Appendix I:
Te Whatu Ora Prevention Adverse Event Process

This Appendix includes

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

Provider and Programme Lead Clinicians

Purpose

The 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 event[2] or a serious adverse event following immunisation[3].

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.

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

[3] 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 preliminary 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@health.govt.nz • **Attach the completed:** Provider with NIP incident notification form (sections A and B) ○ Email Subject: NIP Adverse Event Notification • Please refer to the relevant incident toolkit which can be found on the Connex 'Mahi Tahi' platform or your provider's Clinical/Quality Lead. Programme Resource: **Provide with NIP incident notification form**[4]	Expedited (<48 hours)

Next

Plan and execute open communication with affected consumer/s [5]	Within 7 working days

Next

Investigation and reporting outcomes	Timeframe
• 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

[4] This is the notification form for all incident types including serious adverse events & AEFI.
[5] 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.

Te Whatu Ora
Health New Zealand

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
• 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	• 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**
• 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	• 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.