

## Management of COVID-19 Vaccine Administration Errors and Deviations

Revised May 2, 2022

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 vastus lateralis [alternate site] or ventrogluteal)	<ul style="list-style-type: none"> <li>Consider this an <u>invalid</u> dose if given in site other than the deltoid, vastus lateralis, or ventrogluteal.</li> </ul>	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"> <li>Pfizer-BioNTech - 19 days.</li> <li>Moderna - 21 days.</li> <li>Novavax – 21 days.</li> <li>AstraZeneca - 28 days.</li> </ul>
	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"> <li>Pfizer-BioNTech - 19 days.</li> <li>Moderna - 21 days.</li> <li>Novavax – 21 days</li> <li>AstraZeneca - 28 days.</li> </ul>
Age	Use at a <u>younger age</u> than eligible as per the Alberta Immunization Policy.	<b>Pfizer-BioNTech Pediatric</b> (5 to 11 year vaccine) given to a child less than 5 years old: <ul style="list-style-type: none"> <li>Consider this a <u>valid</u> dose.</li> </ul>	<ul style="list-style-type: none"> <li>Give the second dose using the Pfizer-BioNTech 5 to 11 year or Moderna child dosing for 6 to 11 year vaccine when client is eligible as per the Alberta Immunization Policy respecting the recommended interval between doses.</li> </ul>
		<b>Pfizer-BioNTech</b> (12 years and older vaccine) given to a child less than 12 years old: <ul style="list-style-type: none"> <li>Consider this a <u>valid</u> dose.</li> </ul>	<ul style="list-style-type: none"> <li>Give the second dose using the Pfizer-BioNTech 5 to 11 year or Moderna child dosing for 6 to 11 year vaccine when client is eligible as per the Alberta Immunization Policy respecting the recommended interval between doses.</li> </ul>

Type	Administration Error/Deviations	Consideration for Validity of Dose	Interim Recommended Action
Age (cont.)		<b>Moderna child dosing</b> (50 mcg for 6 to 11 year vaccine) given to a child less than 6 years old <ul style="list-style-type: none"> <li>Consider this a <u>valid</u> dose.</li> </ul>	<ul style="list-style-type: none"> <li>Give the second dose using the Pfizer-BioNTech 5 to 11 year or Moderna child dosing for 6 to 11 year vaccine when client is eligible as per the Alberta Immunization Policy respecting the recommended interval between doses.</li> </ul>
		<b>Moderna adult dosing</b> (100 mcg for 12 years and older) given to a child less than 12 years old: <ul style="list-style-type: none"> <li>Consider this a <u>valid</u> dose.</li> </ul>	<ul style="list-style-type: none"> <li>Give the second dose using the Pfizer-BioNTech 5 to 11 year or Moderna child dosing for 6 to 11 year vaccine when client is eligible as per the Alberta Immunization Policy respecting the recommended interval between doses.</li> </ul>
		<b>Novavax</b> vaccine given to an individual less than 18 years old <ul style="list-style-type: none"> <li>Consider this a <u>valid</u> dose.</li> </ul>	<ul style="list-style-type: none"> <li>Less than 12 years of age - complete second dose using the Pfizer-BioNTech 5 to 11 year or Moderna child dosing for 6 to 11 year vaccine when client is eligible as per the Alberta Immunization Policy respecting the recommended interval between doses.</li> <li>12 to 17 years of age - complete second dose with Pfizer-BioNTech 12 years and older or Moderna child dosing for 12 years and older vaccine at the recommended interval</li> </ul>
		<b>AstraZeneca/COVISHIELD</b> vaccine given to an individual less than 18 years old: <ul style="list-style-type: none"> <li>Consider this a <u>valid</u> dose.</li> </ul>	<ul style="list-style-type: none"> <li>Less than 12 years of age - complete second dose using the Pfizer-BioNTech 5 to 11 year or Moderna child dosing for 6 to 11 year vaccine when client is eligible as per the Alberta Immunization Policy respecting the recommended interval between doses.</li> <li>12 to 17 years of age - complete second dose with Pfizer-BioNTech 12 years and older or Moderna child dosing for 12 years and older vaccine at the recommended interval.</li> </ul>
		<b>Janssen</b> vaccine given to an individual less than 18 years old: <ul style="list-style-type: none"> <li>Consider this a <u>valid</u> dose.</li> <li>The vaccine series is considered complete.</li> </ul>	n/a

Type	Administration Error/Deviations	Consideration for Validity of Dose	Interim Recommended Action
Age (cont.)	WHO approved (non Health Canada approved) vaccines - Use at <u>younger age</u> than approved by WHO	<b>Sinovac, Sinopharm, or Covaxin</b> vaccine given to an individual less than 18 years old: <ul style="list-style-type: none"> <li>Any dose given under 18 years of age is considered invalid.</li> </ul>	Restart series with mRNA vaccine.
		<b>Covovax</b> vaccine given to an individual less than 18 years old: <ul style="list-style-type: none"> <li>Consider this a <u>valid</u> dose.</li> </ul>	<ul style="list-style-type: none"> <li>Less than 12 years of age - complete <u>second</u> dose using the Pfizer-BioNTech 5 to 11 year or Moderna child dosing for 6 to 11 year vaccine when client is eligible as per the Alberta Immunization Policy respecting the recommended interval between doses.</li> <li>12 to 17 years of age - complete second dose with Pfizer-BioNTech 12 years and older or Moderna child dosing for 12 years and older vaccine at the recommended interval.</li> </ul>
	Use at an <u>older age</u> than eligible as per the Alberta Immunization Policy.	See below "Dosage - lower than authorized dose".	
Co-administration	In Children 5 to 11 years of age: COVID-19 vaccine administered on the same day, or within 14 days before or after another vaccine.	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"> <li>Pfizer-BioNTech - less than 19 days after the first dose.</li> <li>Moderna - less than 21 days after the first dose.</li> <li>Novavax – less than 21 days after the first dose.</li> <li>AstraZeneca - less than 28 days after the first dose.</li> </ul> Second dose considered <u>valid if administered</u> : <ul style="list-style-type: none"> <li>Pfizer-BioNTech - 19 days or more after the first dose.</li> <li>Moderna - 21 days or more after the first dose.</li> <li>Novavax – 21 days or more after the first dose.</li> <li>AstraZeneca - 28 days or more after the first dose.</li> </ul>	If invalid, repeat dose. Repeat using <u>at least</u> minimum spacing interval from invalid dose: <ul style="list-style-type: none"> <li>Pfizer-BioNTech - 19 days.</li> <li>Moderna - 21 days.</li> <li>Novavax – 21 days.</li> <li>AstraZeneca - 28 days.</li> </ul>

Type	Administration Error/Deviations	Consideration for Validity of Dose	Interim Recommended Action
<b>Intervals (cont.)</b>	Immunocompromised - third dose of COVID-19 vaccine for immunocompromised as part of the primary series administered at less than the minimal interval (including on the same day)	Third dose considered <u>invalid</u> if administered: <ul style="list-style-type: none"> <li>less than 28 days after the second dose regardless of vaccine type.</li> </ul> Third dose considered <u>valid</u> if administered: <ul style="list-style-type: none"> <li>28 days or more after the second dose regardless of the vaccine type.</li> </ul>	If invalid, repeat dose. Repeat <u>at least</u> 8 weeks after invalid dose.
	Booster/additional dose(s) of COVID-19 vaccine administered at less than the recommended interval [for those that are eligible for a booster/additional dose(s)]	Booster/additional dose(s) considered <u>invalid</u> if administered: <ul style="list-style-type: none"> <li>less than 28 days after the previous dose.</li> </ul> Booster/additional dose(s) considered <u>valid</u> if administered: <ul style="list-style-type: none"> <li>28 days or more after the previous dose.</li> </ul>	If invalid, repeat dose. <ul style="list-style-type: none"> <li>Repeat <u>at least</u> 5 calendar months after invalid dose.</li> </ul> With the exception of individuals who require an additional dose for travel: <ul style="list-style-type: none"> <li>Repeat <u>at least</u> 28 days after invalid dose.</li> </ul>
	Janssen	Janssen COVID-19 given 28 days or more following another COVID-19 vaccine consider dose valid.  If Janssen COVID-19 given at less than 28 days following another COVID-19 vaccine consider dose invalid.	If invalid: repeat dose at least 28 days after invalid dose.
<b>Mixed vaccines for first and second doses</b>	A different vaccine used for the first and second dose	Refer to <a href="#">Defining Fully Immunized – COVID-19</a> for mixed schedules.  Any mix of WHO approved vaccines is acceptable in Alberta as long it respects minimum spacing requirements.  See WHO list <a href="#">here</a> . Follow the status of COVID-19 Vaccines within WHO EUL/PQ evaluation process. Vaccines accepted in Alberta are “Finalized” under status of assessment.	n/a
<b>Mixed vaccine with less than minimal intervals</b>	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"> <li>Pfizer-BioNTech - 19 days.</li> <li>Moderna - 21 days.</li> <li>Novavax – 21 days.</li> <li>AstraZeneca - 28 days.</li> </ul>

Type	Administration Error/Deviations		Consideration for Validity of Dose	Interim Recommended Action
<b>Dosage</b> (see Diluent section below for specific information regarding Pfizer-BioNTech and the diluent)	Higher-than-authorized dose volume administered	5 to 11 years of age	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.
		12 to 17 years of age		
		18 years and older		
		Booster doses of Moderna	Those who received a booster dose of Moderna 100 mcg but were recommended to receive Moderna 50 mcg as per Alberta Immunization Policy - consider the dose <u>valid</u> .	n/a
	Lower-than-authorized dose/volume administered (e.g. incorrect formulation/ dosage, leaked out, equipment failure, recipient pulled away)	5 to 11 years of age	Any partial dose – consider this dose <u>invalid</u> .	For invalid doses - 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"> <li>Pfizer-BioNTech - 19 days.</li> <li>Moderna - 21 days.</li> <li>Novavax – 21 days.</li> <li>AstraZeneca - 28 days.</li> </ul>
		12 to 17 years of age	A dose of the Pfizer-BioNTech 5 to 11 year vaccine (10 mcg dose) Primary Series: <ul style="list-style-type: none"> <li>Only one dose is considered <u>valid</u>; any other doses are considered <u>invalid</u>.</li> </ul> Booster Dose: <ul style="list-style-type: none"> <li>Dose is considered <u>invalid</u>.</li> </ul> A dose of the Moderna child dosing for 6 to 11 year vaccine (50 mcg dose) <ul style="list-style-type: none"> <li>All doses are considered <u>valid</u>.</li> </ul> Any other partial dose – consider the dose <u>invalid</u> .	
		18 years and older	A dose of the Pfizer-BioNTech 10 mcg is considered <u>invalid</u> .  A dose of the Moderna child dosing for 6 to 11 year vaccine (50 mcg dose) is considered <u>invalid</u> .  Any other partial dose is considered <u>invalid</u> .	
		Booster doses of Moderna	Those who received a booster dose of Moderna 50 mcg but were recommended to receive Moderna 100 mcg as per Alberta Immunization Policy – consider the dose <u>valid</u> .	n/a

Type	Administration Error/Deviations	Consideration for Validity of Dose	Interim Recommended Action
<b>Diluent (Pfizer-BioNTech only)</b>	Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)	Contact the manufacturer for guidance. <ul style="list-style-type: none"> <li>If vaccine determined to be not viable by manufacturer – dose is considered invalid.</li> <li>If vaccine determined to be viable by the manufacturer – dose is considered valid.</li> <li>If the manufacturer cannot/does not provide information on vaccine viability – consider the dose invalid.</li> </ul>	For invalid doses – Repeat dose same day or as soon as possible.
	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 invalid	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"> <li>Pfizer-BioNTech - 19 days.</li> </ul>
	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.
<b>Storage and Handling</b>	Dose administered after improper storage and handling (e.g., temperature excursion)	Contact the manufacturer for guidance: <ul style="list-style-type: none"> <li>If vaccine determined to be not viable by the manufacturer – dose is considered <u>invalid</u>.</li> <li>If vaccine determined to be viable by the manufacturer – dose is considered <u>valid</u>.</li> </ul>	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"> <li>If vaccine determined to be not viable by the manufacturer – dose is considered <u>invalid</u>.</li> <li>If vaccine determined to be viable by the manufacturer – dose is considered <u>valid</u>.</li> </ul>	For invalid doses – Repeat dose same day or as soon as possible.



Type	Administration Error/Deviations	Consideration for Validity of Dose	Interim Recommended Action
<b>Vaccines received in other countries</b>	Individual has received one dose of a non-Health Canada authorized COVID-19 vaccine outside of Canada.	Refer to <a href="#">Defining Fully Immunized – COVID-19</a> for the list of non-Health Canada authorized COVID-19 vaccines that are currently accepted and considered valid in Alberta.  See WHO list <a href="#">here</a> . Follow the status of COVID-19 Vaccines within WHO EUL/PQ evaluation process. Vaccines accepted in Alberta are “Finalized” under status of assessment.	<b>If valid dose:</b> complete series with mRNA vaccine at least 28 days after valid dose.  Individuals may receive two doses of mRNA vaccine if they request two doses to be given. All doses are considered valid.  See <a href="#">Vaccine Eligibility and Scheduling</a> document to assess for additional dose eligibility. ADD LINK  <b>If invalid dose:</b> restart series with mRNA vaccine.
	Individual has received two doses of a non-Health Canada authorized COVID-19 vaccine outside of Canada.	Refer to <a href="#">Defining Fully Immunized – COVID-19</a>  See WHO list <a href="#">here</a> . Follow the status of COVID-19 Vaccines within WHO EUL/PQ evaluation process. Vaccines accepted in Alberta are “Finalized” under status of assessment.	<b>If valid doses:</b> offer one dose of mRNA vaccine at least 28 days after the last valid dose to those who received Sinovac, Sinopharm, or Covaxin.  Individuals may receive two doses of mRNA vaccine if they request two doses to be given. All doses are considered valid.  See <a href="#">Vaccine Eligibility and Scheduling</a> document to assess for additional dose eligibility.  <b>If invalid doses:</b> restart series with mRNA vaccine.
	Individual has received a third/booster/additional dose(s) of a non-Health Canada authorized COVID-19 vaccine outside of Canada. (Validity of previous doses requires confirmation as described above.)	See WHO list <a href="#">here</a> . Follow the status of COVID-19 Vaccines within WHO EUL/PQ evaluation process. Vaccines accepted in Alberta are “Finalized” under status of assessment.  For ‘Vaccines accepted in Alberta’: Third/booster/additional dose(s) considered <b>invalid if administered:</b> <ul style="list-style-type: none"> <li>less than 28 days after the previous dose.</li> </ul> Third/booster/additional dose(s) considered <b>valid if administered:</b> <ul style="list-style-type: none"> <li>28 days or more after the previous dose.</li> </ul>	<b>If valid dose:</b> additional doses may be indicated as per Alberta’s COVID-19 <a href="#">Vaccine Eligibility and Scheduling</a> .  <b>If invalid dose:</b> offer mRNA vaccine as per Alberta’s COVID-19 <a href="#">Vaccine Eligibility and Scheduling</a> .

Adapted and based on the Public Health Agency of Canada’s document – “Quick reference quick on use of COVID-19 vaccines for Adults and adolescents (12 or 18 years of age and over)” and “Quick reference guide on use of COVID-19 vaccines for children (5 to 11 years of age)”.