

Management of COVID-19 Vaccine Administration Errors and Deviations

Revised September 10, 2021

This table provides guidance and recommendations for immunization providers when immunization errors/deviations have occurred involving COVID-19 vaccine. These recommendations are applicable to Alberta and may differ from other jurisdictions. Immunization providers should follow their regulatory/employer guidance for reporting vaccine administration errors.

This policy is evergreen and will be updated as new information becomes available.

Type	Administration Error/Deviations	Consideration for Validity of Dose	Interim Recommended Action
Site/route	Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site])	<ul style="list-style-type: none"> Consider this a <u>valid</u> dose if given in an IM site. Consider this an <u>invalid</u> dose if given in a non-IM site. 	If invalid, repeat dose. Recommendation for spacing: Repeat same day, if same day not possible, then at least minimum spacing from invalid dose: <ul style="list-style-type: none"> Pfizer - 19 days. Moderna - 21 days. AstraZeneca - 28 days.
	Incorrect route (e.g., subcutaneous)	Consider this an <u>invalid</u> dose.	Repeat dose. Recommendation for spacing: Repeat same day, if same day not possible, then at least minimum spacing from invalid dose: <ul style="list-style-type: none"> Pfizer - 19 days. Moderna - 21 days. AstraZeneca - 28 days.
Age	Use at a younger age than eligible as per the Alberta Immunization Policy.	Pfizer-BioNTech vaccine: <ul style="list-style-type: none"> Consider this a <u>valid</u> dose. 	Pfizer-BioNTech vaccine: <ul style="list-style-type: none"> Give the second dose when client is eligible as per the Alberta Immunization Policy respecting the recommended interval between doses.
		Moderna vaccine: <ul style="list-style-type: none"> Consider this a <u>valid</u> dose. 	Moderna vaccine: <ul style="list-style-type: none"> Give the second dose when client is eligible as per the Alberta Immunization Policy respecting the recommended interval between doses.
		AstraZeneca/COVISHIELD vaccine: <ul style="list-style-type: none"> Consider this a <u>valid</u> dose. 	AstraZeneca/COVISHIELD vaccine: <ul style="list-style-type: none"> 12 to 17 years of age - complete second dose with Pfizer/Moderna vaccine at the recommended interval. Less than 12 years of age - complete second dose with Pfizer/Moderna vaccine at the recommended interval when client eligible as per the Alberta Immunization Policy.

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		Janssen vaccine: <ul style="list-style-type: none"> Consider this a <u>valid</u> dose. The vaccine series is considered complete. 	n/a
Co-administration	COVID-19 vaccine dose administered on the same day, or within 14 days before or within 14 days after a live attenuated vaccine (Inactivated vaccines may be administered on the same day as COVID-19 vaccines or within 14 days of COVID-19 immunization)	Both the COVID-19 and the other vaccine are considered valid.	n/a
Intervals	Second dose of COVID-19 vaccine administered at less than the minimal interval (including on the same day)	Second dose considered <u>invalid if administered</u> : <ul style="list-style-type: none"> Pfizer-BioNTech - less than 19 days after the first dose. Moderna - less than 21 days after the first dose. AstraZeneca - less than 28 days after first dose. Second dose considered <u>valid if administered</u> : <ul style="list-style-type: none"> Pfizer - 19 or more days after the first dose. Moderna - 21 days or more after the first dose. AstraZeneca - 28 days or more after the first dose. 	If invalid, repeat dose. Repeat using <u>at least</u> minimum spacing interval from invalid dose: <ul style="list-style-type: none"> Pfizer - 19 days. Moderna - 21 days. AstraZeneca - 28 days.
Mixed vaccines for first and second doses	A different vaccine used for the first and second dose	<ul style="list-style-type: none"> Vaccines series with the same platform (mRNA) are considered <u>valid</u> and complete e.g. dose 1 Pfizer and dose 2 Moderna. Vaccine series completed with different platforms (mRNA and viral vector) are considered <u>valid</u> and complete. e.g. dose 1 AstraZeneca and dose 2 Pfizer. 	n/a
Mixed vaccine with less than minimal intervals	A different vaccine used for the first and second dose with less than minimal intervals	Consider the first dose valid. Consider second dose valid if administered at minimum interval associated with the first dose. Consider second dose invalid if administered at less than the minimum interval associated with first dose.	If invalid, repeat dose. Repeat using <u>at least</u> minimum spacing interval from invalid dose based on the vaccine being given for dose 2. <ul style="list-style-type: none"> Pfizer - 19 days Moderna - 21 days AstraZeneca - 28 days

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Dosage (see Diluent section below for specific information regarding Pfizer-BioNTech and the diluent)	Higher-than-authorized dose volume administered	Consider this dose <u>valid</u> .	n/a ** Inform the recipient of the potential for local and systemic adverse events. Encourage self-monitoring and reporting. ACTIVE daily surveillance to monitor for adverse events is not required.
	Lower-than-authorized dose volume administered (e.g. leaked out, equipment failure, recipient pulled away)	Any partial dose – considered <u>invalid</u> .	Repeat dose. Recommendation for spacing; Repeat same day, if same day not possible, then at least minimum spacing from invalid dose: <ul style="list-style-type: none"> • Pfizer - 19 days • Moderna - 21 days • AstraZeneca - 28 days
Storage and Handling	Dose administered after improper storage and handling (e.g., temperature excursion)	Contact the manufacturer for guidance: <ul style="list-style-type: none"> • If vaccine determined to be not viable by the manufacturer – dose is considered <u>invalid</u>. • If vaccine determined to be viable by the manufacturer – dose is considered <u>valid</u>. 	For invalid doses – Repeat dose same day or as soon as possible.
	Dose administered past the expiration/beyond use date	Contact the manufacturer for guidance. <ul style="list-style-type: none"> • If vaccine determined to be not viable by the manufacturer – dose is considered <u>invalid</u>. • If vaccine determined to be viable by the manufacturer – dose is considered <u>valid</u>. 	For invalid doses – Repeat dose same day or as soon as possible.
Diluent (Pfizer-BioNTech only)	Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)	Contact the manufacturer for guidance. <ul style="list-style-type: none"> • If vaccine determined to be not viable by the manufacturer – dose is considered <u>invalid</u>. • If vaccine determined to be viable by the manufacturer – dose is considered <u>valid</u>. • If the manufacturer cannot/does not provide information on vaccine viability – consider the dose <u>invalid</u>. 	For invalid doses – Repeat dose same day or as soon as possible.

Type	Administration Error/Deviations	Consideration for Validity of Dose	Interim Recommended Action
Diluent (Pfizer-BioNTech only) <i>Cont.</i>	ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	No vaccine administered.	Provide valid dose as soon as possible.
	More than the recommended amount of diluent used for reconstitution (more than 2.0 mls of diluent)	This is a partial dose – considered <u>invalid</u> .	Repeat dose. Recommendation for spacing: Repeat same day, if same day not possible then <u>at least</u> minimum spacing from invalid dose: <ul style="list-style-type: none"> • Pfizer - 19 days. • Moderna - 21 days. • AstraZeneca - 28 days.
	No diluent or less than the recommended amount of diluent used for reconstitution, resulting in higher than the authorized dose	Consider this dose <u>valid</u> .	n/a ** Inform the recipient of the potential for local and systemic adverse events. Encourage self-monitoring and reporting. ACTIVE daily surveillance to monitor for adverse events is not required.
Vaccines received in other countries	Individual has received one dose of a non-Health Canada authorized COVID-19 vaccine outside of Canada.	Refer to WHO list - follow the status of COVID-19 Vaccines within WHO EUL/PQ evaluation process here . Check status of assessment If Finalized – consider dose <u>valid</u> . If not finalized OR vaccine type unknown– consider dose <u>invalid</u> .	<u>If valid dose</u> : complete series with mRNA vaccine. Individuals may receive two doses of mRNA vaccine if they request two doses to be given. All doses are considered valid. <u>If invalid dose</u> : restart series with mRNA vaccine.
	Individual has received two doses of a non-Health Canada authorized COVID-19 vaccine outside of Canada.	Refer to WHO list - follow the status of COVID-19 Vaccines within WHO EUL/PQ evaluation process here . Check status of assessment If Finalized – consider <u>valid</u> series. If not finalized OR vaccine type unknown— consider <u>invalid</u> series.	<u>If valid doses</u> : offer one dose of mRNA vaccine. Individuals may receive two doses of mRNA vaccine if they request two doses to be given. All doses are considered valid (i.e. may be up to 4 valid doses). <u>If invalid doses</u> : restart series with mRNA vaccine..

Adapted and based on the Public Health Agency of Canada's document - Guidance Document on the Management of Inadvertent Vaccine Errors (May 2021).