccine ≥12 years adolescent/adult formulation (purple cap):** • Consider this a valid dose, do **not** repeat dose. • Inform the recipient of the potential for local and systemic adverse events. • If 5 to 11 years and the error involved the first dose, offer second dose of Pfizer-BioNTech vaccine pediatric formulation (orange cap) at the Ontario recommended interval.[1] • If less than 5 years old and the error involved the first dose, offer second dose of Pfizer-BioNTech vaccine pediatric formulation (orange cap) at the Ontario recommended interval[1] when the individual is eligible and/or when a pediatric formulation of vaccine is authorized for their age group.

Administration error/deviation	Guidance
	• Document in clinical notes field in COVax$_{ON}$. **Moderna vaccine:** • Consider this a valid dose, do **not** repeat dose. • Inform the recipient of the potential for local and systemic adverse events. • If less than 12 years and the error involved the first dose, offer second dose of the age appropriate Pfizer-BioNTech vaccine formulation at the Ontario recommended interval.[1] • Document in clinical notes field in COVax$_{ON}$. **AstraZeneca vaccine:** • Consider this a valid dose, do **not** repeat dose. • Inform the recipient of the potential for local and systemic adverse events. • If less than 18 years and the error involved the first dose, offer second dose of the age appropriate Pfizer-BioNTech vaccine formulation at the Ontario recommended interval.[1] • Document in clinical notes field in COVax$_{ON}$. **Janssen (Johnson & Johnson) vaccine:** • Consider this a valid dose, do **not** repeat dose. • Inform the recipient of the potential for local and systemic adverse events. • If received dose at less than 18 years, do not give a second dose as the vaccine series is considered complete. • Document in clinical notes field in COVax$_{ON}$.

Administration error/deviation	Guidance
• Use at an age older than authorized by Health Canada and/or recommended by NACI	**Pfizer-BioNTech Comirnaty® vaccine 5-11 years pediatric formulation (orange cap):** If received dose at age **12-17**, in general, consider this a valid dose and do **not** repeat dose. • If the dose given in error was the first dose, offer second dose of Pfizer-BioNTech vaccine ≥12 adult formulation (30 mcg, purple cap) at the Ontario recommended interval to complete the primary series.[1] If the dose given in error is the second dose, consider the dose valid and the series complete. • However, based on clinical judgement (e.g. if the adolescent received two doses of pediatric (10mcg, orange cap) formulation), a repeat dose of Pfizer-BioNTech vaccine ≥12 adult formulation (30 mcg, purple cap) may be administered at the Ontario recommended interval after the dose given in error.[1] • Document in clinical notes field in COVax$_{ON}$. If received dose at age **≥18 years**, the dose should be considered invalid. Repeat dose immediately (no minimum interval) with the age-appropriate dose and formulation. • Document in clinical notes field in COVax$_{ON}$ and "Discounted" administered dose should be updated to "Status – Invalid" by using the "Review Dose Administered" functionality.[2]

[2] In order to use the "Review Dose Administered" functionality the COVax$_{ON}$ user must have the "Site Superuser" role and the client must be in the checked-out status.

Administration error/deviation	Guidance
	• If the dose given in error was the first dose, administer the second dose at the Ontario recommended interval[1] after the repeat dose with the age-appropriate formulation. • Document in clinical notes field in COVax$_{ON}$.

Co-administration

Administration error/deviation	Guidance
For children 5- 11 years of age where the COVID-19 vaccine administered on the same day or within 14 days of another vaccine (e.g., 14 days before or after a non-COVID-19 vaccine)[3]	• Consider this a valid dose of COVID-19 vaccine and the other vaccine(s) valid. Do **not** repeat this dose of the COVID-19 vaccine or dose(s) of other vaccine(s) given. • If this was the first dose, the second dose should be given at the Ontario recommended interval.[1] • Document in clinical notes field in COVax$_{ON}$.

Intervals:

Administration error/deviation	Guidance
• Two doses of a COVID-19 vaccine administered on the same day	• The second dose given in error should be considered invalid. • Any subsequent dose(s) should be given at the Ontario recommended interval.[1] • Inform the recipient of the potential for local and systemic adverse events. • Document in clinical notes field in COVax$_{ON}$ and "Discounted" administered dose should be updated to "Status – Invalid" by using the "Review Dose Administered" functionality.[3]
• Second dose administered earlier than the NACI minimum interval (i.e., fewer than 19 days (Pfizer-BioNTech) or fewer than	• If a second dose was given at less than the minimum recommended interval, the second dose should be considered invalid.

[3] See the COVID-19 Vaccine Administration guidance for more information on co-administration for children 5-11 years of age.

Administration error/deviation	Guidance
21 days (Moderna), or fewer than 28 days (AstraZeneca or COVISHIELD) after the first dose	Administer the replacement third dose at the Ontario recommended interval.[1] • Inform the recipient of the potential for local and systemic adverse events. • Document in clinical notes field in COVax$_{ON}$. To invalidate a documented administered dose in COVax$_{ON}$, use the "Review Dose Administered" functionality and update "Status to Invalid."[3]
• Second dose administered later than the Ontario recommended interval[1]	• Administer the second dose as soon as possible. There is no maximum interval. • No further doses are required. Do **not** restart the series.
• Third dose of extended primary series (for moderately to severely immunocompromised)[5] administered earlier than the minimum interval of 28 days	• If a third dose of the primary series was given at less than the minimum interval of 28 days, the third dose should be considered invalid. • The dose should be repeated after 8 weeks, however, exact timing should be determined at the discretion of the treating health care provider. • Document in clinical notes field in COVax$_{ON}$. To invalidate a documented administered dose in COVax$_{ON}$, use the "Review Dose Administered" functionality and update "Status to Invalid."[3]
• Booster dose[4] given at less than a 3 month (84 days) interval[1] from the last dose in the primary series	• If at least 8 weeks has passed since the last dose in the primary series, consider the booster dose valid, do **not** repeat this dose. • If less than 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 3 months (84 days) from the invalid dose. • Document in clinical notes field in COVax$_{ON}$.

[4] See the Ministry of Health (MOH) COVID-19 Vaccine Third Dose Recommendations for more information.

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, any subsequent age appropriate dose(s) should be given at the Ontario recommended interval.[1] • Document in clinical notes field in COVax$_{ON}$. • Common errors may include inadvertent administration of a higher-than-recommended dose of the Moderna vaccine based on recipients age or immune status (e.g., a 0.5 ml (100 mcg dose) administered to a recipient under 70 years as a booster).[5]
• 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, do **not** repeat this dose. • If this was the first dose, any subsequent dose(s) should be given at the Ontario recommended interval.[1] • Document in clinical notes field in COVax$_{ON}$. **If less than half of the dose was administered or the proportion of the dose administered cannot be estimated (see note/exception):** • Consider this an invalid dose Repeat the full dose volume 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, any subsequent dose(s) should be given at the Ontario recommended interval.[1] • Document in clinical notes field in COVax$_{ON}$. To invalidate a documented

Administration error/deviation	Guidance
	administered dose in COVax$_{ON}$, use the "Review Dose Administered" functionality and update "Status to Invalid."[3] **Note/Exception:** If Moderna is being used as a booster or additional dose and the full 100 mcg dose is recommended[5] and only 50mcg was inadvertently administered, consider the dose valid, **do not** repeat this dose.[6] **Note/Exception:** if an adolescent 12 to 17 years of age inadvertently received a 10 mcg dose (or more than one 10 mcg dose), consider the dose(s) valid and do not repeat. If this was their first dose, the second should be 30 mcg dose 8 weeks later.
If aged 5–11 years and Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap) inadvertently administered	• If 0.1 mL administered, in general, do not repeat dose. However, based on clinical judgement (e.g., child received 2 doses of incorrect formulation – 0.1 mL ≥12 years formulation (purple cap)) a repeat dose of Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap) may be considered and administered at an interval of 21 days after the dose given in error. • If >0.1 mL administered, resulting in a higher-than-authorized dose, do **not** repeat dose. • If the dose given in error is the first dose, administer the second Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation

[5] See the Ministry of Health (MOH) COVID-19 Vaccine Third Dose Recommendations for recommended Moderna dosage for booster doses.
[6] Although NACI recommends a 0.5 ml (100 mcg) Moderna COVID-19 booster dose for certain populations, Health Canada has authorized the 0.25mL (50 mcg) dose for all booster dose indications.

Administration error/deviation	Guidance
	(orange cap) dose at the Ontario recommended interval.[1]

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.[7] In the event that it is determined that the dose is invalid and 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 subsequent dose(s) should be given at the Ontario recommended interval.[1,] • Document in clinical notes field in $COVax_{ON}$. To invalidate a documented administered dose in $COVax_{ON}$, use the "Review Dose Administered" functionality and update "Status to Invalid."[3]
• Dose administered past the expiration/beyond use date	• Contact your local PHU for guidance. Local PHUs will formulate an assessment in consultation with the manufacturer.[6] • In the event that it is determined that the dose is invalid and should be repeated, the repeated dose may be given as soon as possible upon identification of the error, in the opposite arm. • Inform the recipient of the potential for local and systemic adverse events. • If this was the first dose, the subsequent dose(s) should be given at the Ontario recommended interval.[1]

[7] Lot-specific stability data and/or analysis can be requested from the manufacturer for exposed and/or expired vaccine that is inadvertently administered. This information can be used to assess the stability and potency of administered doses, and help inform recommendations for re-immunization.

Administration error/deviation	Guidance
	• Document in clinical notes field in $COVax_{ON}$. To invalidate a documented administered dose in $COVax_{ON}$, use the "Review Dose Administered" functionality and update "Status to Invalid."[3]

Diluent-Pfizer-BioNTech formulations 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 valid dose should be given at the Ontario recommended interval.[1] • Document in clinical notes field in $COVax_{ON}$. To invalidate a documented administered dose in $COVax_{ON}$, use the "Review Dose Administered" functionality and update "Status to Invalid."[3]
• 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. • Document in clinical notes field in $COVax_{ON}$. To invalidate a documented administered dose in $COVax_{ON}$, use the "Review Dose Administered" functionality and update "Status to Invalid."[3]
• No diluent, resulting in higher than the authorized dose	• Consider this a valid dose, do **not** repeat dose. • Inform the recipient of the potential for local and systemic adverse events.

Administration error/deviation	Guidance
	• If this was the first dose, any subsequent dose(s) should be given at the Ontario recommended interval.[1] • Document in clinical notes field in COVax$_{ON}$.
Under-diluted vaccine (higher-than-authorized dose) Note: for the Pfizer-BioNTech ≥ 12 adolescent/adult formulation (purple cap), this would apply to scenarios where less than 1.5 mL of diluent is added.[9]	• 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, any subsequent dose(s) should be given at the Ontario recommended interval.[1] • Document in clinical notes field in COVax$_{ON}$.
Over-diluted vaccine (lower-than-authorized dose) Note: for the Pfizer-BioNTech ≥ 12 adolescent/adult formulation (purple cap), this would apply to scenarios where more than 2.0 mL of diluent is added[8]	• Consider this an invalid dose. Repeat (correctly diluted) authorized dose as soon as possible in the opposite arm. • If this was the first dose, any subsequent dose(s) should be given at the Ontario recommended interval.[1] • To invalidate a documented administered dose in COVax$_{ON}$, use the "Review Dose Administered" functionality and update "Status to Invalid."[3]

[8] For the Pfizer-BioNTech COVID-19 vaccine ≥ 12 adult/adolescent formulation (purple cap) inadvertent dilutions with diluent volumes other than 1.8 ml, but between 1.5 ml and 2.0 ml are still considered a valid dose as per the manufacturer