NCIRS clinical guidance on RSV immunisation product administration errors

This document provides advice on management of a range of possible RSV immunisation product administration errors.

An RSV immunisation product administration error occurs when one of these products – either an RSV vaccine or an RSV-specific monoclonal antibody – is given outside the current clinical recommendations in the Australian Immunisation Handbook.

Immunisation providers should ensure best practice is followed and training is undertaken to minimise the risk of errors occurring.

What to do when an error occurs

When an RSV immunisation product administration error occurs, follow these steps:

- inform the recipient (in keeping with the principle of open disclosure)
- report the error as an adverse event, even if no adverse event has occurred. You can do this either through your state or territory health department or directly to the Therapeutic Goods Administration at www.tga.gov.au/reporting-problems
- follow the advice in the 'Repeat dose recommendation' column of the table above
- continue as per the relevant RSV immunisation schedule, unless otherwise indicated
- review how the error occurred and, if required, implement procedures to prevent it from happening again.

Monitoring should occur for any possible adverse event following immunisation.

Note: 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 (Monday–Friday, 8 a.m.–5 p.m.).

Type of error	Administration error	Repeat dose recommendation
Site/route	Incorrect site (i.e. site other than deltoid or anterolateral thigh)	Do **not** give a repeat dose.
	Incorrect route (i.e. subcutaneous or intradermal)	Do **not** give a repeat dose.
Incorrect immunisation product	Abrysvo or Arexvy vaccine administered to an infant or young child recommended to receive nirsevimab (monoclonal antibody)	Monitor for adverse events. Administer a dose of nirsevimab. This can be done anytime from immediately after the error.
	Arexvy administered to a pregnant woman recommended to receive Abrysvo	Do **not** give Abrysvo during current pregnancy. Arexvy given during pregnancy is expected to provide protection to the infant; however, a dose of nirsevimab to the infant, either at birth or before their first RSV season, may be considered.
Immunisation product not clinically indicated	Product administered to a person who is of appropriate age but is not clinically indicated to receive the product. Examples include: • nirsevimab given to an infant who is already adequately protected by maternal vaccination • nirsevimab given to an infant who is in their second RSV season and is not recommended to receive a second-season dose	Monitor for adverse events.

Type of error	Administration error	Repeat dose recommendation
Incorrect age	Abrysvo or Arexvy administered to a person who is younger than the approved age registered for that vaccine. Examples include: • Abrysvo given to a non-pregnant person aged under 60 years • Arexvy given to a person aged under 50 years.	Monitor for adverse events. Do **not** give a repeat dose at the scheduled age. The need for further doses has not been established; further advice will be given when data are available. See 'Incorrect immunisation product' above for Arexvy inadvertently administered to a pregnant woman.
	Nirsevimab administered to a person aged above 2 years, including during pregnancy	Monitor for adverse events. If the person is recommended to receive Abrysvo or Arexvy, administer a dose of the correct product. This can be done anytime immediately after the error. For pregnant women who receive Abrysvo following inadvertent nirsevimab administration, if the Abrysvo dose is received: • at least 2 weeks before the infant's birth, nirsevimab is not recommended for the infant. • less than 2 weeks before the infant's birth, nirsevimab is recommended for the infant.
	Abrysvo administered to a pregnant woman before 28 weeks gestation	Monitor for adverse events. Do **not** give a repeat dose at the recommended gestational age. If administered before registered gestation (24 weeks), consider a dose of nirservimab for the infant.
Higher than approved dose	Higher than approved dose of correct formulation administered (e.g. 100 mg given to an infant weighing <5 kg)	Monitor for adverse events. Do **not** give a repeat dose.

Type of error	Administration error	Repeat dose recommendation
Lower than approved dose	Lower than approved dose or unknown dose of correct formulation administered	If less than half of the vaccine/monoclonal antibody recommended dose (estimated) was administered, give a repeat dose as soon as feasible. This can be done anytime from immediately after the error. If half or more than half of the vaccine/monoclonal antibody dose (estimated) was administered, do **not** repeat the dose. If the unknown dose was Abrysvo given during pregnancy, consider a dose of nirservimab for the infant.
Immunising products administered after incorrect storage and/or handling	Temperature excursions/cold chain breaches	Assess the impact of temperature excursion on the stability and potency of the immunising product on a case-by-case basis to decide whether a repeat dose is needed. Contact state or territory immunisation health services. See State and territory immunisation cold chain breach contact numbers.
	Immunising product administered past the expiration or use-by date	Contact state or territory immunisation health services. See State and territory immunisation cold chain breach contact numbers.
	Incorrect reconstitution of immunisation product (e.g. diluent only)	Give a repeat dose as soon as possible.
Multiple doses	More doses administered than recommended by the relevant schedule. Examples include: • repeat doses of RSV vaccine given • infant inadvertently given a second dose of nirsevimab.	Monitor for adverse events. As new recommendations for schedules emerge, consider all doses given.

State and territory immunisation cold chain breach contact numbers

State/territory	Contact details
Australian Capital Territory	(02) 5124 9800
New South Wales	1300 066 055 (to connect to the relevant Public Health Unit)
Northern Territory	(08) 8922 8044
Queensland	(07) 3328 9888
South Australia	1300 232 272
Tasmania	1800 671 738
Victoria	1300 882 008
Western Australia	(08) 9222 2486

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