



ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors

Version 2.2

Updated: 8 August 2024

What's changed: Removal of vaccine formulations that are no longer available.

A vaccine administration error occurs when a COVID-19 vaccine is given outside the current clinical recommendations available in the [Australian Immunisation Handbook](#). Immunisation providers should ensure that best practice is followed and training undertaken to minimise the risk of errors occurring.

The table below provides advice on management of a range of possible COVID-19 vaccine administration errors, including when a replacement (repeat) dose is recommended. Note that a risk/benefit discussion may be required with the individual to determine if a replacement dose is needed.

For all vaccine providers:

When a vaccine administration error occurs:

- inform the recipient (open disclosure)
- follow the advice below
- then, continue as per the relevant COVID-19 vaccination schedule, unless otherwise indicated
- review how the error occurred and, if required, implement procedures to prevent it happening again
- report the error as an adverse event, even if no adverse event has occurred – you can do this through your state or territory health department, or directly to the TGA at www.tga.gov.au/reporting-problems
- if a dose is deemed to be invalid but has already been entered into the Australian Immunisation Register (AIR), you may need to advise the AIR. The best way to do this is by calling 1800 653 809.

Type of error	Administration error	Replacement dose recommendation
Site/route	Incorrect site (site other than deltoid or anterolateral thigh)	Do not give a replacement dose.
	Incorrect route (subcutaneous or intradermal)	Do not give a replacement dose.
Higher than the approved dose	Higher than approved dose of correct formulation administered	Do not give a replacement dose. ¹
	A vaccine administered to a person younger than the approved age registered for that vaccine.	Do not give a replacement dose (and regard this dose as clinically valid). ¹ Give the next COVID-19 vaccine dose with a vaccine formulation approved for use for age at the recommended interval.

Type of error	Administration error	Replacement dose recommendation
Lower than approved dose	Lower than approved dose or unknown dose of correct formulation administered	<p>If less than half of the vaccine dose (estimated) was administered, give a replacement dose as soon as feasible.</p> <p>If half or more than half of the vaccine dose (estimated) was administered, do not repeat the dose.</p>
Diluent COMIRNATY (PFIZER) child hood formulations only	Only diluent administered (i.e., no vaccine ingredient)	Give a replacement dose as soon as feasible.
	No diluent or too little diluent (results in a higher than approved dose*)	Do not give a replacement dose. ¹
	Too much diluent (results in a lower than approved dose*)	<p>If less than half of the age-appropriate vaccine dose was administered, give a replacement dose as soon as feasible.</p> <p>If half or more than half of the age-appropriate vaccine dose was administered, do not give a replacement dose.</p>
	Incorrect diluent (sterile water)	Give a replacement dose as soon as feasible.
	Vaccine vial of vaccine re-diluted after use	<p>If the final concentration of the multidose vial can be estimated and it is known which patients received it, apply the 'too much diluent' advice.</p> <p>If it is not clear which patients received the vaccine, or the final concentration of the multidose vial cannot be estimated, seek expert advice from jurisdictional program or specialist immunisation service.</p>
Vaccines administered after incorrect storage and handling ALL VACCINES	Temperature excursions /cold chain breaches	<p>Assess impact of temperature excursion on vaccine stability and potency on a case-by-case basis to decide whether a replacement dose is needed.</p> <p>If temperature excursion is outside storage conditions described in the product information, contact the Vaccine Operations Centre (VOC) on 1800 318 208 for advice.</p>
	Vaccines administered past the expiration or use-by date	Contact the VOC on 1800 318 208 for advice.

Type of error	Administration error	Replacement dose recommendation
Incorrect dose intervals	A dose in a primary series is given earlier than recommended (including third doses for severely immunocompromised)	<p>If a dose was given less than 14 days after the last dose, a replacement dose is generally recommended between 4 and 8 weeks from the invalid dose. A risk-benefit assessment with a vaccine provider is recommended.</p> <p>If a dose was given 14 days or later from the last dose, do not give a replacement dose.²</p>
	The first booster dose is given earlier than recommended	<p>If given less than two months after the last primary dose, a replacement dose is recommended from 6 months after the invalid dose.</p> <p>If a dose is given at 2 months or later after the last primary dose, do not give a replacement dose.²</p>
	Interval between subsequent doses in a schedule is shorter than recommended	Replacement dose generally not recommended, however an individual assessment with a vaccine provider may be required.
	Interval between subsequent doses in a schedule is longer than recommended	Do not give a replacement dose.
Multiple doses	More doses administered than recommended by the relevant schedule	<p>Monitor for adverse events.</p> <p>As new recommendations for vaccines schedules emerge, consider all doses given.</p>

Sources: ATAGI, Centers for Disease Control and Prevention (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html>).

¹ Monitor for adverse events. Subsequent doses should be given at the scheduled time. If serious or ongoing local or systemic adverse events occur, subsequent doses should be assessed on a case-by-case basis in consultation with an immunologist or specialist immunisation service.

² The minimum intervals of 14 days between primary course doses and 2 months between a booster dose and the last primary series dose are considered valid in the Australian Immunisation Register (AIR).