Health Quality & Safety Commission New Zealand
Kupu Taurangi Hauora o Aotearoa

National Adverse Events Reporting Policy 2017

New Zealand health and disability services

June 2017

Contents

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Please send all related enquiries to: adverse.events@hqsc.govt.nz

Purpose

1. The purpose of this Policy is to contribute to improved quality, safety and experience of health and disability services through systems that:
   1.1. are consumer and whānau-centred
   1.2. provide for early identification and review of adverse events affecting consumers of health and disability services
   1.3. ensure lessons are learnt so the risk of repeating preventable adverse events is minimised
   1.4. demonstrate public accountability and transparency
   1.5. are safe.
2. This Policy supports a national approach to reporting, review and learning from adverse events and near misses.

Treaty of Waitangi

3. Crown health and disability services are required to acknowledge the special relationship between iwi and the Crown under the Treaty of Waitangi. The principles of Partnership, Participation and Protection will continue to underpin the relationship that iwi have with Crown health and disability services in New Zealand.

Principles

4. The fundamental role of an adverse events reporting system is to enhance consumer safety by learning from adverse events and near misses that occur in health and disability services. This Policy assists health and disability service providers to build and maintain a robust reporting, review and learning system within their organisation. The following principles underpin this Policy:
   4.1. **Open communication.** Consumers and their whānau are ethically and legally entitled to truthful and open communication at all times following an adverse event. In New Zealand, health and disability service providers have a legal duty to take steps to ensure that open communication is practised by staff and supported by management.[1]
   4.2. **Consumer participation.** Adverse events need to be considered within the context of the whole consumer and whānau experience of care. Including the consumer perspective in the review process enables a broader understanding of the circumstances surrounding an adverse event. It is expected that, at a minimum, consumers and whānau who have been involved in an adverse event will be offered the opportunity to share their story as part of the review process and that review findings and recommendations will be shared with them. Health and disability service providers should also consider involving independent consumer representatives in the review process.

1 Right 6 of the Code of Health and Disability Services Consumers' Rights gives all consumers the right to be fully informed (ie, to receive the information that a reasonable consumer in his or her situation would expect to receive) (www.hdc.org.nz/the-act--code/the-code-of-rights).

4.3. **Culturally appropriate review practice.** The cultural viewpoint and practices of a consumer and their whānau should be considered in the open communication, reporting, review and learning process.

4.4. **System changes.** Reporting is only of value if it is accompanied by meaningful analysis that leads to system changes designed to prevent recurrence of adverse events and near misses. Lessons learnt must be shared locally by individual health and disability service providers. Health and disability service providers are also strongly encouraged to share learnings with other providers and centrally with the Health Quality & Safety Commission. The Commission's role is to share learnings nationally and promote a national approach to reporting, review and learning.

4.5. **Accountability** is provided by assuring consumers, whānau and the wider community that when adverse events and near misses occur, action is taken at both the local and the national level. Action at the local level focuses on learning, improving safety and reducing the possibility of recurrence. This includes a role for governors of health and disability service providers to ensure that recommendations are implemented and followed up. At the national level, action focuses on analysing aggregated data, reporting publicly on adverse events and near misses, and sharing information about actions taken to reduce the possibility of recurrence. Governors of national organisations are responsible for ensuring these activities happen in a timely way.

4.6. **Reporting must be safe.** Consumers, whānau and staff must be empowered to report adverse events and near misses without fear of retribution. Reported events must be investigated with a focus on determining the underlying system failures and not blaming or punishing individuals. Health and disability service providers must ensure a just culture[2] prevails so individuals are not held accountable for system failures. Incidents that involve a criminal act, substance abuse by a health practitioner, a deliberate unsafe act or deliberate consumer harm will be managed in a separate process and may involve the relevant regulatory authorities.

Scope

5. In scope:

5.1. All New Zealand health and disability service providers who have obligations under the Health and Disability Services (Safety) Act 2001.[3]

5.2. All New Zealand health and disability service providers who voluntarily comply but are not obliged to under the Health and Disability Services (Safety) Act 2001.

5.3. All adverse events and near misses that occur, or have the potential to occur, to any person as a result of, or related to, the provision of health and disability services.

2 A just culture is one in which frontline personnel are comfortable disclosing errors, including their own, while maintaining professional accountability. It recognises individual practitioners should not be held accountable for system failings over which they have no control, yet does not tolerate conscious disregard of clear risks to patients or gross misconduct (Center for Patient Safety, www.centerforpatientsafety.org/patient-safety-glossary).

3 Obligations arise under the Health and Disability Services (Safety) Act 2001, Section 5; New Zealand Public Health and Disability Act 2000, Section 59C; and the Ministry of Health's Operational Policy Framework 2016/17. Obligations may also be contained in other formal agreements/contracts such as a Crown Funding Agreement between a provider and the Crown, or a contract between a district health board and a local provider of disability, community or aged care services.

6. Out of scope:
    6.1. Occupational health and safety events affecting any employee, employer, contractor or volunteer within health and disability service settings in New Zealand. These are managed under the Health and Safety at Work Act 2015 (and regulations), which aims to secure the health and safety of workers and workplaces.[4]
    6.2. Employment relationship issues and events affecting any employee in health and disability service settings in New Zealand. These are managed under the Employment Relations Act 2000 (and regulations), which aims to build productive employment relationships by promoting good faith in all aspects of the employment environment and the employment relationship.[5]

Policy

7. This is a national Policy. In the interests of national consistency and continuous improvement, all health and disability service providers obliged to comply and those who voluntarily agree to comply with this Policy are expected to:
    7.1. have a local policy, processes and systems in place for reporting, review and learning from adverse events and near misses; local policies, processes and systems must meet the requirements of this Policy and the Health and Disability Service Standards NZS8134:2008[6]
    7.2. openly communicate with consumers and their whānau in line with the Health and Disability Commissioner's guidance on open disclosure[7]
    7.3. stay up-to-date with national reporting requirements
    7.4. have processes in place to support staff involved in an adverse event and subsequent review.
8. All health and disability service providers obliged to comply and those who voluntarily agree to comply with this Policy are expected to:
    8.1. determine the severity of every reported adverse event using the Severity Assessment Code (SAC)[8]
    8.2. refer to the Always Report and Review list when triaging adverse events and near misses for reporting;[9] the Always Report and Review list is a subset of events that should be reported and reviewed, irrespective of whether or not there was harm to the consumer
    8.3. report all SAC 1 and 2 rated adverse events, plus events from the Always Report and Review list, to the Health Quality & Safety Commission **within 15 working days** from the date the event is reported to the provider[10]
    8.4. undertake formal review of all SAC 1 and 2 rated adverse events, plus events from the Always Report and Review list, develop recommendations to eliminate, control or accept causal or contributory factors, and develop a pathway to oversee the implementation and operation of those recommendations

4 Health and Safety at Work Act 2015 (www.legislation.govt.nz/act/public/2015/0070/latest/DLM5976667.html?search=ts_act%40bill%40regulation%40deemedreg_health+safety+work_resel_25_a&p=1).

5 Employment Relations Act 2000 (www.legislation.govt.nz/act/public/2000/0024/latest/DLM58317.html).

6 Health and Disability Services Standards NZS8134:2008 (www.health.govt.nz/our-work/regulation-health-and-disability-system/certification-health-care-services/services-standards).

7 Health and Disability Commissioner, *Guidance on Open Disclosure Policies* (www.hdc.org.nz/media/18328/guidance%20on%20open%20disclosure%20policies%20dec%2009.pdf).

8 See the Severity Assessment Code (SAC) rating tool (Appendix A).

9 See the Always Report and Review list (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2936).

10 Use the adverse event brief: part A (Appendix B).

8.5. send a summary of review findings and recommendations for all SAC 1 and 2 rated adverse events, plus events from the Always Report and Review list, to the Health Quality & Safety Commission **within 70 working days** from the date the event is reported to the provider.[11] This summary must include an outline of the actions agreed by the chief executive officer (or equivalent), or senior delegate on their behalf, or the reasons for not implementing the recommendations of the review.

9. In the interests of national consistency and continuous improvement, all health and disability service providers are encouraged to:

   9.1. notify the Health Quality & Safety Commission of near miss events with a high potential for causing serious harm, or those adverse events rated as SAC 3 or 4 where national learning can occur

   9.2. send non-identifiable versions of full review reports to the Health Quality & Safety Commission to further enhance the opportunity for national learning.

Referral

10. The Health Quality & Safety Commission may have a common law duty[12] to refer adverse events to other agencies in situations where it is necessary to protect and promote public health and safety. The Health Quality & Safety Commission will be transparent, open and inclusive with affected health and disability service providers when discharging this duty.

Review of this Policy, operational guidance and forms

11. This Policy, supporting operational guidance and forms will be reviewed at least every five years.

11 Use the adverse event brief: part B (Appendix B).

12 For discussion refer: *Attorney-General, ex rel Lewis v Lower Hutt City* [1964] NZLR 438 (Court of Appeal), S v MidCentral District Health Board (No 2) [2004] NZAR 342 (HC).

Definitions

Adverse event

An event with negative or unfavourable reactions or results that are unintended, unexpected or unplanned[13] (also referred to as 'incident' or 'reportable event'). In practice this is most often understood as an event which results in harm or has the potential to result in harm to a consumer.

Adverse event brief

This is the two-part form used to transmit information about adverse events and near misses to the Health Quality & Safety Commission.[14]

Part A of the adverse event brief is used to communicate the nature of the event. It must be sent to the Health Quality & Safety Commission **within 15 working days** of notification of the event to the provider. Part A is also used to transmit urgent information (alerts) to the Commission.

Part B of the adverse event brief is used to provide a summary of the review findings and recommendations related to the adverse event or near miss. It must be sent to the Health Quality & Safety Commission **within 70 working days** of notification of the event to the provider.

Always Report and Review events

The Always Report and Review list is a subset of adverse events that should be reported and managed in the same way as SAC 1 and 2 rated events, irrespective of whether or not there was harm to the consumer.[15] Always Report and Review events are events that can result in serious harm or death but are preventable with strong clinical and organisational systems. Reporting Always Report and Review events can highlight weaknesses in how an organisation manages fundamental safety processes.

The Always Report and Review list is updated regularly by the Health Quality & Safety Commission.

Consumer

For the purposes of this Policy a consumer can also be a client, patient or resident. It is the person who uses/receives health and disability services, or their representative.

13 Health and Disability Services Standards NZS8134:2008 (www.health.govt.nz/our-work/regulation-health-and-disability-system/certification-health-care-services/services-standards).

14 See Appendix B.

15 See the Always Report and Review list (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2936) and the Severity Assessment Code (SAC) rating and triage tool for adverse event reporting (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2937).

Near miss

This is an event which, under different circumstances, could have caused harm to a consumer but did not, and which is indistinguishable from an adverse event in all but outcome.

Open communication

Open communication, or open disclosure, refers to the timely and transparent approach to communicating with, engaging with and supporting consumers and their whānau when adverse events occur.[16]

Review

A review is another name for a formal process that is carried out by the health or disability service provider to analyse an adverse event or near miss and develop recommendations based on the findings. There are a variety of review methodologies.[17] Reviews can be undertaken at different levels, depending on the adverse event (eg, comprehensive, concise, desk-review or single aggregated review of similar events).

Severity Assessment Code (SAC)

The SAC is a numerical rating which defines the severity of an adverse event and as a consequence the required level of reporting and review to be undertaken for the event.[18]

Whānau

The family or extended family/group of people who are important to the consumer.

16 Health and Disability Commissioner, *Guidance on Open Disclosure Policies* (www.hdc.org.nz/media/18328/guidance%20on%20open%20disclosure%20policies%20dec%2009.pdf).

17 Examples include root cause analysis (RCA), RCA2, London Protocol, Serious Event Analysis, Critical Systems Analysis, Yorkshire Contributory Factors Framework, Functional Resonance Analysis Method and Serious Incident Review.

18 See Appendix A and the Severity Assessment Code (SAC) rating and triage tool for adverse event reporting (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2937).

Appendix A: Severity Assessment Code (SAC) rating tool[19]

Rate severity of adverse events on ACTUAL outcome (near misses are rated SAC 4)

Severe	Major	Moderate	Minor	Minimal
Death or permanent severe loss of function • not related to the natural course of the illness • differs from the immediate expected outcome of the care management • can be sensory, motor, physiological, psychological or intellectual	Permanent major or temporary severe loss of function • not related to the natural course of the illness • differs from the immediate expected outcome of the care management • can be sensory, motor, physiological, psychological or intellectual	Permanent moderate or temporary major loss of function • not related to the natural course of the illness • differs from the immediate expected outcome of the care management • can be sensory, motor, physiological, psychological or intellectual	Requiring increased level of care including: • review and evaluation • additional investigations • referral to another clinician	• No injury • No increased level of care or length of stay • Includes near misses
SAC 1	SAC 2	SAC 3	SAC 4	

19 See also the Severity Assessment Code (SAC) rating and triage tool for adverse event reporting (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2937).

Appendix B: Adverse event brief – parts A and B

Part A[20]

To be sent to the Health Quality & Safety Commission within 15 working days from the date the event is notified to the provider

Organisation:		
Organisation event reference:		
Contact	Name:	
	Tel:	
	Email:	
Date of event:		
Date of internal notification:		
Type of organisation: *(check all that apply)*		
DHB ☐		Private medical/surgical ☐
Mental health ☐		NGO ☐
Aged care ☐		PHO ☐
Ambulance service ☐		Disability services provider ☐
Other (please specify) ☐		

Provisional event code:[21]	
Provisional SAC rating:[22]	

Further event information:

	Y/N
Near miss?	
On Always Report and Review list?	
Any other providers involved in the event?	
Alert required?[23]	

20 An editable online version of this form in Microsoft Word format is available at: www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2939.

21 See Appendix C.

22 See Appendix A.

23 Alert Y/N: State 'Y' if the reporting provider wishes to raise an alert, which will result in the Health Quality & Safety Commission contacting the provider.

Description of event:

Include brief description of event and outcome/impact for consumer. Clinical context is useful.

Consumer details:

Age:	
Gender:	
Ethnicity:	

This adverse event brief: part A has been approved for transmission to the Health Quality & Safety Commission by the organisation's **chief executive (or equivalent) or senior delegate** who endorses the accuracy and content of the document on their behalf.

Name:	
Position:	
Date sent:	

Please send completed form and any related enquiries to: **adverse.events@hqsc.govt.nz**

Part B[24]

To be sent to the Health Quality & Safety Commission within 70 working days from the date the event is notified to the provider

Organisation event reference:		
Contact	Name:	
	Tel:	
	Email:	
Date review complete:		

Final event code:[25]	
Final SAC rating:[26]	

Summary of review findings (or insert/attach non-identifiable version of full review report):

If withdrawing or reclassifying SAC rating for event, include rationale.

24 An editable online version of this form in Microsoft Word format is available at: www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2940.

25 See Appendix C.

26 See Appendix A.

List of review recommendations, including changes to systems and processes:

Are findings reflected in recommendations? Consider effectiveness of recommendations made.

Other comments:

Include reasons for not implementing any of the recommendations.

Further review information:

	Tick
Confirm review findings and recommendations have been shared with consumer involved and their whānau (in line with principles of open communication and consumer participation).	☐
Would your organisation like to receive the Health Quality & Safety Commission's feedback on the quality of your adverse event review?	☐

This adverse event brief: part B has been approved for transmission to the Health Quality & Safety Commission by the organisation's **chief executive (or equivalent) or senior delegate** who endorses the accuracy and content of the document on their behalf.

Name:	
Position:	
Date sent:	

Please send completed form and any related enquiries to: **adverse.events@hqsc.govt.nz**

Appendix C: Event codes

The event codes below are derived from the World Health Organization classifications for patient safety.[27]

Following receipt of the adverse event brief: part B, the Health Quality & Safety Commission may classify the event in more detail or request additional clarifying information.

If there are any queries about what classification to apply to the event being reported, please contact **adverse.events@hqsc.govt.nz** for advice.

General classification of event	Event code
Clinical administration (eg, handover, referral, discharge)	01
Clinical process (eg, assessment, diagnosis, treatment, general care)	02
Documentation	03
Healthcare associated/acquired infection	04
Medication/IV fluids	05
Blood/blood products	06
Nutrition	07
Oxygen/gas/vapour (eg, wrong gas, wrong concentration, failure to administer)	08
Medical device/equipment	09
Behaviour (eg, intended self-harm, aggression, assault, dangerous behaviour)	10
Consumer/patient accidents (not falls) (eg, burns, wounds not caused by falls)	11
Consumer/patient falls	12
Infrastructure/buildings/fittings	13
Resources/organisation/management	14

27 *Conceptual Framework for the International Classification for Patient Safety, Version 1.1; Final Technical Report, January 2009* (www.who.int/patientsafety/taxonomy/icps_full_report.pdf).

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