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

A guide to the National Adverse Events Reporting Policy 2017

June 2017

Contents

Published in June 2017 by the Health Quality & Safety Commission.

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Policy changes at a glance

- A more consumer-centred approach to adverse event reporting, review and learning, including an expectation of culturally appropriate review practice and consumer involvement in the review process
- Improved clarity regarding national and local roles in reporting, review and learning systems, and an increased emphasis on the roles and responsibilities of organisational governance
- Explicit expectation that health and disability service providers will have processes to support staff involved in adverse events
- Enhanced mechanisms to support shared learnings, including encouragement to send full, non-identifiable review reports to the Health Quality & Safety Commission ('the Commission') and ability to report near misses and Severity Assessment Code (SAC) 3 and 4 events to the Commission
- Flexibility to use a wide range of review methodologies, and opportunity to receive feedback from the Commission on reviews
- Introduction of an Always Report and Review list,[1] a subset of events that should be reported and reviewed irrespective of whether or not there was harm to the consumer
- Classification of event severity based on actual outcome; removal of likelihood table (table can still be used to determine likelihood of an event happening again for local risk management systems)
- Development of a SAC rating and triage tool for adverse event reporting[2] to clearly show pathways for classifying, reporting and reviewing adverse events, near misses and Always Report and Review events
- Clear intention to extend coverage of the national reporting, review and learning system across the whole health and disability sector, including a single policy and reporting process for events that occur in different parts of the sector (including mental health and addictions)

1 See: www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2936.

2 See: www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2937.

Introduction

The 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.

In New Zealand, reporting of adverse events and near misses is guided by the National Adverse Events Reporting Policy 2017 ('the Policy').[3] The Policy supports a nationally consistent approach to reporting, review and learning from adverse events and near misses. Under the Policy, health and disability service providers with obligations under the Health and Disability Services (Safety) Act 2001, and those who voluntarily comply, are expected to (a) notify the Health Quality & Safety Commission ('the Commission') of serious adverse events and (b) provide the Commission with findings and recommendations from review of these events to enable national learning.

The Policy, which was first released in 2012 as the National Reportable Events Policy, has recently been reviewed. This document summarises key changes to the Policy and highlights implications for national and local adverse events reporting, review and learning systems.

Please read the guide in conjunction with the Policy and associated documents (listed on page 11).

The 2017 Policy comes into effect 1 July 2017. All events occurring on or after 1 July 2017 are covered by the 2017 Policy. It is expected that health and disability service providers will modify their practice to accommodate changes associated with the 2017 Policy as soon as possible (highlighted as practice updates in this document). However, the Commission recognises that some of the changes may take time to embed into systems and practice, and, as such, the 2017–18 year will represent a transitional year with regard to reporting, review and learning practice.

3 Available at: www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2933.

Policy review process

In 2016, informed by literature review findings and key stakeholder discussions, the Adverse Event Learning Programme expert advisory group approved five overarching themes for policy change:

1. Increase the focus on people who use services (consumers/patients).
2. Expand the purpose statement to clarify national and local roles and expectations.
3. Increase the focus on learning and action to strengthen implementation and monitoring of recommended actions.
4. Make it easier for organisations to report and prioritise for national reporting.
5. Make the policy relevant to the whole health and disability sector and move to greater coverage over time.

Proposed changes to the Policy were summarised in a discussion document and stakeholders were invited to provide feedback on specific questions relating to each of the five themes.[4] The expert advisory group reviewed stakeholder feedback in March 2017 and as a result of this feedback recommended a number of changes to the Policy. These changes were approved by the Commission Board in April 2017.

The Policy review process was informed by a number of information-gathering activities:

- online stakeholder survey seeking initial input on changes to the Policy (2015)
- review of overseas literature on patient safety reporting systems (2016)
- interviews and meetings with key stakeholders on ways to improve the Policy (2016)
- online and written stakeholder feedback on proposed changes to the Policy (November 2016 to January 2017).

4 See the Review of the National Reportable Events Policy 2012: Discussion document (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2681) and the Review of the National Reportable Events Policy 2012: Summary of stakeholder feedback on proposed policy changes (March 2017)) (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2935).

Policy changes

Terminology

There were mixed views among stakeholders on whether terminology other than 'adverse event' should be used in the updated Policy (eg, 'patient safety incident' or 'consumer safety incident'). Overall, however, there was support for continued use of 'adverse event' due to its familiarity, perceived ability to accommodate a broader range of events, consistency with terminology used in New Zealand standards and overseas jurisdictions, and lack of a strong rationale for change.

Policy changes:

1. The term 'adverse event' continues to be used in the 2017 Policy and related material. The definition of adverse event has been updated to align with the Health and Disability Services Standard NZS8134:2008.[5]
2. Reporting forms are now called adverse events briefs or AEBs (parts A and B).[6] Previously they were called reportable event briefs or REBs.

Theme 1: Increase the focus on people who use services

The 2017 Policy supports a consumer-centred approach to adverse event reporting, review and learning. Adverse events must be considered in the context of the consumer and whānau whole experience of care. Providers should acknowledge the effects of an adverse event on the consumer and their whānau and assure them action has been taken to reduce the possibility of recurrence.

Policy changes:

1. The principle of open communication has been strengthened to make it explicit that consumers and their whānau are ethically and legally entitled to truthful and open communication following an adverse event, and that health and disability service providers have a legal duty to ensure open communication is practised and supported in the organisation (clause 4.1).
2. The principle of consumer participation is now explicit in the Policy (clause 4.2), including expectations that:
    a. involved consumers and their whānau will be offered the opportunity to share their story as part of the review process
    b. review findings and recommendations will be shared with involved consumers and their whānau
    c. providers will consider involving independent consumer representatives in the review process.
3. The principle of culturally appropriate review practice has been added to the Policy (clause 4.3). The cultural viewpoint and practices of a consumer and their whānau should be considered in the open communication, reporting, review and learning process.

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

6 Part A is available at www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2939; part B is available at www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2940.

4. Information on the affected consumer's ethnicity is now collected in the adverse event brief: part A reporting form.
5. Information on whether a review has been shared with the affected consumer and their whānau is asked for in the adverse event brief: part B reporting form.

Support for health and disability service providers:

1. The Commission will develop and strengthen education, training, guidance and resources on consumer and whānau involvement in reporting, review and learning.
2. The Commission will develop and strengthen education, training, guidance and resources on culturally appropriate review practice. As part of this, the Commission will seek input from health and disability service providers on their approaches to, and experiences of, culturally appropriate review practice.

Practice updates:

- Offer involved consumers and their whānau the opportunity to share their story as part of the review process.
- When planning a review, consider involving an independent consumer representative in the review process.
- Share review findings and recommendations with involved consumers and their whānau.
- Record the involved consumer's ethnicity, age and gender in the adverse event brief: part A.
- Record whether the review has been shared with the involved consumer and their whānau in the adverse event brief: part B.

Theme 2: Expand the purpose statement to clarify national and local roles and expectations

The updated Policy clarifies national and local roles in adverse event reporting, review and learning.

Policy changes:

1. The role of the Policy in (a) supporting a national approach to reporting, review and learning and (b) assisting health and disability service providers to build and maintain robust organisational reporting, review and learning systems has been made more explicit (see clauses 2 and 4, respectively).
2. There is now an explicit expectation that accountability at the local level includes a role for governors of health and disability service providers in ensuring review recommendations are implemented and followed up, and a role for governors of national organisations in ensuring analysis, national reporting and information sharing takes place in a timely way (clause 4.5).

Support for health and disability service providers:

1. Reporting, review and learning from adverse events should all happen within a clinical governance framework, including an expectation that organisational governors are included in the reporting, review and learning feedback loop. The Commission has a range of guidance to assist organisations in understanding the role of governance in reporting and learning, including:
   a. *Governing for quality: A quality and safety guide for district health boards*[7]
   b. *Clinical governance: Guidance for health and disability providers*[8]
   c. *From knowledge to action: A framework for building quality and safety capability in the New Zealand health system.*[9]
2. The expectation that an organisation's chief executive officer (or senior delegate on their behalf) will sign-off adverse event brief: parts A and B reports has been retained in the updated Policy. The Commission will follow up with providers where parts A and B are submitted without executive sign-off.
3. The Commission will work with agencies such as the Accident Compensation Corporation, the Office of the Health and Disability Commissioner, the Ministry of Health and Coronial Services to develop an infographic that describes reporting responsibilities, mechanisms, jurisdictions and inter-agency relationships. This will enhance knowledge and understanding of different national reporting systems and how they interact with each other.

Practice update:

- Ensure adverse event brief: parts A and B are signed off by the chief executive officer (or equivalent), or a senior delegate on their behalf, before being sent to the Commission.

Theme 3: Increase the focus on learning and action to strengthen implementation and monitoring of recommended actions

The updated Policy has a strong focus on enhanced learning and action from adverse events, particularly through improved quality of reviews, increased action following reporting and encouragement to report SAC 3 and 4 rated and near miss events where there is value for national learning.

There is also a greater focus on supporting staff involved in adverse events and subsequent reviews.

Policy changes:

1. In addition to the expectation that health and disability service providers will share lessons learned locally, providers are strongly encouraged to also share learnings with other providers and with the Commission (clause 4.4).
2. Further to the expectation that health and disability service providers will send a summary of review findings and recommendations to the Commission (for SAC 1 and 2 rated events and events on the Always Report and Review list), providers are encouraged to also send non-identifiable versions of full review reports to the Commission to support national learning (clause 9.2).

7 See: www.hqsc.govt.nz/our-programmes/improving-leadership-and-capability/publications-and-resources/publication/2488.
8 See: www.hqsc.govt.nz/our-programmes/improving-leadership-and-capability/publications-and-resources/publication/2851.
9 See: www.hqsc.govt.nz/our-programmes/improving-leadership-and-capability/publications-and-resources/publication/2669.

3. The adverse event brief: part B form offers health and disability service providers the option of receiving feedback on the quality of their adverse event review from the Commission.
4. The adverse event brief: part A form includes a tick-box to indicate that an event is a near miss. This is consistent with the expectation that near miss events with high potential for causing serious harm should be considered for reporting to the Commission. Note that near miss and SAC 3 and 4 events will not (at this stage) be reported on in the same way as SAC 1 and 2 events; instead they will be used to develop learning cases and Open Book reports, published by the Commission.[10]
5. There is an explicit expectation that health and disability service providers will have processes in place to support staff involved in an adverse event and subsequent review (clause 7.4).

Support for health and disability service providers:

1. The Commission will review and strengthen the guidance and resources it currently provides on carrying out high-quality reviews and making effective recommendations.
2. The Commission will further develop its training programme to include masterclass training and to ensure its existing training workshops are relevant and inclusive for non-district health board parts of the sector (eg, primary care and disability support providers).
3. The Commission will develop a shared learning tool to help providers share learnings locally and nationally to support the development of Open Book reports. The Commission will also review its Open Book process to enable faster turnaround of shared learnings.
4. The Commission has developed a SAC rating and triage tool for adverse event reporting that shows pathways for classifying, reporting and reviewing adverse events and near misses, including guidance on reporting near miss events with high potential for causing harm and adverse events rated SAC 3 and 4 with potential for national learning. The tool highlights an expectation that organisations will maintain an actions register, linked to organisational governance structures, to ensure review learnings are actioned and monitored for progress.
5. The Commission will develop and strengthen guidance and facilitate learning opportunities related to reporting, review and learning from near miss and SAC 3 and 4 rated adverse events.
6. The Commission has provided a link to Assist Me – guidance on how to support staff involved in an adverse event – on its website. The Commission will also explore other opportunities to provide education, training and resources on supporting staff through an adverse event and any subsequent review process.

Practice updates:

- Ensure processes are in place to support staff involved in an adverse event and the subsequent review process.
- Consider sharing review learnings widely with other health and disability providers and the Commission, not just locally.
- Consider sending non-identifiable versions of full review reports to the Commission to support national learning.
- Identify near miss and SAC 3 and 4 rated events with value for national learning on the adverse event brief: part A.
- Consider taking the opportunity to seek feedback from the Commission on the quality of adverse event reviews.

10 See: www.hqsc.govt.nz/our-programmes/adverse-events/projects/open-book.

Theme 4: Make it easier for organisations to report and prioritise for national reporting

The updated Policy includes a number of measures to make it easier for health and disability service providers to understand and manage their reporting requirements, including the introduction of an Always Report and Review list, flexibility for providers to use a range of review methodologies and a simplified approach to classification of severity.

Policy changes:

1. There is an expectation that health and disability service providers will refer to the newly developed Always Report and Review list when triaging adverse events and near misses for reporting (clause 8.2). The Always Report and Review list is a subset of adverse events that should be reported and reviewed, *irrespective of whether or not there was harm to the consumer.* Always Report and Review events are events that can result in serious harm or death but are preventable with strong clinical and organisational systems. The Always Report and Review list will be regularly updated by the Commission in consultation with health and disability service providers.
2. The Policy sets out the expectation that, along with SAC 1 and 2 rated events, events on the Always Report and Review list will be reported to the Commission using the adverse event brief: part A form (clause 8.3) and will undergo formal review (clause 8.4). A summary of review findings and recommendations should be sent to the Commission using the adverse event brief: part B form (clause 8.5).
3. Health and disability providers are encouraged to use a formal review methodology of their choice when reviewing SAC 1 and 2 rated events and events from the Always Report and Review list (clause 8.4 and 'Review' definition). Previously the expectation was that all providers would use a root cause analysis methodology (or, for mental health events, a Serious Incident Review London Protocol).
4. Classification of the severity of an event, and therefore management of an event, has been simplified so that the SAC rating is determined only by outcome (severe, major and moderate harm are rated SAC 1, 2 and 3, respectively; minor and minimal harm are both SAC 4; see Appendix A of the 2017 Policy). The likelihood table has been removed from the Policy. Providers may continue to assess the likelihood of an event happening again to determine whether the event needs to be on the organisation's risk register.

Support for health and disability service providers:

1. The SAC rating and triage tool for adverse event reporting provides:
   a. management pathways based on an event's SAC rating
   b. management pathways for events on the Always Report and Review list.
2. The Commission will develop and share guidance, tools and templates on different review methodologies. The Commission will also provide guidance on determining the level of review appropriate for different adverse events (eg, whether a comprehensive, aggregated or concise review is required).

Practice updates:

- From 1 July 2017, events on the Always Report and Review list should be reported to the Commission using the adverse event brief: part A form, and findings and recommendations from reviews of Always Report and Review events should be provided to the Commission using the adverse event brief: part B form.
- From 1 July 2017, classification of the severity of an event should not consider likelihood; severity should be determined solely by outcome.
- Use any formal review methodology when reviewing SAC 1 and 2 rated events and events from the Always Report and Review list.

Theme 5: Make the Policy more relevant to the whole sector

There is strong support for continued work to extend national reporting, review and learning across the whole health and disability sector, including primary care, disability support services and aged residential care. Consumers receive care from various parts of the sector and often view transitions between various services as seamless, as opposed to finite, separate episodes of care. A whole-of-sector reporting, review and learning system can provide a complete picture of adverse events and near misses across the continuum of care and enable shared learning across the sector.

The updated Policy supports nationally consistent reporting, review and learning across the whole health and disability sector, including a single policy and reporting process for events that occur in different parts of the sector.

Policy changes:

1. A variety of formal review methodologies are supported in the updated Policy, some of which are more suited to use in non-secondary care settings.

Support for health and disability service providers:

1. The Always Report and Review list and the SAC examples table[11] include events relevant to all parts of the health and disability sector.
2. The Commission will continue to engage with wider sector stakeholders to explore ways of extending coverage of the national reporting, review and learning system across the health and disability sector. This will include consideration of reviews that span different parts of the sector.

Mental health events

Currently adverse events relating to users of mental health and addiction services are reported to the Commission, in line with the Policy, but publicly reported by the Office of the Director of Mental Health (ODMH). Mental health adverse events have most often been reviewed using the London Protocol as it was deemed more suitable than root cause analysis by mental health service providers. The 2017 Policy supports a move towards mental health and addiction events following the same reporting and review processes as non-mental health events. This was strongly supported in sector feedback on proposed policy changes.

11 See: www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2938.

Policy changes:

1. Specific processes for mental health reporting and review have been removed from the updated Policy. The 2017 Policy better accommodates mental health and addiction events by allowing for use of a broader range of review methodologies.

Support for health and disability service providers:

1. The SAC examples table includes events relevant to the mental health and addiction sector.
2. The Commission has recently embarked on a national mental health and addictions quality improvement programme, of which one work stream will be looking at adverse events. This work will further enhance guidance on mental health adverse event reporting, review and learning.
3. The Commission will work with the ODMH to determine how best to report and share learnings from events that occur in mental health and addiction services. In the meantime, numbers of events will continue to be shared through the ODMH's annual report and learnings from reviews will be shared through Open Book reports and other learning forums.

Referral of serious concerns to other agencies

In rare circumstances, it is possible that a significant issue could be identified through the Commission's receipt of an adverse event report that raises concerns about the ongoing safety of a provider. The updated Policy outlines the Commission's process for escalating these concerns.

Policy changes:

1. The Commission's process for escalating concerns where it is necessary to protect and promote public health and safety has been included in the updated Policy (clause 10). The Commission will be transparent, open and inclusive with affected health and disability service providers when discharging this duty.

Associated documents

1. Review of the National Reportable Events Policy 2012: Discussion document (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2681)
2. Review of the National Reportable Events Policy 2012: Summary of stakeholder feedback on proposed policy changes (March 2017) (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2935)
3. National Adverse Events Reporting Policy 2017 (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2933)
4. Always Report and Review list 2017–18 (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2936)
5. 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)
6. Severity Assessment Code (SAC) examples (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2938)
7. Adverse event brief: part A (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2939)
8. Adverse event brief: part B (www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2940)