

Appendix I:

Health New Zealand Te Whatu Ora Prevention Adverse Event Process

This Appendix includes

1. Introduction
2. Process Steps
3. Severity Assessment Code (SAC) examples
4. NIP incident notification form.

Provider and Programme Lead Clinicians

Purpose

The Health New Zealand Te Whatu Ora Prevention (Prevention) implementation phase is based on a devolved service delivery model. The Prevention Clinical Lead is committed to supporting a person-centred, safe and high-quality Programme with all Programme providers.

To support a provider when a serious adverse event occurs, the following process includes timely notification to the Programme and consideration of Prevention support to the provider.

The following detail outlines the notification process and describes roles/responsibilities of Prevention provider lead clinicians in relation to COVID-19 vaccination-related serious adverse event¹ or a serious adverse event following immunisation².

Scope

This process outlines the notification of Prevention adverse events and uses severity assessment code (SAC) ratings. Any of the following must follow this notification process:

- SAC 1 (e.g., Anaphylaxis resulting in death or permanent loss of function)
- SAC 2 (e.g., Serious adverse reaction with delayed administration of adrenaline or delayed presence of emergency services)
- SAC 3 (e.g., Medication error, vaccine dilution error, or dose error)
- Several similar or close sequenced SAC 4 events (e.g., Breach of confidentiality).
- Near miss with likely significant consequences

Note: For more examples of the SAC ratings please refer to the table below.

This protocol aligns with existing expectations of health and disability service providers under the Health and Disability Services (Safety) Act 2001, as articulated by the Health Quality & Safety Commission, whereby those who voluntarily comply are expected to:

1. Report serious adverse events (SAC rating 1 and 2) and events on the Always Report and Review list to the Commission, using the adverse event brief – part A reporting form. This report should be made within 15 working days of notification of the event to the provider.
2. Undertake formal investigation of serious adverse events (SAC 1 and 2) and events on the Always Report and Review list and send review findings and recommendations to the Commission, using the adverse event brief – part B reporting form. This report should be made within 70 working days of notification of the event to the provider.

Exclusions

This Prevention serious adverse event process does not apply to other Prevention non-clinical incident types e.g., equipment or vaccine damage/loss.

The notification process is not a substitute for the provider's responsibility concerning an adverse event including their normal processes of reporting, reviewing and open communication with the affected person. The outcome may recommend clinical and quality continuous improvement actions.

¹ An adverse event is an incident resulting in harm, or with the potential to result in harm to a health consumer.

² Adverse event following immunisation (AEFI) - an untoward medical event which follows immunisation and does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease

Process Steps

Pharmacovigilance	Timeframe
Ensure COVID-19 CARM report is completed for any suspected AEFI. CARM Resource https://report.vaccine.covid19.govt.nz	Day 1 (< 8 hours)
Participate in follow-up activities with CARM if required.	On contact by CARM



Next

Notification to NPHS Te Whatu Ora NIP and provider leads	Timeframe
Commence reporting process. You should use the attached provider or organisation process steps and ensure you identify a <u>preliminary</u> SAC rating. Programme Resource: NIP SAC examples in table below HQSC resource A Guide to the National Adverse Events Reporting Policy 2017	Day 1 (< 8 hours)
Notify Te Whatu Ora Prevention via email address: NIP.incidentnotification@tewhatauora.govt.nz <ul style="list-style-type: none"> • Attach the completed: Provider with NIP incident notification form (sections A and B) <ul style="list-style-type: none"> ○ Email Subject: NIP Adverse Event Notification • Please refer to the relevant incident toolkit which can be found on the Connex 'Mahi Tahī' platform or your provider's Clinical/Quality Lead. Programme Resource: Provide with NIP incident notification form³	Expedited (< 48 hours)



Next

Plan and execute open communication with affected consumer/s⁴	Within 7 working days
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Next

Investigation and reporting outcomes	Timeframe
<ul style="list-style-type: none"> • Investigate the incident using the provider or organisation's clinical quality and safety governance process, and in accordance with HQSC expectations. • Inform NIP on investigation findings and recommendations. • This includes confirming the final SAC rating. HQSC resource https://www.hqsc.govt.nz/our-work/system-safety/adverse-events/	Commenced (< 24 hours) Reporting to HQSC according to timeframes above.
If required, please arrange an ACC treatment injury claim. Also see the Treatment injury claim lodgement guide and the Treatment Injury Flowchart.	
Updating of NIP incident form and send an update to NPHS Te Whatu Ora NIP	Ongoing/ until closed

³ This is the notification form for all incident types including serious adverse events & AEFI.

⁴ As a guide, the Health Quality and Safety Commission's "Root Cause Analysis for clinical incidents - A Practical Guide" have the expectation for communication with affected consumers during week 1 – 2 of the incident investigations.

Provider please:

As an adverse event, either following immunisation or other cause, please arrange for open communication with the affected person/s.

If required, please arrange ACC treatment injury claim per ACC2152 form: <https://www.acc.co.nz/assets/provider/3e3bd2aded/acc2152-treatment-injury-claim.doc>

SAC 1 Death or permanent severe loss of function	SAC 2 Permanent major or temporary severe loss of function
<ul style="list-style-type: none"> • Medication or dose error resulting in death or causing renal failure and need for permanent renal replacement therapy • Anaphylaxis resulting in death or permanent loss of function • Wrong site of vaccine resulting in removal of healthy limb or organ • Delayed referral, treatment resulting in treatment options limited to palliation (delay direct contributor) • Delayed recognition of patient deterioration resulting in permanent disability or death 	<ul style="list-style-type: none"> • Fall resulting in fracture • Serious adverse reaction with delayed administration of adrenaline or delayed presence of emergency services • Delayed recognition of patient deterioration resulting in unplanned transfer to intensive care or to another hospital for higher acuity care, cardiopulmonary resuscitation and/or intubation • Medication or vaccine dose error resulting in major harm (e.g., requiring dialysis, intervention to sustain life, anaphylaxis) • Consumer serious assault occurring within vaccination care setting when a known safety plan is not upheld (e.g., protection order) • A vaccination incident affecting > 1 consumer
SAC 3 Permanent moderate or temporary major loss of function	SAC 4 Requiring increased level of care OR no injury, no increased level of care; includes near misses
<ul style="list-style-type: none"> • Fall resulting in laceration requiring sutures • Failure of essential service with moderate consequence to consumer • Medication error, vaccine dilution error, or dose error • Temporary nerve damage or pain from vaccine administration • Severe injection site infection • Vasovagal event following immunisation resulting in injury • Never events: wrong vaccine, early vaccination doses & underage vaccination 	<ul style="list-style-type: none"> • Additional monitoring, investigations, or interventions due to the event post vaccination • Medication, vaccine dilution or dose error resulting in no increased level of care or monitoring- not reaching the consumer is a near miss • Breach of confidentiality • Near miss events

Version 4: Adapted for the National Immunisation Programme (NIP) from Severity Assessment Code (SAC) examples 2019–20 | Health Quality & Safety Commission 2019. This list is guidance only.

NIP incident notification form

Notify and attach this completed form to: nip.incidentnotification@tewhatauora.govt.nz

Email Subject: NIP Adverse Event Notification

Verified from the NIP Detecting Failsafe Report: Y N

Section A – Provider notification details

Provider or Health District to complete information below

Incident date/ time		
Date/ time reported		
Site		Health District

Person reporting incident:

Name	
Contact phone number/s	
Email address	

Section B – Description (Provider to complete)

Type of incident / adverse event / AEFI (it's possible two of the four options apply)

Near miss <input type="checkbox"/>	Incident <input type="checkbox"/>	Serious adverse event <input type="checkbox"/>	AEFI <input type="checkbox"/>
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Vaccine type and dose (e.g. Comirnaty 30mcg XBB.1.5 single dose vial)	Dose details (circle):	Primary Dose 1 / Dose 2 / Dose 3 Booster 1 / Booster 2 Other:
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Age of consumer:		Ethnicity:	
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Have the Health District's/Provider's Clinical Lead or Quality Lead been notified?	Y <input type="checkbox"/> N <input type="checkbox"/>
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If there is an adverse event following immunisation or a medication error, has this been reported to CARM?	Y <input type="checkbox"/> N <input type="checkbox"/>
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Has IMAC been contacted for advice and given to the consumer:	Y <input type="checkbox"/> N <input type="checkbox"/>
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Has the relevant system been updated to reflect actual dose given?	Y <input type="checkbox"/> N <input type="checkbox"/>
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Has a preliminary investigation been undertaken? List details below	Y <input type="checkbox"/> N <input type="checkbox"/>
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Has the consumer been informed and received an apology?	Y <input type="checkbox"/> N <input type="checkbox"/>
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Assign a preliminary SAC rating (circle one):	SAC 1 / 2 / 3 / 4
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- **Incident** means any unplanned event resulting in, or having a potential for injury, ill health, damage or other loss, an incident includes an accident.
- **Adverse event** is an incident resulting in harm, or with the potential to result in harm to a health consumer. Please assign an adverse event SAC rating. Report a SAC 1,2 or 3 SAC event, a cluster of SAC 3/ 4 events +/- near misses.

- **Adverse event following immunisation (AEFI)** is an untoward medical event which follows immunisation and does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Provider please note:

- Include information regarding open communication with an affected consumer, including date completed
- Include your findings in the actions you have taken to prevent reoccurrence
- Update this section of the form over time as incident investigation is progressed and then closed

Please provide as much detail of the incident as possible:

What went wrong? Were there any contributing factors? What were the immediate actions taken? What advice were you given and from whom? What changes will you be making to prevent this happening again? What follow up has been arranged for the consumer?

If the consumer received an early dose, please provide the number of days between doses.