SA Health COVID-19 Immunisation (Program) Error Guidelines

An immunisation (program) error is any preventable event that involves inappropriate use of vaccine or may result in patient harm. This document is intended to assist vaccination providers with managing exceptional situations in which an immunisation (program) error has occurred and will be updated as additional information and/or vaccines become available. Immunisation (program) errors are a type of medication incident and include errors relating to:

1. the type or formulation of vaccine used, including where a contraindication exists, or the vaccine is not approved for the age group of the recipient
2. incorrect vaccine preparation, dosage, dosage interval or administration site/route
3. use of vaccines which have expired or were incorrectly stored e.g. cold chain breach

Some of these error types may occur secondary to inaccurate patient information (e.g. age, date of birth or previous vaccinations) being provided in the absence of access the Australian Immunisation Register, such as when internet access is temporarily unavailable.

The relevant **TGA COVID-19 Vaccine Product Information Sheets** and **ATAGI COVID-19 Clinical Guidance** and **Statements** on use of COVID-19 vaccines in Australia, should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation and administration of COVID-19 vaccines. The tabulated information provided over page about management of immunisation (program) errors should not be interpreted as a recommendation or promotion of unauthorized use of these vaccines.

Procedures following all immunisation (program) errors

1. **Inform** the recipient/guardian of the immunisation (program) error.
2. **Report** all immunisation (program) errors, including those not associated with known patient harm, to **both**:
    a. SA Health Communicable Disease Control Branch (CDCB) Immunisation Section COVID-19 Clinical Advisory Service online via COVID-19 Vaccination: Program Error Report or via phone on 1300 232 272 during business hours; **and**
    b. National COVID-19 Vaccine Operations Centre (VOC) via email: COVID19VaccineOperationsCentre@health.gov.au or phone: 1800 318 208 between 7am to 10pm (AEST).
3. **Report** any serious or unexpected adverse events following immunisation (AEFI) occurring in the associated vaccine recipient(s) to SA Health using the South Australian Vaccine Safety Surveillance System (SAVSS) Vaccine Reaction Reporting Form, or if unable to complete an online report, phone 1300 232 272 during business hours. In the case of serious or fatal AEFIs, this phone number should be used for urgent after hours reporting.
4. **Contact** Australian Immunisation Register (AIR) on 1800 653 809 to update AIR record if a dose is deemed to be invalid.
5. **Analyse** how the error occurred. **Implement** strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in the "Preparing for Vaccination" and "Administration of Vaccines" chapters of the Australian Immunisation Handbook.

Vaccine(s)	Error type	Error subcategory	Interim recommendation
COVID-19 vaccines currently TGA - approved and supplied for use in Australia: Astra Zeneca Moderna Novavax Pfizer Pfizer paediatric	Site or route of administration error	Incorrect site i.e. site other than deltoid muscle (preferred) or anterolateral thigh (alternate site)	• Do **not** repeat dose[1] • Inform the recipient/guardian of the potential for local and systemic adverse events[1]
		Incorrect route (e.g. subcutaneous)	• Do **not** repeat dose* • Inform the recipient/guardian of the potential for local and systemic adverse events[1]
	Unapproved use of vaccine	Any COVID-19 vaccine given to a child aged less than 5	• Do **not** give a replacement dose • If the child is almost 5 years old at time of administration, seek expert advice on schedule completion once they turn 5[4]
		Unapproved vaccine type given to child aged 5 to 11 years	• If a COVID-19 vaccine is administered which is not approved for the child's age group (Pfizer paediatric formulation if 5-11 years or Moderna (50 µg) if aged 6-11 years), do **not** repeat dose • Inform the recipient/guardian of the potential for local and systemic adverse events[1] • If dose given in error is the **first dose**, administer dose two of an age-appropriate vaccine at the recommended interval after the first dose • If dose given in error is the **second dose**, and the child meets the criteria for receiving a third dose, administer an age-appropriate vaccine 2 months after the second dose
		Booster dose given to an ineligible child aged 5 to 15 years	• Booster doses of Pfizer are recommended for children aged 12-15 years who are severely immunocompromised, have a disability with significant or complex health needs or have complex and/or multiple health conditions that increase the risk of severe COVID-19 • If a booster dose is given to a child not meeting the above criteria, inform the recipient/guardian of the potential for local and systemic adverse events, which if occurring should be reported
		Astra Zeneca or Novavax given to child aged 6 to 17 years	• Inform the recipient/guardian of the potential for local and systemic adverse events[1] • If **Astra Zeneca or Novavax is** administered as **first** dose, administer Pfizer or age-appropriate dose of Moderna as dose two at the recommended interval after the first dose[9] • If **Astra Zeneca or Novavax is** administered as a **second** dose, do **not** give any additional dose of COVID-19 vaccine as the course is considered complete at this time. • If a 3rd primary dose is required i.e. in severely immunosuppressed individuals, administer Pfizer or Moderna (at age appropriate dose) 2 months after the second dose, although a minimum interval of 4 weeks may be considered in exceptional circumstances (e.g. anticipated intensification of immunosuppression; outbreaks)[6,7]

Vaccine(s)	Error type	Error subcategory	Interim recommendation
COVID-19 vaccines currently TGA - approved and supplied for use in Australia: Astra Zeneca Moderna Novavax Pfizer Pfizer paediatric *(continued)*	Unapproved use of vaccine *(continued)*	Pfizer paediatric formulation given to child aged 12 to 17 years	• If it is a single dose error (1st, 2nd, or 3rd dose) a replacement dose is generally not required. • However, a replacement dose can be considered 21 days after the last dose if the error has occurred on more than one occasion (e.g. 2 doses of incorrect paediatric formulation have been given), or based on specialist advice regarding immunocompromised or otherwise medically-at risk children
		Pfizer paediatric formulation given to individuals aged 18 years and over	• If Pfizer-BioNTech Vaccine 5–11 years formulation (orange cap) is administered, resulting in a lower-than-authorized dose, i.e. less than half of the vaccine dose (estimated), give a replacement dose as soon as feasible after the invalid dose, and subsequent dose(s) as indicated[4]
		Unapproved vaccine type used as booster	• If a vaccine other than Pfizer is administered as a booster dose to eligible individuals[10] aged 12 to 17 years, do **not** repeat dose. • If Novavax is used as a booster in individuals aged 16 or older, do **not** repeat dose. • Inform the recipient/guardian of the potential for local and systemic adverse events
	Dosage error	More than the recommended dose volume administered	• A replacement dose is **not** recommended[†]
		Less than half dose volume (estimated) administered (e.g. leaked out, equipment failure, recipient pulled away, incorrect diluent volume)	• Give a replacement dose as soon as feasible after the invalid dose, and a subsequent dose as indicated[4]
	Storage or handling breach	Dose administered after improper storage and handling (e.g. temperature excursion, exceeding acceptable time after first vial puncture)	• Report to the Commonwealth Vaccine Operations Centre (VOC) 1800 318 208 and South Australian Communicable Disease Control Branch (CDCB) 1300 232 272 • If replacement dose administration is advised, it should be given as soon as feasible after the invalid dose, and a subsequent dose as indicated[4]

Vaccine(s)	Error type	Error subcategory	Interim recommendation
COVID-19 vaccines currently TGA - approved and supplied for use in Australia: Astra Zeneca Moderna Novavax Pfizer Pfizer paediatric *(continued)*	Storage or handling breach *(continued)*	Dose administered past the expiration/beyond-use date	• Report to Commonwealth Vaccine Operations Centre 1800 318 208 and CDCB 1300 232 272 • If replacement dose administration is advised, it should be given as soon as feasible after the invalid dose, with a subsequent dose(s) if indicated in vaccination schedule[4]
	Coadministration error	COVID-19 vaccine is administered at less than recommended interval from administration of another medication (e.g. immunosuppressants)	• Case-by-case assessment with treating physician/specialist is warranted to guide the most appropriate actions in these situations

	Dosing interval error	Second primary course dose administered **less than 14 days** after the first dose	• **Recommended intervals** between dose 1 and 2 for COVID-19 vaccines are:
			  ○ Pfizer paediatric formulation for children aged 5-11 years and Moderna (50 µg) for children aged 6-11 years): **8 weeks**, or a minimum of 3 weeks in special circumstances (prior to the initiation of significant immunosuppression or international travel,[5] or for higher risk ('Medical At Risk') groups (such as those with medical risk factors for severe illness) in the context of ongoing community transmission[6] according to ATAGI recommendations
			  ○ Pfizer for 12 years and older: **8 weeks** (approved range: 3 to 8 weeks)
			  ○ Moderna: **8 weeks** (approved range: 4 to 8 weeks)
			  ○ Novavax: **3 to 8 weeks**[11]
			  ○ AstraZeneca: **12 weeks** (approved range 4 to 12 weeks)[4]
			• Second dose is considered an invalid dose if administered <14 days after first dose
			• Recommended interval between invalid second dose and replacement dose is 4-12 weeks after invalid second dose, with **individual risk-benefit assessment**[4] including consideration of recommended primary dose intervals, risk of exposure to infection, and medical conditions
			• The same COVID-19 vaccine formulation should be used for the replacement dose to complete the primary vaccination course, unless special circumstances necessitate use of an alternative[9]
			• If invalid second COVID-19 vaccine dose was **not** the same type as first dose, replacement dose may be of either vaccine type (unless contraindications or precautions exist)

		Second primary course dose given early but **≥14 days** between dose 1 and dose 2	• A replacement dose of a COVID-19 vaccine is **not** recommended

Vaccine(s)	Error type	Error subcategory	Interim recommendation
COVID-19 vaccines currently TGA - approved and supplied for use in Australia: Astra Zeneca Moderna Novavax Pfizer Pfizer paediatric *(continued)*	Dosing interval error *(continued)*	Third dose of primary course administered **less than 14 days** after dose 2	• Third dose is considered an invalid dose if administered <14 days after first dose • Recommended interval between invalid third dose and replacement dose is 4-12 weeks after invalid second dose, with **individual risk-benefit assessment**[4] including consideration of recommended primary dose intervals, risk of exposure to infection, and medical conditions • The same COVID-19 vaccine formulation should be used for the replacement dose to complete the primary vaccination course, unless special circumstances necessitate use of an alternative[9] • If invalid third COVID-19 vaccine dose was **not** the same type as both previous doses, replacement dose may be of either vaccine type (unless contraindications or precautions exist)
		Third dose of primary course given early but **≥14 days** between dose 2 and dose 3	• A replacement dose of a COVID-19 vaccine is **not** recommended
		First booster dose given **less than 3 months** following completion of primary course	• If this dose was given less than 2 months following completion of the primary course, it is considered an invalid dose, in which case a repeat dose should be given 3 months following this invalid dose. • A replacement dose of a COVID-19 vaccine is **not** recommended if this dose was given 2 or more months following completion of the primary course
		Subsequent booster dose given **earlier than recommended**	• Replacement dose generally not recommended, although an individual assessment with a vaccine provider may be required[4]
		Primary course dose OR booster dose given with an **interval longer than the recommended interval**	• A replacement dose of a COVID-19 vaccine is **not** recommended[4]
	Excessive number of doses	More doses administered than recommended by the relevant schedule	• Monitor for adverse events, and report an AEFI • As new recommendations for vaccine schedules emerge, consider all doses given, including those given in excess of a current schedule[4]

Vaccine(s)	Error type	Error subcategory	Interim recommendation
COVID-19 vaccines currently TGA - approved and supplied for use in Australia: Astra Zeneca Moderna Novavax Pfizer Pfizer paediatric *(continued)*	Booster given close in time to confirmed COVID-19 infection	Booster dose given just prior to or soon after a diagnosis of COVID-19 based on a positive RAT or PCR test	• A replacement dose of a COVID-19 vaccine is **not** recommended.
	Mixed vaccine types in primary course	Incorrect COVID-19 vaccine product administered for second dose in 2-dose primary course	• A replacement dose of a COVID-19 vaccine is **not** recommended as the primary course is considered complete at this time. • If administered <14 days refer to 'Intervals'
Pfizer and Pfizer paediatric	Diluent error	Only the diluent administered (i.e. sterile 0.9% sodium chloride)	• Inform the recipient that no vaccine was administered • Administer the replacement dose as soon as feasible, in the opposite arm
		No diluent added, resulting in higher than authorized dose (i.e. undiluted vaccine administered)	• Do **not** repeat dose[*†] • Inform the recipient of the potential for local and systemic adverse events
		Incorrect diluent type added (e.g. sterile water, bacteriostatic 0.9% NS)	• Give a replacement dose of Pfizer as soon as feasible after the invalid dose, and a subsequent dose as indicated[4]
		Incorrect diluent volume (i.e. incorrect concentration results in incorrect dosage given)	• For dilution ratios resulting in a higher vaccine dosage, do **not** repeat dose, and inform the recipient of increased potential for local and systemic adverse events[*†] • For dilution ratios resulting in a lower vaccine dosage, see Dosage section
Pfizer and Pfizer paediatric *(continued)*	Diluent error *(continued)*	Incorrect diluent used e.g. sterile water	• Give a replacement dose of Pfizer as soon as feasible[4]

Footnotes

#The same COVID-19 vaccine brand should be used for the replacement dose to complete the primary vaccination course, unless there are special circumstances necessitating the use of an alternative vaccine (as specified in the ATAGI clinical advice on use of a different COVID-19 vaccine as the second dose in special circumstances).[3]

*The interval between the invalid second dose and the replacement dose is flexible, recommended at 4 to 12 weeks after the invalid second dose. Timing of the replacement dose warrants individual risk-benefit assessment, including consideration of risk of exposure to SARS-CoV-2 (e.g., workers in healthcare, aged care, disability care, border and quarantine facilities may warrant vaccination with a replacement dose sooner), local disease epidemiology, mandatory requirements for work (such as aged care or healthcare workers) and individual medical conditions associated with increased risk of severe COVID-19 (such as immunocompromise).[4]

†If the administration error resulted in a higher-than-authorized vaccine first dose, in general the second dose may still be administered at the 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 may be assessed on a case-by-case basis.[1]

§Although ATAGI provides considerations for the use of mixed dose scheduling in special circumstances, this is still considered an administration error that requires Program Error reporting.

References

1. Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC,
2. Australian Technical Advisory Group on Immunisation (ATAGI) Clinical guidance on use of COVID-19 vaccine in Australia in 2021
3. ATAGI clinical advice on use of a different COVID-19 vaccine as the second dose in special circumstances
4. ATAGI Clinical Guidance on COVID-19 Vaccine Administration Errors
5. ATAGI recommendations on Pfizer COVID-19 vaccine use in children aged 5 to 11 years
6. ATAGI update following weekly COVID-19 meeting – 12 January 2022 (17.01.22)
7. ATAGI recommendations on the use of a third primary dose of COVID-19 vaccine in individuals who are severely immunocompromised (17.01.2022)
8. ATAGI Statement on the Omicron variant and the timing of COVID-19 booster vaccination (24.12.21)
9. COVID-19 vaccination – Clinical advice on the use of a different COVID-19 vaccine as the second dose
10. ATAGI recommendations on first booster dose in adolescents aged 12-15 years
11. ATAGI update following weekly COVID-19 meeting – 27 April 2022