The Royal New Zealand College of General Practitioners
Te Whare Tohu Rata o Aotearoa

1. Foundation Standard 13.3: Adverse event reporting and management

1.1 Policy and procedures resource for general practices

The 2023 National Adverse Events Policy: Healing, Learning, and Improving from Harm replaces the 2017 National Adverse Events Policy.

All practices are required to develop/revise their adverse events reporting and management policy and procedures so that it meets the expectations of the 2023 National Adverse Events Reporting Policy.

This resource is designed to assist practices. Content from this document may be copied and adapted/tailored to suit the practice as required.

1.2 PART 1: Policy content guide

1.2.1 Purpose

The following purpose statements should be included in the practice policy:

a. Enhance patient and whānau safety by preventing harm through timely, accurate and objective reporting of events, as per the principles of the Healing, Learning and Improving from Harm – National Adverse Events Policy 2023.

b. Enhance open communication and a more relational approach when managing events.

c. Provide a consistent process for reporting all SAC 1 and 2 events to the appropriate organisations – PHO or equivalent and Te Tāhū Hauora | Health Quality & Safety Commission (HQSC).

d. Provide processes for team members to understand and improve harm (adverse) event management through reporting, reviewing and learning from all types of harm.

e. Promote and support a culture of shared learnings and quality improvement from harm (adverse) events.

1.2.2 In scope

The following should be identified as being in scope in the practice policy:

All harm (adverse) events and near miss events that occur, or have the potential to occur, to any person (patients, whānau or health care workers) because of, or related to, the provision of health and disability services.

1.2.3 Out of scope

The following should be identified as out of scope in the practice policy and managed by separate policies and procedures:

- Occupational health and safety events affecting any employee
- Employment relationship issues affecting any employee
- Fires, flood, or property damage
- IT failure or service delivery interruptions.

1.2.4 Context

The following context can be included in the practice policy:

An adverse event is defined by Te Tāhū Hauora | HQSC as an event that results in harm to a patient, or has the potential to result in harm (near miss).

The 2017 National Adverse Events Reporting Policy has been superseded by the 2023 National Adverse Events Reporting Policy: Healing, Learning, and Improving from Harm.

The practice acknowledges that the 2023 National Adverse Events Policy defines harm as negative consequences for patients and whānau directly arising from, or associated with, plans made, actions taken or omissions during the provision of health care, rather than an underlying disease or injury.

Harm may be:

- **Physical harm:** which leads to bodily injury or impairment or disease. This includes limitations in cognitive functioning and skills, including communication, social and self-care skills.
- **Psychological harm:** which causes mental or emotional trauma or that causes behavioural change or physical symptoms.
- **Cultural harm:** the marginalisation of a consumer's belief and value systems.
- **Spiritual harm** (also known as spiritual distress): a state of suffering, related to the impaired ability to experience meaning in life through connectedness with self, others, world or a superior being.

The 2023 National Adverse Events Reporting Policy places greater emphasis on the relationships between those involved in a harm (adverse) event and is structured around three key themes:

- **Healing:** Listening to, understanding, and addressing the needs of all individuals affected by a harmful event or experience.
- **Learning:** Understanding how people typically create safety and recognising when risks become difficult to manage.
- **Improving:** Applying what is learned to enhance system safety and improve experiences for patients, whānau, and health care workers.

1.2.5 Policy principles underpinning adverse event management

The role of our practice is to enhance safety by learning and healing from harm and ensuring sustainable improvement.

Our practice policy will align with the principles of the National Adverse Events Policy 2023 as they relate to general practice, noting that Principle 5 and certain criteria within the other principles require national enablers and additional infrastructure before they can be implemented at the general practice level.

The principles are:

- **Principle 1:** Consumer and whānau participation
- **Principle 2:** Culturally responsive practice
- **Principle 3:** Equity
- **Principle 4:** Open communication
- **Principle 5:** Restorative practice and restorative responses
- **Principle 6:** Safe reporting: Reporting all SAC 1 and 2 harm events to Te Tāhū Hauora | HQSC
- **Principle 7:** System accountability
- **Principle 8:** System learning.

These principles are described in more detail in the **National Adverse Events Policy 2023: Healing, Learning and Improving from Harm** and the **Te Tāhū Hauora user guide: National adverse events policy 2023** .

1.2.6 Definitions

Please refer to pages 15 and 16 of the **National Adverse Events Policy 2023: Healing, Learning and Improving from Harm** for a full list of definitions.

1.3 PART 2: Procedure and processes content guide

1.3.1 The practice's procedure and processes will need to include:

- clearly defined roles and responsibilities of all practice team members
- timelines for reporting, managing, and communicating with all parties involved in a harm (adverse) event
- documentation of events in a designated event register
- approaches for engaging patients and whānau in the process
- strategies for managing relationships with those affected to support healing and restoration
- processes for learning from harm (adverse) events, including physical, cultural, spiritual, and psychological harm
- mechanisms for closing the loop through quality improvement initiatives based on identified learnings
- categorisation of events using the Severity Assessment Code (SAC) tool and relevant primary care examples
- procedures for timely reporting and review of SAC 1 and 2 harm events in accordance with required timeframes
- methods for sharing key learnings at local, regional, and national levels.

1.4 PART 3: Procedure and process content (exemplar)

The following content is an example of what should be included in the practice procedures and processes. It should be adapted to reflect the practice's environment and way of working.

This resource is designed to assist practices. Content from this document may be adapted and tailored to suit the practice as required.

1.4.1 Roles and responsibilities of team members are clearly defined within the process and procedure (example only)

Adverse event (harm) management is a whole team/organisation approach. Included here are the suggested roles and responsibilities for team members, although practices will need to adapt these to suit their own working environment.

All team members

- All team members are responsible for identifying and reporting events and taking steps to avoid further harm
- Initial appropriate emergency response as required
- Notification to management of an adverse (harm) event using an Incident Management Reporting Form to their immediate manager within 24 hours unless serious harm/injury has occurred, in which case the the manager is to be notified immediately.

Incident management lead

- Reports to the clinical governance group
- Assists in severity assessment code (SAC) rating
- Begins open disclosure process
- Monitors process and timelines
- Completes Learning from Harm assessment tool once review and learning opportunities completed.

Health and safety lead

- Ensures all incidents are managed using the correct reporting forms
- Provides oversight and guidance
- Follows up reporting timelines
- Reports to and sits on the clinical governance group.

Practice manager and or clinical director

- SAC rating
- Notification of SAC 1 and 2 harm events to Te Tāhū Hauora | HQSC
- Theming of SAC 3 and 4.

Equity champion(s)

- Guidance with relational approaches, as applicable
- Reports to and sits on clinical governance group.

Clinical governance group

- Analyses how and why the incident happened
- Checks compliance with this policy
- Seeks expert advice if needed
- Conducts a learning review or other type of review for SAC 1 and 2 harm events
- Conducts quality improvement activity related to the learning outcome, as applicable
- Shares learnings in health networks locally, regionally, nationally, as applicable.

Primary Health Organisation (PHO) may assist with:

- restorative practice
- cultural support for consumer engagement
- learning review assistance
- system accountability and learning.

1.4.2 Key steps for when harm or potential harm is reported (example only)

For all adverse events

1. An incident of adverse (harm) is reported to the general practice
2. All incidents received within the practice will be entered into an incident register within <<timeframe>>. The location of the incident register is: << practice to enter location>>
3. The <<identify role>> will ensure immediate actions have been taken to prevent further harm and support the wellbeing of everyone involved.
4. The appropriate team member(s) <<identify role(s)>> discuss the harm with the patient and whānau, and their immediate needs, within <<timeframe>>. (Consider appropriate tikanga for engaging with patients and whānau.) If they are not ready to engage, respect their wishes but provide them with a contact they can use for future engagement if they choose.
5. A provisional level of harm rating is established using:
   - the discussion (no. 3 above)
   - the **Severity Assessment Code (SAC) rating tool** to categorise incidents
   - the **primary care SAC examples**.
6. If the harm rating is SAC 3 or SAC 4, we will:
   - manage the event through our practice processes and report the event at the next clinical governance group meeting
   - identify any trends and patterns and actions for improvement as part of the review
   - close the loop – we will evaluate our improvement actions to ensure sustainable change.

Managing and reporting adverse reactions

1. If an adverse event involves a suspected reaction to a therapeutic product, it must be reported to Medsafe. In addition, the event should be managed in accordance with the adverse event procedure outlined in Step 2 of this guide.
2. If the event is rated SAC 1 or 2, It needs to be reported to Te Tāhū Hauora| HQSC.

For SAC 1 and 2 events only

1. If the harm rating is SAC 1, SAC 2, we will:
   - immediately notify leadership and the clinical governance group and manage the event in line with this process/procedure
   - where appropriate, identify and review any similar events together
   - conduct a formal review and submit a report of harm to Te Tāhū Hauora| HQSC
   - close the loop – we will evaluate our improvement actions to ensure sustainable change.

2. Reporting
   - See Appendix 1 on how to report SAC 1 or 2 event to Te Tāhū Hauora| HQSC. Note that part A must be submitted within 30 working days.

3. Review
   - For a SAC 1 or 2 harm event, we will complete a **learning review** in collaboration with/ with the support of our PHO.

   Throughout the review, the practice will need to:
   - engage regularly with the patients, whānau and health care worker(s) involved in the harm (adverse) event so that the review meets their needs.
   - allocate a key contact for the patient and whānau (where possible, get consent from the patient before involving whānau).
   - undertake a review that meets the policy principles and write a draft report.
   - develop learning opportunities and recommend actions for sustainable system improvement.
   - share the draft report with patients, whānau and team members (as applicable) for feedback before finalising the report.
   - finalise the learning opportunities and recommended actions for improvement within the clinical governance process.
   - decide on a final SAC rating based on the harm experienced (rather than on the learning opportunities and recommended actions for improvement).

4. Sharing and learning
   - Share anonymised learning opportunities, as well as regular updates on progress, with the patient(s), whānau and team members.
   - Share anonomysed information locally and regionally (with a wider learning review).
   - Consider sharing anonomysed information nationally where appropriate or among professional forums.
   - Team members will be supported to undertake CPD ‘Learning from Harm’ education to understand open communication, offered by Te Tāhū Hauora| HQSC.

1.4.3 Resources to assist with process and procedure building:

Te Tātū Hauora | HQSC:

- National Adverse Events Policy 2023: Healing, Learning and Improving from Harm
- Te Tāhū Hauora user guide: National adverse events policy 2023
- Primary care SAC examples
- Severity Assessment Code rating tool
- Code of expectations for health entities' engagement with consumers and whānau (2022)

Relevant legislation

- Health and Disability Commission Act and Patient Code of Rights 1994
- Privacy Act 2020
- Health and Safety at Work Act 2015
- Pae Ora (Health Futures) Act 2023

Contracts

PHO Services Agreement.

2 APPENDIX 1: Reporting and submitting SAC 1 OR 2 events

NOTE: For more detailed information, please refer to: **Te Tāhū Hauora user guide: National adverse events policy 2023**

How to submit a report of harm and timelines

For all SAC 1 and SAC 2 events, complete Part A learning from harm form within 30 working days of the provider receiving notification of the event.

Once the review is finished, complete Part B learning harm form within 120 working days of the provider receiving notification of the event.

To complete both parts, use the 2023 Part A and B templates, available on the Healing, Learning and Improving from Harm web hub under system accountability.

To upload, go to **www.hqsc.govt.nz/our-data/data-submission/** and click on the 'Adverse events' tab.

1. This takes you to the login page, where you enter your generic organisation username and password.
2. If you require a generic login for your organisation, please contact: **adverse.events@hqsc.govt.nz**
3. Once you reach the adverse event submissions page, upload your files to the links.

You can also upload your anonymised final reports with the Part B form.

A confirmation email will be sent to you automatically to confirm receipt of your upload.

Accessing and reconciling the dashboard

Refer to the Te Tātu Hauora **Healing, Learning and Improving from Harm: User Guide** for step by step guidance on accessing your organisation's individual dashboard.

Each quarter, download a report through the 'Event list' tab and send the spreadsheet with any required changes to: **adverse.events@hqsc.govt.nz**