

Incorrect Vaccination Incident Toolkit

COVID-19 Vaccine

Version 1.0

Last Updated February 2022

Document Version Control

Revision history

Version	Date	Section/Appendix
1.0	February 2022	First version of the document

Contents

Document Version Control.....	2
Revision history	2
Definition.....	4
Introduction	4
Purpose	5
Principals.....	6
1. Immediate actions.....	7
2. Follow-up phone call completed (within 3 to 5 days).....	9
3. Subsequent dose.....	10

Definition

Word or phrase	Definition
Incorrect COVID-19 vaccine administered incident	An incident whereby the wrong COVID-19 vaccine was administered to a consumer and/or they did not consent for the dose.

Introduction

COVID-19 Vaccines are being rolled out in New Zealand through the COVID-19 National Immunisation Programme (The Programme) run by the Ministry of Health (The Ministry). This will be New Zealand's largest immunisation rollout ever.

The programme aims to provide free COVID-19 vaccines to everyone in Aotearoa. Enough COVID-19 Vaccines (the vaccine) has been secured for everyone in Aotearoa aged over 5 years.

The Programme has the following success goals to ensure balanced decision making:

- Honours and upholds Te Tiriti o Waitangi principles.
- Quality and safety – vaccines and immunisation processes are clinically and culturally safe, backed by a strong evidence base, appropriate kaupapa and capability.
- Experience – renewed/increased trust and confidence in the health sector and immunisation, underpinned by positive experiences at system, programme and whānau/individual levels.
- Equity – Māori, Pacific and people with disabilities achieve equitable immunisation outcomes. Everyone in New Zealand and the Pacific has equal opportunity to access the vaccine.
- Access – New Zealand's and Pacific's immunisation needs are met at the right time and place with minimal waste.

Purpose

To provide guidance for the Ministry to work collaboratively with clinical and quality leads from DHB and non-DHB providers to ensure a safe and high-quality outcome for the affected consumer(s).

In the event of an incorrect COVID-19 vaccine being administered, it is important to follow usual local organisational process to report, review, communicate and learn from the incident. This also includes following the standard CVIP Serious Adverse Event notification process (found in Appendix I of the COVID-19 Vaccine Operating Guidelines) to the Ministry of Health as per the CVIP Vaccine Operating Guidelines.

Examples of COVID-19 vaccination administration incidents:

- Adult Pfizer vaccine (12 years and older formulation) administered to a consumer under the age of 12 years.
- Paediatric Pfizer vaccine (5-11 years formulation) administered to a consumer over the age of 12 years.
- A dose of an unconsented vaccine administered to a consumer (e.g., an adult Pfizer vaccine administered when the consumer consented for an AstraZeneca vaccine and vice versa).

Note: This document is intended to be a guide and should be read as complementary information to the organisation's incident and adverse event management processes. This document does not take the place of your own DHB, provider or workplace clinical quality and safety processes.

If a person resides in your District Health Board (DHB) and has received an incorrect COVID-19 vaccine, the following needs to be considered;

1. Immediate actions
2. Follow-up phone call
3. Subsequent vaccination events

Principals

The core principals of this toolkit are:

- **Code of Health and Disability Services Consumers' Rights:** Every provider is subject to the duties of this code, including informing consumers of their rights and enabling consumers to exercise their rights.
- **Early reporting of incidents:** Timely notification and reporting of incidents by providers to District Health Boards and the Ministry of Health.
- **Early and open disclosure with consumers:** Open disclosure is required to occur within 7 working days of the incident.
- **Subsequent dose clinical guidance:** Every provider has the responsibility of accurately communicating with the consumer(s) and/or whanau, the plan for their next vaccination following an incident.

1. Immediate actions

Step	Action
1	Contact the person and or whānau immediately, apologise and explain the situation.
2	If the affected consumer is at the site, they should remain for a 30-minute observation period instead of 15-minutes OR until their follow up care plan has been formulated (whichever takes longest).
3	<p>Responsibility of Site Clinical Lead:</p> <ol style="list-style-type: none"> 1. Notify and escalate to the DHB's/Provider's Clinical Lead or Quality Lead. 2. Contact IMAC on 0800 466 863 for clinical advice specific to the affected consumer. Before calling have any relevant details ready for example the consumer's age, weight (may be appropriate for a child), co-morbidities, known health risks etc. <p>Note: The advice may vary based on affected consumer's details, which dose in schedule etc.</p>
4	Clarify the spacing of the next vaccine for the affected consumer if appropriate.
5	<p>Ensure the affected consumer or whānau understand the following (this may be different for each consumer depending on IMAC advice):</p> <ol style="list-style-type: none"> 1) Common reported reactions may be more severe in case of a higher administered dose. 2) If the affected consumer is an adult, refer them to the "After your vaccination" handout given at the vaccination event. 3) If the affected consumer is a child, ensure whānau understand how to comfort their child and refer them to the "After your child's Pfizer vaccination" handout given at the vaccination event. 4) Red flags to seek medical help (also in post vaccine handout) <ul style="list-style-type: none"> Note: If the affected consumer is still in the site this should be provided verbally and in writing. 5) Where they can go to for help. This includes after hours services in the area. Provide the service address and contact number, highlight Healthline number on post vaccine handout. 6) Inform the consumer and or whānau the medical practitioner will be able to advise on any required ACC documentation. <p>Ensure the consumer and or whānau understand there will be no cost to attend a follow-up appointment at their GP, urgent care, or ED.</p>
6	Offer to contact their GP or Healthcare provider to inform them of the situation.

Step	Action
7	If appropriate arrange a follow up phone call/calls to the affected consumer or whānau to check on the affected consumer and to confirm all advice is understood. Set a time for the call and confirm contact phone number.
8	Complete CARM report in CIR.
9	<p>Follow the appropriate reporting processes:</p> <ol style="list-style-type: none"> 1. Ensure the DHB's/Provider's Clinical Lead or Quality lead has been notified. 2. Follow standard CVIP (Serious Adverse Event Process) – email initial notification as soon as able. 3. Follow local/DHB reporting, investigation, and mitigation processes.
10	<p>Ensure the CIR record is accurate to reflect the actual dose administered including the vial batch and expiry date for the antigen and diluent.</p> <p>For example, if an adult Pfizer dose was mistakenly administered to a child ensure this is recorded (as original record would have been a Paediatric Pfizer dose). Contact CIR Helpdesk if required for assistance.</p>
11	Document the care plan in CIR notes, associated with this vaccine event.

2. Follow-up phone call completed (within 3 to 5 days)

Step	Action
1	Apologise to the person, whānau, caregivers, and parents again.
2	Check on the wellbeing of the affected consumer
3	Allow time for the affected consumer or whānau to express their concerns and comments on incident
4	Confirm all clinical safety advice and follow up care including seeking medical advice from for example a GP if have additional clinical concerns.
5	Check they have what they need to care for the affected consumer
6	Clarify the spacing of the second or any subsequent doses as appropriate.
7	Explain to the affected consumer or whānau that they should inform the vaccinator of the incident when they attend for their next dose BEFORE the vaccine is given.
8	Document a summary of the follow-up phone call with the consumer or whānau in the CIR notes.

3. Subsequent dose

At the subsequent vaccination event following an incorrect vaccine administration the below actions should be followed prior to vaccination:

- 1) Check in detail for any unexpected vaccine side effects or response including any possible cardiac symptoms and complete a CARM report as required (if not already completed).
- 2) Ask if any medical advice or review was required.
- 3) If there were any concerns or alerts call IMAC (0800 466 863) and confirm this vaccination can proceed.
- 4) Ensure subsequent dose is documented correctly in CIR.

Note: This may occur if a decision is made to bring the second vaccine dose forward. Document anything relevant under 'notes' in CIR.