Appendix I:
Health New Zealand Te Whatu Ora Prevention, Adverse Event Process

This Appendix includes

1. Introduction
2. Adverse event management process

Introduction

Purpose

To support a vaccination provider when an adverse event occurs, the following outlines the notification process and roles/responsibilities in relation to vaccination-related adverse events[1]or adverse events following immunisation[2]

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.

Scope

This process outlines the notification of adverse events and uses severity assessment code (SAC) ratings:

- SAC 1 - Severe; death or harm causing severe loss of function and/or requiring lifesaving intervention
- SAC 2 - Major; harm causing major loss of function and/or requiring significant intervention
- SAC 3 - Moderate; harm causing short-term loss of function and/or requiring moderate additional intervention
- SAC 4 – Minor; harm causing no loss of function and requiring little or no intervention (includes near misses)

Note: For more details and examples of SAC ratings, please refer to the **HQSC Primary Care SAC example guide**.

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

1. Report serious adverse events (SAC rating 1 and 2) and events on the Always Report and Review (ARR) list to the HQSC, using the adverse event brief – part A reporting form. This report should be made within 30 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 (ARR) 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 120 working days of notification of the event to the provider.

See **HQSC templates to support adverse event reporting and review processes**

Adverse Event Management Process

Notification to Medsafe	
Ensure CARM report is completed for any suspected adverse events following immunisation AEFI. **CARM reporting form: https://pophealth.my.site.com/carmreportnz/s/** Further information on reporting adverse reactions to vaccines can be found on the **Medsafe website: https://www.medsafe.govt.nz/Safety/report-a-problem.asp**	Day 1 (< 8 hours)
Participate in follow-up activities with CARM if required.	On contact by CARM

Next

Incident/Adverse Event notification to vaccination provider and regional leads	

• Follow your local/organisation/provider incident/adverse event process.
• Seek guidance/clinical advice as per your local/organisation/provider process and contact the following:
  ○ **Immunisation Coordinators and Regional Advisors**
  ○ IMAC on 0800 IMMUNE (466 863)
• Identify a preliminary severity assessment code SAC rating.
 	
SAC resource: HQSC Primary Care SAC example guide
HQSC resource: National Adverse Events Reporting Policy 2023 - User Guide
	Day 1
	(< 8 hours)

• Complete the **online vaccination error reporting form** sent by your Immunisation Coordinator or IMAC with advice related to the error. • Escalate to regional and nation and national stakeholders as required. ○ If the harm rating is SAC 3 or SAC 4, manage the event through local processes. If the harm rating is SAC 1, SAC 2 or Always Report and Review (ARR,) notify the appropriate local governance group and manage the event in line with local processes.	Expedited (<48 hours) Report SAC 1, SAC 2 or ARR: to HQSC within 30 days

Next

Plan and execute open communication with affected consumer/s
Follow local/organisation/provider incident/adverse event process and engage with consumer and whānau in a way that meets their needs and follows their tikanga in all steps in the process. **HQSC resource: Code of expectations for health entities engagement with consumers and whānau**

Next

Investigation and learning outcomes	
• Investigate the incident using the provider or organisation's clinical quality and safety governance process, and in accordance with HQSC expectations. • Reporting should be accompanied by meaningful analysis that leads to system improvement. • Te Tāhū Hauora Health Quality & Safety Commission use the 'learning review' method when reviewing harm because it takes a systems approach **HQSC Event of harm review tool** Templates are available to support providers in the **HQSC National Adverse Event Reporting Policy 2023**. Using these templates is not mandatory. Their purpose is to encourage national consistency in the way harm is reviewed and reported	Commenced (<24 hours)
If required, please arrange an **ACC treatment injury claim**. Also see the **Treatment injury claim lodgement guide** and the Treatment Injury **Flowchart**.	