Evidence review to inform development of the mental health and addiction quality improvement programme 'Learning from adverse events and consumer experience' project

February 2019

We acknowledge the experiences of the consumers, family and whānau affected by serious adverse events and we honour this with a commitment to learn and improve.

Contents

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Structure of this document

This evidence review is designed to inform the development of a mental health and addiction (MHA) quality improvement project to improve learning from adverse events and consumer experience within the framework of the National Adverse Events Reporting Policy 2017. The initiative will begin in 2019.

An adverse event is an event with negative or unfavourable reactions or results that are unintended, unexpected or unplanned[1] (also referred to as an 'incident' or 'reportable event'). In practice this is most often understood as an event that results in harm or has the potential to result in harm to a consumer.

This evidence review will provide:

- the Health Quality & Safety Commission's ('the Commission') MHA quality improvement programme team with useful information and an evidence base to design the improvement project
- teams participating in the project with:
  - an understanding of the evidence that underpins the National Adverse Events Reporting Policy 2017
  - evidence-based approaches that they can include in their projects.

The evidence review consists of three parts.

Part 1 provides a summary of *Patient safety reporting systems: A literature review of international practice*. This document was published by the Commission in June 2016 to help inform the review of the National Adverse Events Reporting Policy, which was published in June 2017. It covers the history of patient safety reporting systems (PSRS), challenges facing PSRS, characteristics of successful PSRS, and best practice approaches for local and national PSRS, and it answers some key questions. It is not specific to MHA services.

> We recommend reading the full report, which is available at: www.hqsc.govt.nz/assets/Reportable-Events/Publications/Patient-safety-reporting-systems-literature-review-Nov-2016.pdf.

Part 2 is a review of evidence about learning from adverse events and consumer experience specifically focused on MHA services. It covers:

- international approaches to learning from serious adverse events in MHA services and a selection of related tools and resources
- recent evidence relating to learning from serious adverse events and consumer experience in MHA services.

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

Part 2 of this document draws on an evidence review completed for the Commission by Linda Gilbert, Drawn Together Ltd, in February 2018.

Part 3 focuses on consumers as partners in learning from adverse events. It presents a full chapter from the Commission's *Learning from adverse events: Adverse events reported to the Health Quality & Safety Commission 1 July 2016 to 30 June 2017.*[2]

[2] Health Quality & Safety Commission. 2017. *Learning from adverse events: Adverse events reported to the Health Quality & Safety Commission 1 July 2016 to 30 June 2017.* Wellington: Health Quality & Safety Commission. URL: www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/3111.

Executive summary

The evidence

A scan of overseas literature outlined in the Health Quality & Safety Commission's (the Commission's) 2016 document *Patient safety reporting systems: A literature review of international practice*[3] describes the introduction of patient safety reporting systems (PSRS) to health care systems around the world and the challenges that have emerged since then. The report indicates that:

- there is a shortage of evidence that PSRS are effective
- people face barriers to reporting
- PSRS generate a large volume of highly diverse reports that health care organisations often do not have the resources to process
- there is insufficient action from reporting
- PSRS objectives are unclear.

By detailing best-practice approaches to PSRS, the report offers some possible solutions to the challenges for PSRS, answers some questions, and indicates the following clear directions that emerged from the review.

- Be clear about the distinct yet complementary roles of national versus local PSRS and design systems that take account of these different roles.
- Be clear about what the role of a particular patient safety reporting system is. In particular, identify whether its primary focus is on learning or on reporting and accountability.
- Prioritise reports submitted at national level and, at both national and local levels, prioritise the degree/level of investigation.
- Improve feedback. This is a critical dimension of a learning system and essential for motivating reporting.
- Take full advantage of new digital technologies, electronic health records and understanding of human behaviour to make reporting easier and more engaging and to improve the quality and effectiveness of data transfer and information sharing.
- Re-orient PSRS to put patients (consumers) and their experience of health and the health care system at the centre.

A recent evidence review specific to MHA services (included in Part 2 of this document) noted that the challenges of reporting and learning from serious adverse events were similar to those identified by the generic evidence review. The literature on MHA specifically notes challenges relating to:

[3] www.hqsc.govt.nz/assets/Reportable-Events/Publications/Patient-safety-reporting-systems-literature-review-Nov-2016.pdf

- low levels of reporting where a blame culture exists
- identifying causation of incidents and so determining the appropriate actions to prevent similar incidents – due to complexities of the organisation, the reporting process and the challenges of predicting consumer responses
- media attention
- clinicians being less willing to use the system and sceptical of its value
- lack of organisational support, high workload and leadership style.

The evidence review identified the following facilitating factors:

- a 'no-blame' learning culture within an organisation in which the reporting of errors is encouraged and seen as a positive action
- simple reporting, which is expected and the norm
- strong safety leadership
- organisational legitimacy, administrative support, training and resources.

In the few MHA studies that have been undertaken, most staff felt that incident reporting had a positive effect on safety, not only by leading to changes in care but by changing staff attitudes and knowledge. Over the past two years in particular there has been significant progress to develop systems, processes and tools suitable and applicable to the MHA sector. These meet the need for structured analysis, reporting and learning from errors and omissions. Examples of some of the key systems, processes and tools are highlighted in the review.

Some interesting issues are raised relating to the unique nature of MHA services that add a level of complexity to the analysis of serious adverse events. There is an understanding that although the particular state of mind of the MHA consumer is taken into account for the purposes of understanding what happened, reporting what happened and learning from what happened, it is a contributory factor, rather than the root cause. Given there will be known vulnerabilities and risks for MHA consumers, the emphasis needs to be placed on the system and its duty of care, rather than the mental health of the consumers the system is there to support.

The report also raises the argument that the structured root cause analysis (RCA) process used in general health care is too clinically focused and unable to account for the complexities and context presented within the mental health sector. It notes a number of alternatives, including some revised RCA models (Scotland and USA); the Canadian model, which follows a non-linear systems thinking approach; and the Serious Incident Review London Protocol used in New Zealand.

The National Adverse Events Reporting Policy 2017 encourages providers to use a formal review methodology of their choice. Previously, the expectation was that all providers would use an RCA methodology (or, for mental health events, the Serious Incident Review London Protocol). The 2017 policy accommodates MHA events by allowing for use of a broader range of review methodologies. The sector has indicated that the Serious Incident Review London Protocol remains its preferred option.

Evidence relating to consumers as partners in learning from adverse events

Part 3 of this document outlines the benefits, challenges and key approaches to partnering with consumers affected by adverse events in the review and learning processes that follow an adverse event.[4] It provides evidence and recognises that including the affected consumer's perspective in the review enables a broader understanding of the circumstances surrounding the event.

In accordance with the evidence, the National Adverse Events Reporting Policy 2017 requires providers, when reviewing an adverse event, to:

- consider the event within the context of the whole consumer experience of care or support
- offer consumers who have been involved in an adverse event the opportunity to share their story as part of the review process
- share review findings and recommendations with affected consumers
- consider involving independent consumers in the review process.

The Commission provides resources to help providers involve consumers in adverse event review and learning.[5]

New Zealand and international policy approaches to reporting and learning from adverse events in MHA services

The literature surveyed for this report shows there are a variety of policy approaches to reporting and learning from adverse events in MHA. Some countries have broad legislative frameworks (such as the USA) and national adverse events policies that include mental health within their scope (New Zealand, Australia, Scotland, England, Canada, USA), while others have designed their own bespoke reporting policies for adverse events in MHA that sit within, or alongside, the general health national adverse events policies (eg, Ireland).

While there is variation across the models in use, the literature typically calls for consistency, transparency, consumer, family and whānau involvement in the process, ownership, and straightforward systems that ensure reports are made and changes follow.

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4 Part 3 includes a full chapter from the Commission's *Learning from adverse events: Adverse events reported to the Health Quality & Safety Commission 1 July 2016 to 30 June 2017*.

5 www.hqsc.govt.nz/our-programmes/adverse-events/projects/engaging-with-consumers.

Part 1:
Patient safety reporting systems: a literature review of international practice

Summary of evidence relating to patient safety reporting (generic – not specific to MHA services)

The 2016 document *Patient safety reporting systems: A literature review of international practice* informed the review of the National Adverse Events Reporting Policy 2017.

The scan of overseas literature explored a wide range of topics relating to patient safety reporting. The report describes the introduction of patient safety reporting systems (PSRS) to health care systems around the world and the challenges that have emerged since then. The report indicates that:

- there is a shortage of evidence that PSRS are effective
- people face barriers to reporting
- PSRS generate a large volume of highly diverse reports that health care organisations often do not have the resources to process
- there is insufficient action from reporting
- PSRS objectives are unclear.

By setting out the characteristics of successful PSRS, outlining the role of national PSRS as distinct from local PSRS, and detailing best-practice approaches to national and local PSRS, the report offers some possible solutions to the challenges for PSRS and answers some questions about PSRS, such as:

- What is the role of national versus local systems?
- What should be reported?
- How can we give patients a stronger voice in reporting and learning?
- How do we enable reporting and learning from all care settings across the patient journey?
- How do we close the feedback loop?

From the discussion of new ways of thinking about patient safety, coupled with information about approaches in other jurisdictions and planned directions, the report further indicates how patient safety measurement might develop in the future.

The following clear directions emerged from this review.

- Be clear about the distinct yet complementary roles of national versus local PSRS and design systems that take account of these different roles.
- Be clear about what the role of a particular patient safety reporting system is. In particular, identify whether its primary focus is on learning or on reporting and accountability.
- Prioritise reports submitted at national level and, at both national and local levels, prioritise degree/level of investigation.
- Improve feedback. This is a critical dimension of a learning system and essential for motivating reporting.
- Take full advantage of new digital technologies, electronic health records and understanding of human behaviour to make reporting easier and more engaging and to improve the quality and effectiveness of data transfer and information sharing.

- Re-orient PSRS to put patients and their experience of health and the health care system at the centre.

You can read the full review at www.hqsc.govt.nz/assets/Reportable-Events/Publications/Patient-safety-reporting-systems-literature-review-Nov-2016.pdf.

We recommend reading this review alongside the remainder of this document.

Part 2:
Evidence review to inform the MHA quality improvement programme ‘Learning from serious adverse events and consumer experience’

Background

Mental health and addiction (MHA) problems are highly prevalent in New Zealand. Approximately 39.5 percent of people experience a mental illness during their lifetime,[6] and psychiatric conditions are now the leading cause of health loss in New Zealand.

The demand for MHA services is also increasing. For example, the number of people accessing specialist mental health services increased from 143,000 in 2011 to 162,222 in 2015 (accounting for 3.5 percent of the population).[7]

The increase in demand for services may be attributed to growing inequalities and changes in environments and cultures, such as increasing poverty, increasing globalisation, social media, and work type changes. This appears to be a global phenomenon with some more specific local drivers, such as the methamphetamine issue in New Zealand and the opioid crisis in the USA and Canada.

The growing awareness about MHA may also be contributing to increased demand. For example, the Like Minds, Like Mine and National Depression initiatives have reduced stigma and discrimination. As a result, people are becoming more willing to talk about these problems, and more willing to seek help and support if they need to.

With the positive elements that come with increased awareness there are also challenges, and with MHA in the public eye, these challenges are often highly publicised. Some of these challenges relate to service provision (eg, access to services and waiting times) and others relate to the outcomes for people with MHA problems (eg, high rates of suicide, in particular for Māori and youth,[8] and inequitable outcomes and disparities).

The quality and safety in MHA services impacts consumers, their families and whānau, and the wider community. There are opportunities to improve the quality and safety of MHA services by reducing unwarranted variation, boosting performance, fostering a recovery approach, and creating a culture of quality improvement and learning within MHA services.

To make the most of the opportunities to improve the quality and safety of MHA services, district health boards (DHBs) have funded the Health Quality & Safety Commission (the Commission) to undertake a five-year MHA quality improvement programme.

The programme will use improvement science to test evidence-based changes and interventions locally, measure the impact of these changes and, if the changes are successful, work with other services to implement the changes more widely. It will focus on five areas prioritised by MHA sector leaders:

- zero seclusion: towards eliminating seclusion by 2020
- improving medication management and prescribing
- connecting care: improving service transitions

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6 Oakley Browne MA, Wells JE, Scott KM (eds). 2006. *Te Rau Hinengaro: The New Zealand Mental Health Survey.* Wellington: Ministry of Health.

7 Ministry of Health. 2016. *Office of the Director of Mental Health Annual Report 2015.* Wellington: Ministry of Health.

8 http://socialreport.msd.govt.nz/health/suicide.html.

- maximising the physical health of people with MHA problems
- learning from serious adverse events and consumer experience.

An adverse event is an event with negative or unfavourable reactions or results that are unintended, unexpected or unplanned[9] (also referred to as an 'incident' or 'reportable event'). In practice this is most often understood as an event that results in harm or has the potential to result in harm to a consumer.

In New Zealand, reporting of adverse events, including MHA events, is guided by the National Adverse Events Reporting Policy 2017.[10] The purpose of the policy is to improve the quality, safety and experience of health and disability services through systems that:

- are safe
- are consumer, family and whānau-centred
- provide for early identification and review of adverse events
- ensure lessons are learnt so that the risk of repeating preventable adverse events is minimised
- demonstrate public accountability and transparency.

Adverse events in MHA services often relate to serious self-harm, suicide or harm to others. Feedback from sector leaders[11] identified that reviews are currently far too slow and that there is significant variation in the way that the reviews are carried out. They identified a clear opportunity to support providers in their efforts to learn from and reduce serious adverse events by providing guidelines and facilitating timely, consistent reporting and review. In addition to learning from the review of serious adverse events, a well-executed review process can minimise harm to both the family and whānau of the affected consumer as well as staff members involved in the event.

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

10 Health Quality & Safety Commission. 2017. *National Adverse Events Reporting Policy 2017: New Zealand health and disability services*. URL: www.hqsc.govt.nz/assets/Reportable-Events/Publications/National_Adverse_Events_Policy_2017/National_Adverse_Events_Policy_2017_WEB_FINAL.pdf.

11 National and regional meetings.

Scope and approach

Scope

The scope of the MHA quality improvement programme includes learning from adverse events and consumer experience. Learning from consumer experience in the context of this paper relates to the role that consumers (and families and whānau) play in the process of identifying, reviewing and learning from adverse events. It does not relate to the broader learning that can be obtained from consumer surveys, experience of consumer advisors or involvement of consumers in co-design processes.

Approach

Patient safety reporting mechanisms used in national and international mental health settings during 2012–17 have been reviewed. Inpatient as well as community-based settings are included.

The following evidence was gathered.

- *Experience-based evidence* from individual consumers and consumer groups. The Commission's MHA quality improvement team conducted, collected and collated information during 2017 from four regional workshops (see Appendix 1). Case studies from individual consumers, family and whānau are also included where appropriate to illustrate points made in the paper.

- *Published, peer-reviewed literature* from the Cochrane, Embase, Medline, Scopus, and PsychInfo databases. The key words used in the search strategy were ('mental health' OR suicid* OR antipsychotic* or psychiatric) AND ("adverse event*" OR "quality improvement' OR 'trigger tool*' OR 'incident reporting' OR 'london protocol' OR 'safety reporting system*' OR 'reporting and learning system*' OR 'organisational learning' OR 'organizational learning' OR 'near miss'). A more detailed list of search terms is included in Appendix 3.

- *Grey literature*.[12] A full list of all grey literature surveyed is included in the Bibliography section, and information used is included as footnotes throughout the paper. In addition, many websites were researched and these are included in the footnotes.

The literature review considered:

- patient safety reporting systems (PSRS) as part of a wider programme to understand how best to learn from adverse events and consumer experience
- how adverse events are currently reported in New Zealand – for the general population and for consumers of MHA services
- PSRS used in other countries similar to New Zealand
- levels of consumer participation in the processes related to PSRS
- administrative burdens of the identified PSRS

[12] The term 'grey literature' refers to research that is either unpublished or has been published in non-commercial form. Examples of grey literature include government reports, policy statements and issues papers.

- learning opportunities provided by the PSRS
- evidence of effectiveness
- alternatives to existing reporting mechanisms and systems
- opportunities to improve learning from near misses and adverse events.

National and international policies, systems, tools and resources

This section looks at New Zealand and international policies, systems, tools and resources for reporting and learning from adverse events. It shows that there are a variety of approaches.

New Zealand

Policy

In New Zealand, reporting of adverse events and near misses is guided by the National Adverse Events Reporting Policy 2017 ('the policy'). The policy supports a nationally consistent approach to reporting, review and learning from adverse events and near misses.

The purpose of the policy is to contribute to improved quality, safety and experience of health and disability services that:

- are consumer, family and whānau-centred
- provide for early identification and review of adverse events affecting consumers of health and disability services
- ensure lessons are learnt so the risk of repeating preventable adverse events is minimised
- demonstrate public accountability and transparency
- are safe.

The policy notes that the fundamental role of an adverse events reporting system is to enhance consumer safety by learning from adverse events and near misses. The principles underpinning the policy are:

- open communication
- consumer participation
- culturally appropriate review practice
- system changes (to prevent recurrence)
- accountability
- reporting must be safe.

The principle of consumer participation recognises that including the affected consumer's perspective in the review of an adverse event enables a broader understanding of the circumstances surrounding that event. When reviewing an adverse event, the policy requires that providers:

- consider the event within the context of the whole consumer experience of care or support
- offer consumers who have been involved in an adverse event the opportunity to share their story as part of the review process
- share review findings and recommendations with affected consumers
- consider involving independent consumers in the review process.

The policy requires providers to rate the severity of adverse events using a severity assessment code (SAC). The SAC is a numerical rating that defines the severity of an adverse event (outcome) and as a consequence the required level of reporting and review to be undertaken for the event.

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. Previously the expectation was that all providers would use a root cause analysis (RCA) methodology (or, for mental health events, the Serious Incident Review London Protocol). The 2017 policy better accommodates MHA events by allowing for use of a broader range of review methodologies.

Under the policy, providers must:

- notify the Commission of serious adverse events (SAC 1 and 2)
- provide the Commission with findings and recommendations from review of these events to enable national learning.

Tools and resources

Template for reporting adverse events to the Commission

Appendix B of the policy provides a template for providers. Part A is for reporting the adverse event. Part B is for summarising the review findings and recommendations, including an outline of the actions agreed by the chief executive officer (or equivalent) or the reasons for not implementing the recommendations of the review.

A guide to the National Adverse Events Reporting Policy 2017

This document provides operational guidance on the policy and highlights important changes from the previous policy. It provides advice on support available for providers and commits the Commission to further specific work on developing guidance, tools and resources.[13]

Severity Assessment Code (SAC) rating and triage tool for adverse event reporting

Appendix A of the policy includes a description of the SAC rating (based on actual outcome). Further guidance can be found at www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2937.

A guide to engaging with consumers

The Commission provides resources to help providers involve consumers in adverse event review and learning.[14]

Open Book reports

Open Book reports alert providers to the main findings of adverse events reviews. The reports are short and emphasise changes implemented by a provider to prevent a similar event happening again. The accessibility of the Open Book format, using information

[13] www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2934

[14] www.hqsc.govt.nz/our-programmes/adverse-events/projects/engaging-with-consumers

directed to particular services, allows lessons learned to be shared quickly between organisations. Providers are encouraged to consider Open Book learning and whether the changes made are relevant to their own local systems.

A new shared learning tool[15] enables organisations to share learnings from the review of any adverse event they consider to have national learning value. These events do not have to be SAC 1 or 2 rated, but could relate to learning from the review of near miss or SAC 3 or 4 events, or clustered event review. The shared learning tool can also be used by organisations that have not previously reported adverse events.

Suicide mortality review

A Suicide Mortality Review Committee has been established under Section 59e of the New Zealand Public Health and Disability Act 2000. Its role is to review and advise the Commission on how to reduce the number of suicide deaths in New Zealand.

Under the legislation, mortality review committees have authority to collect a wide range of personal information and, in turn, must securely protect that information. These unique data collection powers enable mortality review committees to match data from different government data sets and conduct in-depth case and systems reviews of agency reports and inquiries. This provides a more detailed picture of the life and death of the deceased, which then informs the committees' recommendations for sector change and guides future prevention efforts.

Australia (federal level)

In June 2017, the Australian Commission on Safety and Quality in Health Care released the 2nd edition of the National Safety and Quality Health Service Standards. They were developed by the Australian Commission with the Australian Government, state and territory partners, consumers and the private sector. The second edition now includes mental health. The standards apply nationally. They are the overarching standards of quality assurance and quality improvement in health care in Australia.[16]

New South Wales

Policy

All licensed private health facilities are required to have a written incident management system outlining the procedures to be followed in the case of an incident or adverse event. In 2014 the New South Wales Ministry of Health and the Clinical Excellence Commission published the most recently updated Incident Management Policy and procedures.[17]

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15 www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2995

16 Australian Commission on Safety and Quality in Health Care. nd. *National Standards and Accreditation.* URL: www.safetyandquality.gov.au/our-work/national-standards-and-accreditation.

17 Clinical Excellence Commission. 2014. *Incident Management Policy Directive (and Procedures).* URL: www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2014_004.pdf. Also see Clinical Excellence Commission. nd. *Incident Management – Incident Reporting.* URL: www.cec.health.nsw.gov.au/incident-management/incident-reporting.

Root cause analysis (RCA)[18] is required to investigate every SAC 1 clinical incident, and selected SAC 2–4 clinical incidents, in the New South Wales public health system, and this includes the MHA sector. The RCA method is used to identify how organisational systems can cause or contribute to clinical incidents. The RCA report findings and state-wide aggregated analysis inform system improvements that could prevent similar incidents from occurring in the future.

The Clinical Excellence Commission reviews all clinical RCA reports through four RCA review committees: Clinical Management; Maternal and Perinatal; Mental Health/Drug & Alcohol; and Child and Young Person. The RCA review committees classify each RCA report using a standard taxonomy.[19] The classification taxonomy is revised as emerging issues and clinical practice changes are identified.

Tools and resources

In 2003 the Clinical Excellence Commission in New South Wales developed a flip chart to ensure a systematic approach for conducting an RCA.[20]

Victoria

Policy

The State of Victoria also implements the National Safety and Quality Health Service Standards under the Victorian Health Incident Management System. The policy outlines the reporting obligations of health services and agencies and applies to the MHA sector.[21] It does not apply to non-governmental or private health providers. It is a comprehensive guideline that incorporates a standardised framework for the collection and management of incidents.

The policy covers three sections:

- policy scope
- health service and agency requirements
- incident review process and open disclosure.

The policy requires the mental health service provider to conduct a review of the person's treatment and management if the death is a reportable death or where there are any concerns about clinical practices, procedures or systemic issues.

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[18] RCA is a method of problem solving used for identifying the root causes of faults or problems. A factor is considered a root cause if its removal from the problem-fault-sequence prevents the final undesirable outcome from recurring, whereas a causal factor is one that affects an event's outcome, but is not a root cause. Though removing a causal factor can benefit an outcome, it does not prevent its recurrence with certainty.

[19] Taxonomy is the practice and science of classification of things or concepts.

[20] Clinical Excellence Commission. 2003. *Checklist Flipchart for Root Cause Analysis Teams.* URL: www.cec.health.nsw.gov.au/__data/assets/pdf_file/0007/313297/rca-flipchart.pdf.

[21] Department of Health. nd. *Victorian health incident management policy*. URL: www2.health.vic.gov.au/about/publications/researchandreports/Victorian-health-incident-management-policy.

Queensland

Policy

Queensland operates under a system of health directives and guidelines that have been produced to comply with the National Safety and Quality Health Service Standards referred to above.

The Patient Safety Directive 2014 sets out the policy documents and procedures for investigating patient safety matters.[22]

The Guideline for Clinical Incident Management[23] includes a scope statement. It applies to all hospital and health service employees working in or for hospital or health services. It includes visiting medical officers, other partners, contractors, consultants and volunteers.

A clinical incident is defined as any event or circumstance that has actually or could potentially lead to unintended and/or unnecessary mental or physical harm to a patient. Therefore, like all countries considered in this report, it applies to MHA. The procedure includes reporting within 90 days, applying SAC ratings and undertaking RCA.

In 2008, Queensland established a statutory framework to ensure the RCA process was carried out. Amending legislation was introduced for the Health Services Act 1991 and the Ambulance Service Act 1991. These amendments were reviewed and stakeholder consultation took place in 2010. No submissions suggested that RCA should be abolished. The final report was published in 2013 and noted the following.

Positive aspects of the RCA process in Queensland included:

- it was a robust process
- staff being treated more fairly after a serious adverse event
- improved boundaries and confidentiality during RCA, preventing bias
- facilitation of open disclosure with affected patients and families
- focus on improvement rather than blame
- protections for RCA team members support their participation
- greater chance of change due to requirement for executive commissioning and response to RCAs.

The negative points included:

- perceived complexity of the legislative requirements
- enabling nature of the legislation gives organisations the choice of whether or not to undertake RCAs
- extent of privilege hinders sharing information from RCAs
- lack of information available for consumers regarding the RCA process
- private practitioners are not funded to participate

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[22] Queensland Health. 2014. *Health Service Directive #QH-HSD-032:2014.* URL: www.health.qld.gov.au/__data/assets/pdf_file/0020/150734/qh-hsd-032.pdf.

[23] Queensland Health. 2013. *Health Service Directive Patient Safety: Guideline for Clinical Incident Management.* URL: www.health.qld.gov.au/__data/assets/pdf_file/0018/155016/qh-hsdgdl-032-2.pdf.

- concerns that RCA teams cannot provide any information to assist a Commissioning Authority if they suspect a blameworthy act.[24]

The final report published in 2013 recommends that the legislation for RCAs should be amended to:

- maintain the current enabling legislation approach to RCA
- treat the Chain of Events documentation as part of the RCA report and subject to the same disclosure and release provisions – the Chain of Events documentation should remain inadmissible in legal and disciplinary proceedings
- include a decision of an RCA team member to report 'public risk notifiable conduct' to the Australian Health Practitioner Regulation Agency (AHPRA)* as an explicit ground for stopping an RCA
- require RCA teams to notify the Commissioning Authority of the grounds for stopping an RCA and the information that forms the basis for that ground
- expand the scope of the legislation to include non-governmental organisations prescribed under regulation.

** Note: The function of receiving mandatory reporting notifications transferred from AHPRA to the Health Ombudsman in 2014 upon commencement of the Health Ombudsman Act 2013.*

The following aspects refer to the areas responsible for policy for the development of further guidance and education on provisions in the existing legislation relating to:

- perceived restrictions on the ability to:
  - consult outside the RCA team in formulating recommendations
  - share an RCA report with staff, and persons involved in the adverse event
- uncertainty about:
  - when to stop an RCA on the grounds of reasonable belief of a 'blameworthy act'
  - a health practitioner's mandatory reporting obligations to AHPRA when they are acting as an RCA team member
- a chief executive's perceived lack of power to delegate the role of Commissioning Authority to more than one person or position.[25]

England

Policy

In 2015 the National Health Service (NHS) updated its Serious Incident Framework – Supporting Learning to Prevent Recurrence. The framework describes the process and procedures to help ensure serious incidents are identified correctly, investigated thoroughly and, most importantly, learned from to prevent the likelihood of similar incidents happening again. All NHS-funded care in the primary, community, secondary and tertiary sectors is

[24] Queensland Health. 2013. *Review of Root Cause Analysis Legislation.* URL: www.parliament.qld.gov.au/documents/tableoffice/tabledpapers/2013/5413t4151.pdf.

[25] *Ibid*; p1.

within scope. This includes private sector organisations providing NHS-funded services.[26] Concern has been expressed that the approach, which clusters serious incidents, suicide and homicides together, could give an exaggerated impression of the perceived dangerousness of mental health consumers.

The Serious Incident Framework builds on and replaces the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation issued by the National Patient Safety Agency (March 2010) and NHS England's Serious Incident Framework (March 2013). It also replaces the National Patient Safety Agency's *Independent Investigation of Serious Patient Safety Incidents in Mental Health Services: Good Practice Guide* (2008).

Of note, the Serious Incident Framework states that the principles of RCA or robust Significant Event Audit and relevant National Patient Safety Agency guidance should be applied to all NHS investigations.

The National Reporting and Learning System is administered by NHS Improvement. The National Reporting and Learning System reports and publishes Serious Incident Framework data monthly, quarterly and annually.[27]

Tools and resources (England and Wales)

The Safer Mental Health Services Toolkit was produced in 2013 following the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness. It supports mental health care providers to self-assess their local services and individual practice against key inquiry recommendations.[28] The toolkit includes a requirement for policies for multi-disciplinary review and information sharing with families. The report notes that such review and information sharing is associated with a 23.5 percent fall in suicide rates in implementing Trusts, which indicates a learning or training effect.

Scotland

Policy

In 2017 the Scottish Government published a new 10-year Mental Health Strategy that is viewed as its centrepiece for improving mental health.[29] The strategy contains 40 specific actions. Each action is intended to tackle a specific issue aimed to make a positive and meaningful difference to people with mental health issues.

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[26] NHS Improvement. 2015. *Serious Incident Framework.* URL: https://improvement.nhs.uk/resources/serious-incident-framework.

[27] NHS Improvement. 2017. *Monthly data on patient safety incident reports.* URL: https://improvement.nhs.uk/resources/monthly-data-patient-safety-incident-reports.

[28] National Confidential Inquiry into Suicide and Homicide by People with Mental Illness. 2013. *Safer mental health services: a self-assessment toolkit.* URL: https://mentalhealthpartnerships.com/resource/safer-mental-health-services-toolkit.

[29] Scottish Government. 2017. *Mental Health Strategy 2017–2027.* URL: www.gov.scot/Topics/Health/Services/Mental-Health/Strategy.

Reporting adverse events occurs under the National Framework for Adverse Events 2013, which was reviewed and refreshed in 2018.[30]

The framework applies nationally and incorporates mental health services. It includes a national definition of an adverse event, guidance on reporting, accountability, responsibilities and learning, and the principles for establishing an open, just and positive safety culture.

The framework defines an adverse event as 'an event that could have caused (a near miss), or did result in, harm to people or groups of people'.

The aims of the national approach to learning from adverse events in Scotland are to:

- learn locally and nationally to make service improvements that enhance the safety of the care system for everyone
- support adverse event management in a timely and effective manner
- provide a consistent national approach to the identification, reporting and review of adverse events, and allow best practice to be actively promoted across Scotland
- present an approach that allows reflective review of events which can be adapted to different settings
- provide national resources to develop the skills, culture and systems required to effectively learn from adverse events to improve services across Scotland.

This policy is accompanied by a detailed knowledge base of practical tools and resources to support implementation. An interactive website supports a Community of Practice[31] so national learning from recent events can be discussed and shared. There are a series of templates and tools that enable methodical and consistent management of adverse events across the whole of Scotland.

The Scottish approach covers all care provided throughout the country, including:

- acute care and managed community services
- primary care (GP practices, dental practices, community pharmacies and optometrists)
- social care
- employees and independent contractors
- clinical and non-clinical events (including information governance, health and safety at work, adverse publicity and finance).

Clinical leaders in MHA services in New Zealand have noted the difficulty of finding a root cause for adverse events, so the Scottish model is of particular interest as it has included RCA tools, including a contributory factors classification framework. This is a checklist that

[30] Healthcare Improvement Scotland. 2018. *Learning from adverse events through reporting and review: A national framework for Scotland – 3rd edition.* URL: www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/national_framework.aspx.

[31] NHS Education for Scotland. 2015. *Adverse events toolkit.* URL: www.knowledge.scot.nhs.uk/adverse-events/adverse-events-toolkit.aspx.

covers patient factors, staff factors, task factors, communication, equipment, work environment, organisational factors, educational and training, and team factors.[32]

Scotland's national approach is not intended to prescribe a management system, but provides a framework to support standardised processes for managing adverse events across all care settings in Scotland. Consistent definitions and a standardised approach aim to ensure a robust and reliable process and maximise the opportunities for organisations to share and actively learn from each other so that they can put improvements into practice.[33]

Mental/psychological factors are included within the framework. The Learning and Improvement Summary published in 2016 highlighted the topic of suicide risk. It is included under the Tools and resources section below as it provides analysis of a complex issue with practical ways to review these incidents.

Scotland has a Suicide Reporting and Learning System (SRLS). When a suspected suicide occurs within 12 months of contact with mental health services, it must be reported to the SRLS by NHS boards. The SRLS aims to assist NHS boards to improve the way that suicide reviews are carried out and reduce risk. The reviews produce many detailed learning points and recommendations for improvement.

A framework has been developed that helps mental health multidisciplinary teams and managers get into the habit of working together to think about risk and how to reduce it in the work that they do. The framework does not give specific guidance on risk assessment and management. It promotes dialogue between multidisciplinary teams to ensure a common understanding of knowledge, practice and attitudes about the way consumer care is organised and managed. The framework is available on the Suicide Review Community of Practice web page.[34]

The SRLS publishes briefing papers twice a year based on the reports received to understand the themes and learnings. The most recent briefing from February 2017 summarises information about the following topics:

- Feedback from family members of people who have completed suicide – what can be learned from the concerns of family members?
- Learning from reviews – examples of recommendations from the reporting period include:
  - multidisciplinary working
  - clinical risk screening and adult support and protection
  - clarity of responsibility between integrated alcohol teams and community mental health teams for communicating with family members

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[32] NHS National Patient Safety Agency. 2009. *Root Cause Analysis Investigation Tools – Contributory Factors Classification Framework.* URL: www.knowledge.scot.nhs.uk/media/CLT/ResourceUploads/4069038/Contributory%20Factors%20Classification%20Framework.pdf.

[33] Healthcare Improvement Scotland. 2016. *Learning from adverse events – learning and improvement summary: May 2016.* URL: www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/learning_report_2016.aspx.

[34] NHS Education for Scotland – The Knowledge Network. nd. *Suicide Review Community of Practice.* URL: www.knowledge.scot.nhs.uk/suicidereviews.aspx.

- risk assessment and frequent multiple contacts with services
- SRLS programme updates, local suicide prevention and the best practice checklist for suicide prevention at a local level.[35]

Tools and resources

RCA checklist used by the NHS Scotland

Scotland uses the Root Cause Analysis Investigation Tools – Contributory Factors checklist, which also includes mental and psychological factors.[36]

Mental health team discussion framework

In 2014. Healthcare Improvement Scotland was directed by the Government to produce a document for Scotland similar to the one developed for England and Wales. NHS boards are required to report to the SRLS team any suspected suicide of a person who has been in touch with mental health services 12 months prior to death. The Scottish model is based on the reports received from NHS boards, supplemented by the Safer Mental Health Services Toolkit.

The aggregated themes are designed to help services prioritise change under six key quality improvement themes. These themes are:

- transitions of care
- risk management
- effective management of safe therapeutic observation practices
- medicines management
- family involvement
- life factors or contributory social factors.[37]

Ireland

Policy

In 2017 the Irish Mental Health Commission and the Health Information and Quality Authority published a set of national standards for reviewing patient safety incidents in mental health. There are 19 standards that support four themes. The themes of the standards are:

- governance and accountability
- person-centred approach to the review of patient safety
- workforce
- reviews of patient safety incidents.

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35 NHS Education for Scotland – The Knowledge Network. nd. *Suicide Review Community of Practice Briefing Papers.* URL: www.knowledge.scot.nhs.uk/suicidereviews/other-resources/briefing-papers.aspx.

36 NHS – National Patient Safety Agency. 2009. *Root Cause Analysis Investigation Tools – Contributory Factors.* URL: www.knowledge.scot.nhs.uk/media/CLT/ResourceUploads/4069038/Contributory%20Factors%20Classification%20Framework.pdf.

37 www.knowledge.scot.nhs.uk/suicidereviews.aspx.

The standards fit within a service's overall incident management process of reporting, open disclosure and notification to external bodies. They endorse setting up and implementing structures and procedures for conducting reviews.[38]

USA

Policy

In 2005 the Patient Safety and Quality Improvement Act came into force. It is known as the Patient Safety Act. The Patient Safety Rule is the regulation that implements the Act, with subsidiary guidance under that. This legislative framework enables the formation of patient safety organisations.

The aim of the legislation is to improve quality and safety through the collection and analysis of aggregated confidential data on patient safety events. This process enables patient safety organisations to more quickly identify patterns of failures and develop strategies to eliminate patient safety risks and hazards.

The Agency for Healthcare Research and Quality (AHRQ) is the lead federal agency charged with improving the safety and quality of the USA's health care system. AHRQ offers a range of practical research-based tools and resources. Their patient safety arm is Patient Safety Net, a national web-based resource featuring the latest news and essential resources on patient safety.

Citing a 2016 article[39] that contrasted event reporting in health care with event reporting in other high-risk industries (such as aviation), AHRQ supports the view that there has been too much emphasis on collecting reports instead of learning from the reason the events were reported. They consider that event reporting systems are best used as a way of identifying issues that require further, more detailed investigation.[40] The key components of an effective reporting system set out by the AHRQ are that:

- the institution must have a supportive environment for event reporting that protects the privacy of staff who report occurrences
- reports should be received from a broad range of personnel
- summaries of reported events must be disseminated in a timely fashion
- a structured mechanism must be in place for reviewing reports and developing action plans.

There is considerable debate about RCA in the USA. In 2015 a new, improved version called RCA^2 was released.[41]

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38 Mental Health Commission Ireland. 2017. *National Standards for the Conduct of Reviews of Patient Safety Incidents.* URL: www.mhcirl.ie/File/final_patient_safety_review2017.pdf.

39 Macrae C. 2016. The problem with incident reporting. *BMJ Quality Safety* 2016(25): 71–5. URL: http://dx.doi.org/10.1136/bmjqs-2015-004732.

40 AHRQ Patient Safety Primer, Reporting Patient Safety Events, 2017. URL: https://psnet.ahrq.gov/primers/primer/13/reporting-patient-safety-events.

41 National Patient Safety Foundation. 2015. *RCA^2: Improving Root Cause Analyses and Actions to Prevent Harm*. Boston, MA: National Patient Safety Foundation. URL: https://c.ymcdn.com/sites/www.npsf.org/resource/resmgr/PDF/RCA2_first-online-pub_061615.pdf.

Tools and resources

RCA²

The National Patient Safety Foundation convened a panel of subject matter experts and stakeholders to examine best practices around RCAs and develop guidelines to help health professionals by standardising the process around the investigation of medical errors, adverse events and near misses. The ultimate objective was to prevent future harm. As prevention requires actions to be taken, the process was renamed Root Cause Analyses and Actions, or RCA^2 (RCA 'squared') to emphasise the importance of taking action after investigation. This was developed in 2015, but note there is more recent debate about the whole efficacy of RCA, and Canada has opted to not use RCA methodology in favour of a non-linear systems thinking approach.

Common formats

To help the standardised collection of data, AHRQ has developed a set of 'Common Formats'. These formats were released in 2009 and continue to be updated regularly. It is not clear to the author if these formats include MHA, but there is a section for 'other', which would possibly support reports from MHA settings.

The National Inventory of Mental Health Quality Measures

The Center for Quality Assessment and Improvement in Mental Health developed the National Inventory of Mental Health Quality Measures, which has a searchable database with over 300 process measures for assessment and improvement of mental health and substance abuse care. It is available on the AHRQ website.[42]

Canada

Policy

Canada uses the Canadian Incident Analysis Framework (CIAF), which is administered by the Canadian Patient Safety Institute. Relevant legislation is set out within the CIAF.

The CIAF was updated in 2012 and a key change was to move away from the term 'root cause analysis'. It was decided the term was too narrow and suggested that there is just one cause for an adverse event. The CIAF favours a non-linear approach based on complexity theory and systems thinking, putting related concepts into clusters to form constellations, rather than boxes. It also recognises that information comes from many varied sources, which has led to including the viewpoint of patients/consumers within the framework itself to remind those using it of this important consideration within any investigation. The personal story of the Lewis family, a section on incident analysis from a patient/family perspective, and the provision of a checklist and advice for effective meetings with patients/families are

[42] Center for Quality Assessment and Improvement in Mental Health. nd. *National Inventory of Mental Health Quality Measures*. URL: http://cqaimh.org/NIMHQM.htm.

all part of the new CIAF.[43] There are six phases for an investigation set out in a circular shape with key points to consider and a variety of processes to apply depending on the level of harm and complexity. The phases are:

- before the incident
- immediate response
- prepare for analysis
- analysis process
- follow through
- close the loop.

The policy includes templates and checklists as well as succinct theory about applying a systems-thinking approach. It is focused on system improvement rather than accountability, and the scope includes MHA.

Tools and resources

The Canadian Patient Safety Institute has a comprehensive website that includes incident analysis tools and resources.[44] Under the mental health section there is a set of five patient safety modules addressing:

- patient safety issues in mental health
- preventing suicide and self-harm
- absconding and missing patients
- diminishing violence and aggressive behaviour
- seclusion and restraint.[45]

The modules are designed to raise awareness of individual and system factors that contribute to the specific safety issues, and identify steps and strategies for prevention.

The website provides guidance on how to engage patients in patient safety[46] and has links to the new Canadian Patient Engagement Network, which is designed for the public and accessed via social media of LinkedIn or Facebook.[47]

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43 Incident Analysis Collaborating Parties. 2012. *Canadian Incident Analysis Framework*. Edmonton, Alberta: Canadian Patient Safety Institute. URL: www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF.

44 www.patientsafetyinstitute.ca/en/Pages/default.aspx.

45 www.patientsafetyinstitute.ca/en/education/PatientSafetyEducationProgram/PatientSafetyEducationCurriculum/MentalHealthModules/Pages/default.aspx.

46 www.patientsafetyinstitute.ca/en/toolsResources/Patient-Engagement-in-Patient-Safety-Guide/Pages/default.aspx.

47 www.patientsafetyinstitute.ca/en/toolsResources/Canadian-Patient-Engagement-Network/Pages/default.aspx.

Singapore

Tools and resources

In 2008 the Institute for Healthcare Improvement developed a trigger tool for measuring adverse drug events in mental health settings.[48] In 2016, the Institute of Mental Health in Singapore presented its trigger tool for mental health, which was based on the Institute for Healthcare Improvement model. The Singapore tool is broader than adverse drug events and encompasses particular issues in mental health ward safety like aggressive behaviours and absconding. Using a multi-disciplinary team, it went through a rigorous process to develop and test 25 triggers appropriate to the mental health setting.[49]

International

Tools and resources

SMARTS

It is common for patients to experience negative effects from anti-psychotic drugs, and systematic collection and assessment over time is considered good clinical practice.[50,51] However, documented clinical reviews have been shown to be haphazard,[52] and sometimes patients fail to spontaneously report negative effects, so they can be missed.

Haddad et al (2014)[53] addressed this issue by developing a pragmatic, patient-completed checklist to assess antipsychotic drug negative effects. SMARTS stands for: **S**ystematic **M**onitoring of **A**dverse Events **R**elated to **T**reatment**S.**

A team of 12 experts (including psychiatrists, a general physician and a psycho-pharmacologist)[54] developed an evidence-based checklist of the 11 most common known negative effects, along with an open question so consumers can add their own comments. The checklist is short, written specifically for consumers and designed to be done at the time the clinician sees the person in the waiting room. It assesses current problems and can be

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48 Institute for Healthcare Improvement. 2008. *Trigger Tool for Measuring Adverse Drug Events in Mental Health.* URL: www.ihi.org/resources/Pages/Tools/TriggerToolMeasuringADEsinMentalHealthSetting.aspx.

49 Institute for Healthcare Improvement. 2016. *Mental Healthcare Quality Improvement – An International Collaborative supported by IHI*. URL: http://aws-cdn.internationalforum.bmj.com/pdfs/B2_Tricia_Woodhead.pdf.

50 National Institute for Health and Care Excellence (NICE). 2009. *Depression in adults: recognition and management.* URL: www.nice.org.uk/guidance/cg90.

51 Clinical Standards Board of Scotland. 2001. Local Report on service provision for Schizophrenia. URL: Local report on Service Provision for Schizophrenia.

52 Barnes TR and Paton C. 2012. Role of the prescribing observatory for mental health. *British Journal of Psychiatry* 201(6): 428–9.

53 Haddad PM, Fleischhacker WW, Peuskens J, et al. 2014. SMARTS (Systematic Monitoring of Adverse events Related to TreatmentS): The development of a pragmatic patient-completed checklist to assess antipsychotic drug side effects. *Therapeutic Advances in Psychopharmacology* 4(1): 15–21.

54 It appears that there were no consumer representatives as part of this project. If such a project was undertaken in New Zealand, a consumer representative would be a recommended and necessary member of an interdisciplinary team.

used longitudinally to understand changes. To date, the SMARTS checklist has been translated into Italian and Turkish.

Recent evidence

This section of the report provides evidence on reporting and learning from MHA adverse events.

Effectiveness of incident reporting for improving patient safety in MHA services

Can incident reporting improve safety in MHA services?

A 2013 study[55] carried out in England examined the perceived effectiveness of incident reporting for improving patient safety. The study took place within two large teaching hospitals – one acute, the other mental health. Sixty-two health care practitioners (31 from each site) with experience in reporting and analysing incidents were interviewed for this qualitative study.

The study found that mental health staff were less willing to use the system, less experienced in using it, and more likely to perceive the existence of a blame culture that they related to low levels of reporting, than acute care staff.

Respondents from the mental health hospital discussed the problems associated with identifying causation of incidents and so determining the appropriate actions to prevent similar incidents from recurring in future. As serious incidents also attracted media attention, this was seen as added pressure on staff responsible for carrying out an investigation. An added challenge for this study was the geographical separation of mental health departments, and clinicians involved were often not consulted about the feasibility and potential benefits of recommended solutions.

Generally, staff were positive about the effects of incident reporting, more so in acute care than mental health. Respondents also viewed incident reporting as an indicator of team culture and attitudes towards safety.

The authors identified three important contributions to knowledge from this study. The first was evidence that incident reporting was perceived by most staff as having a positive effect on safety, not only by leading to changes in care but by changing staff attitudes and knowledge.

Second, the study identified problems using incident reports as an improvement tool. They found challenges at all stages of the process, including reporting, investigation, implementation, evaluation of actions taken and feedback to staff. Staff were challenged with the inherent complexities of the organisation as well as the reporting process itself. In mental health care they found an added layer of complexity involving the challenges of predicting patient responses.

[55] Anderson JE, Kodate N, Walters R, et al. 2013. Can incident reporting improve safety? Healthcare practitioners' views of the effectiveness of incident reporting. *International Journal for Quality in Health Care* 25(2): 141–50.

Thirdly, the study identified differences between acute and mental health settings where incident reporting was being used. They linked this to the attitudes around incident reporting. In acute care there was a system of risk embedded in clinical teams, and clinical staff were directly involved in reviewing incidents, with high ownership of the incident reporting system. On the other hand, data collected from the mental health hospital showed clinicians were less willing to use the system and more sceptical of its value. Similar findings were also reported in regard to incident reports of assault in mental health care.

The impact of RCA on improving patient outcomes in a regional mental health service

A 2018 study[56] evaluated the impact of RCA on improving patient outcomes in a regional mental health service in New South Wales, Australia, and to discover whether the RCA model is the most appropriate model in mental health. It found that while the RCA model offers a formal and systematic approach to the review of serious critical incidents in mental health, it is not the model of best fit. Only 65 percent of recommendations made through RCA reviews are implemented within 12 months.

Attitudes to incident reporting

Factors that facilitate and hinder group learning from incident data

In 2015, Anderson and Kodate[57] (England) published a study that aimed to identify factors that facilitated and factors that hindered group learning from incident data. Mental health care was included. They also developed and tested a framework of process indicators to assess the effectiveness of incident review meetings. The factors hindering analysis were lack of organisational support, high workload, and a managerial, autocratic leadership style. Facilitating factors were participatory interactions and strong safety leadership. They concluded that 'efforts to improve learning from adverse incidents will not be effective unless the people involved in this difficult task are supported'. Organisational legitimacy, administrative support, training and resources in incident investigation and mitigation for all participants, effective well-trained leaders who empower the team, and sufficient resources to manage the high workload were all identified in this study as necessary changes to improve learning.

Barriers that psychiatric nurses experience in reporting medication errors or near misses

It is not uncommon for medication errors to occur, and this includes within MHA services. A 2014 study[58] in the UK was the first to describe the barriers that psychiatric nurses

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[56] Vrklevski LP, McKechnie L, O'Connor N. 2018. The causes of their death appear (unto our shame perpetual): Why root cause analysis is not the best model for error investigation in mental health services. *Journal of Patient Safety* 14(1) 41–8. DOI: 10.1097/PTS.0000000000000169.

[57] Anderson JE, Kodate N. 2015. Learning from patient safety incidents in incident review meetings: Organisational factors and indicators of analytic process effectiveness. *Safety Science* 80: 105–14. URL: https://doi.org/10.1016/j.ssci.2015.07.012.

[58] Haw C, Stubbs J, Dickens GL. 2014. Barriers to the reporting of medication administration errors and near misses: An interview study of nurses at a psychiatric hospital. *Journal of Psychiatric and Mental Health Nursing* 21(9): 797–805.

experience in reporting medication errors or near misses. Fifty mental health nurses caring for inpatients were interviewed using clinical vignettes. The aim of the study was to understand how they would respond to near misses or medication errors. The study found that less than half of the nurses would report an error made by a colleague (48 percent) or a near miss involving themselves (40 percent). Analysis revealed that the common themes for both not reporting an error or a near miss were knowledge, fear, burden of work, and excusing the error. The first three reasons align with similar research in general medical settings, but the last reason – excusing the error – was novel and contrary to hospital policy and the medical error system that was in place.

The authors conclude that efforts should be made to encourage a 'no-blame' learning culture within an organisation in which the reporting of errors is encouraged and seen as a positive action. Reporting needs to be simple, expected and the norm. Excusing describes a set of beliefs and behaviours that may provide a barrier to appropriate reporting of medication events. Nurses, leaders and managers should supportively challenge practice while providing a supportive environment for reporting errors and near misses through education, training and policy.

Implementing service changes as a result of a review

Reviewing suicide cases, implementation of changes and impact

A very large study about which aspect of service provision in mental health has a role in preventing suicide was carried out between 1997 and 2012 in England.[59] A total of 19,248 people who died by suicide within 12 months of contact with mental health services were included. The question asked was: 'What is the role that health services have in suicide prevention?'

Three main objectives of the study were to:

- examine the association between implementation of service changes and suicide
- consider how wider organisational factors such as staff and patient satisfaction and staff turnover would be associated with suicide
- investigate if the impact of service changes varied according to available measures of the organisational context in which they occurred.

As a before and after study, 16 service changes were examined. The service changes examined were those recommended as a result of the first study (nine), along with an additional eight that were selected for their clinical and policy importance (eg, relating to the implementation of national clinical guidance). Those service changes that related to ward safety, improved community services, staff training, and implementation of policy and guidance were associated with lower suicide rates after their introduction. Some wider organisational factors, such as non-medical staff turnover and incident reporting, were also related to suicide rates, but others, such as staff sickness and patient satisfaction, were not.

[59] Kapur N, Ibrahim S, While D, et al. 2016. Mental health service changes, organisational factors, and patient suicide in England in 1997–2012: a before-and-after study. *The Lancet Psychiatry* 3(6): 526–34.

Service changes had more effect in organisations that had low rates of staff turnover but high rates of overall event reporting.

They found that across the 62 sites, those that implemented all 16 recommendations for service changes were associated with a significant decrease in the suicide rate. The study found it difficult to establish the exact nature of the associations between suicide rates and non-medical staff turnover and incident reporting, but they suggest that staff turnover could affect continuity of care, which could impact negatively on safety. Conversely, high staff turnover might indicate wider problems within the organisation. High numbers of safety incidents are sometimes thought to indicate an open reporting culture. While this might be the case, their study suggests that such incidents might be linked with the number of suicide deaths overall and be safety markers in their own right. They also found an interaction between service changes and organisational context. In services where staff turnover was high, the effect of service change on suicide rates was low. Service change might also have had more of a positive effect in providers with higher levels of reported safety incidents. This outcome could indicate efficient reporting systems or a better learning culture, but could also be a result of so-called regression to the mean in services with a greater number of safety incidents and higher suicide rates.

Their study suggests that service changes are important in determining safety, but it did not establish which changes were the most important. System-wide change implemented across the patient care pathway could be a key strategy to reduce suicide rates, but the organisational context in which they are introduced might be at least as important as the initiatives themselves. The authors state we need to pay attention to both to make mental health services as safe as they can be.

Patient safety issues for people with serious mental illness during medical and surgical hospitalisations

Factors contributing to patient safety events for people with serious mental illness during medical and surgical hospitalisation

A US study published in 2017[60] looked at patient, provider and system perspectives to explore the factors that contribute to patient safety events during medical and surgical hospitalisations for people with serious mental illness. Medical records over a 10-year period were reviewed from a sample of 790 patients. While the three perspectives were independently measured and assessed, the study notes that each perspective plays a part in the overall safety of the patient. The study found that patients' mental status, level of consciousness, disease severity, and providers' lack of patient monitoring, delay or failure to seek consultation, lack of trainee supervision, and delays in care were positively associated with adverse events. The authors concluded that this cohort of people is at high risk of adverse patient safety events during medical/surgical hospitalisation. Impaired mental status and severity of medical co-morbidities make this group particularly vulnerable to patient safety related harm. Modifiable provider and system factors such as patient monitoring,

[60] McGinty EE, Thompson DA, Pronovost PJ, et al. 2017. Patient, provider and system factors contributing to patient safety events during medical and surgical hospitalizations for persons with serious mental illness. *Journal of Nervous and Mental Disease* 205(6): 495–501.

consultative care, and hospital policies and procedures may play an important role in patient safety. The authors suggest that efforts to reduce the unique patient safety risks of this group will need to be multifaceted and address system, provider, and patient level factors**.**

Patient safety issues unique to MHA services

Patient safety issues unique to mental health care in Canada

In 2009, the Canadian Patient Safety Institute and the Ontario Hospital Association collaborated and commissioned a team from British Columbia Mental Health and Addiction Services to prepare a research paper that defines the patient safety issues unique to mental health care in Canada.[61] The paper notes that even though many of the patient safety risk factors that exist in medical settings also apply to mental health settings, there are unique patient safety issues in mental health that are different to those in medical care.

Seclusion and restraint use, self-harming behaviour and suicide, absconding, and reduced capacity for self-advocacy are particularly prominent to mental health patients. Both the patient population and the environment make patient safety in mental health unique. In some circumstances, the uniqueness is associated more with the diagnosis and patient population than with the mental health setting, and in other circumstances the uniqueness is related more to the setting than the patient population or diagnosis.

Self-harm in adult inpatient psychiatric care (UK)

A national study of incident reports in the UK that focused on self-harm of inpatients was published in 2012.[62] A total of 500 reports were analysed across inpatient services in England and Wales. The results showed (inter alia) that the most common antecedents to self-harm were a distressing psychological state, conflict behaviours (behaviours which threatened staff, or consumer safety), and conflict with staff. A key finding that relates to this paper was a suggestion that future research should focus on how staff behaviour contributes to self-harm. The development of a reporting system was also required – one that would include a detailed account of incidents.

Type and frequency of adverse events in mental health units (USA)

A US study published in 2017[63] set out to:

- determine the type and relative frequency of adverse events that occurred on Veterans Health Administration mental health units
- determine the primary root causes of the events
- make recommendations that would lead to improvements.

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61 Brickell TA, Nicholls TL, Procyshyn RM, et al. 2009. *Patient safety in mental health*. Edmonton, Alberta: Canadian Patient Safety Institute and Ontario Hospital Association. URL: www.patientsafetyinstitute.ca/en/toolsResources/Research/commissionedResearch/mentalHealthAndPatientSafety/Documents/Mental%20Health%20Paper.pdf.

62 James K, Stewart D, Wright S, et al. 2012. Self harm in adult inpatient psychiatric care: A national study of incident reports in the UK. *International Journal of Nursing Studies* 49(10): 1212–9.

63 Mills PD, Watts BV, Shiner B, et al. 2017. Adverse events occurring on mental health units. *General Hospital Psychiatry* 50: 63–8.

The study searched the Veterans Affairs National Center for Patient Safety database for all adverse events in Veterans Health Administration mental health units between 1 January 2015 and 31 December 2016 and revealed 87 RCA reports and 9780 safety reports. The safety reports were categorised as suicide attempt, medication events, missing patient, fall, or other type. This study is useful for developing categories relevant to MHA adverse events.

This is one of the first studies to examine all types of adverse events in MHA in a large national medical system. It is a useful paper for developing categories and classifications within the New Zealand context, but it should also be noted that the authors suggest mental health unit staff should undertake a structured assessment of *all* risk and hazards on their units. A broad approach may be more successful than prematurely narrowing on a particular event type. They state that just as in medical units, MHA patients are at risk for many types of adverse events and so the same overall focus on patient safety is just as important for MHA patients as it is for medical patients.

Part 3:
Consumers as partners in learning from adverse events

Evidence for consumers as partners in learning from adverse events

Requirements for consumer participation in the National Adverse Events Reporting Policy 2017

The National Adverse Events Reporting Policy 2017 includes consumer participation as one of six core principles. This principle recognises that including the affected consumer's perspective in the review of an adverse event enables a broader understanding of the circumstances surrounding that event. When reviewing an adverse event, the policy requires that providers:

- consider the event within the context of the whole consumer experience of care or support
- offer consumers who have been involved in an adverse event the opportunity to share their story as part of the review process
- share review findings and recommendations with affected consumers
- consider involving independent consumers in the review process.

The principle of consumer participation is supported in the policy by the principles of open communication and culturally appropriate review practice. These two principles guide providers to communicate with the affected consumer in a timely, truthful and open way following an adverse event, and consider the cultural viewpoints and practices of the consumer in every stage of the adverse event review and learning process.

Resources to support involving consumers in adverse event review and learning include:

- Health Quality & Safety Commission. 2017. *Representing the consumer voice in an adverse event review* (video). URL: www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/3076.
- Health Quality & Safety Commission. 2015. *Engaging with consumers: a guide for district health boards*. Wellington: Health Quality & Safety Commission. URL: www.hqsc.govt.nz/our-programmes/partners-in-care/news-and-events/news/2213.
- Patient Engagement Action Team. 2017. *Engaging Patients in Patient Safety – a Canadian Guide*. Edmonton, Alberta: Canadian Patient Safety Institute. URL: www.patientsafetyinstitute.ca/engagingpatients.
- Canadian Patient Safety Institute. nd. *Communicating after harm in healthcare*. Alberta: Canadian Patient Safety Institute. URL: www.patientsafetyinstitute.ca/en/toolsResources/InformingMediaAdverseEvent/Pages/default.aspx.

Chapter from the Commission's 'Learning from adverse events: Adverse events reported to the Health Quality & Safety Commission 1 July 2016 to 30 June 2017'

The Commission's *Learning from adverse events: Adverse events reported to the Health Quality & Safety Commission 1 July 2016 to 30 June 2017*[64] includes a chapter on consumers as partners in learning from adverse events. It is supported by evidence and outlines the benefits, challenges and key approaches to partnering with consumers affected by adverse events in the review and learning processes that follow an adverse event.

The chapter is included in full below.

[64] Health Quality & Safety Commission. 2017. *Learning from adverse events: Adverse events reported to the Health Quality & Safety Commission 1 July 2016 to 30 June 2017*. Wellington: Health Quality & Safety Commission. URL: www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/3111.

Chapter 2: Consumers as partners in learning from adverse events

> 'Consumer[65] safety requires that consumers and families partner with providers to prevent consumer safety incidents. When these incidents do happen, consumers, families and providers can take actions to protect those involved from further harm, allow them to heal and understand what happened, and to make improvements to the process or system. Rather than blaming or punishing, the goal is to balance and understand care processes and systems that may cause consumer safety incidents.'[66]

The role of an adverse events reporting, review and learning system is to enhance consumer safety by learning from adverse events and near misses that occur in health care and disability support services. Partnering with consumers, their families and whānau in the review and learning process is pivotal to improving safety and quality. As such, consumer engagement is a key expectation of the Policy.[67]

Consumer engagement in health care and disability support

Improving consumer engagement in health care and disability support is a global movement. In its 2013 report, *Patient and family engagement,* the World Innovation Summit for Health (WISH) focuses on the critical role consumer engagement plays in shaping future health and disability services.

[65] For consistency with terminology used throughout the chapter, 'patient' has been changed to 'consumer' in this quote. See Box 1 for definitions of terms used in this chapter.

[66] Canadian Patient Safety Institute, Patient Engagement Action Team. 2017. Engaging patients in patient safety – a Canadian Guide. Ontario: Canadian Patient Safety Institute. p21. URL: www.patientsafetyinstitute.ca/en/toolsResources/Patient-Engagement-in-Patient-Safety-Guide/Documents/Engaging%20Patients%20in%20Patient%20Safety.pdf.

[67] Health Quality & Safety Commission. 2017a. *National Adverse Events Reporting Policy 2017*. Wellington: Health Quality & Safety Commission. URL: www.hqsc.govt.nz/our-programmes/adverse-events/publications-and-resources/publication/2933.

Box 1: Key terms

- Consumer: Individuals, families and whānau who have had personal experiences in the health and disability system, or who might use health and disability services in the future.
- Affected consumer: Individuals, families and whānau who have experienced an adverse event or a near miss in the health and disability system.
- Independent consumer: A member of an adverse events review team who is there to provide a consumer perspective on the event; this person has not been affected by the adverse event under review.
- Consumer engagement: A process where consumers of health and disability services are encouraged and empowered to actively participate in decisions about the treatment, services and care they need and receive.

'The solutions to the health challenges of today and tomorrow won't come from doing business as usual; they will come from building effective partnerships and harnessing the untapped global power of ordinary people who care about improving their health.'[68]

The WISH report positions consumer engagement as 'a powerful tool' for improving global health. It describes the large and growing body of international evidence to support the benefits of engaging with consumers in health care and disability support. Benefits include better health outcomes, safer care, better quality of care, reduced health care utilisation, lower costs, improved consumer knowledge and experience, and increased health worker satisfaction.

In New Zealand, consumer engagement is underpinned by the Code of Health and Disability Services Consumers' Rights[69] and the Treaty of Waitangi. The Treaty of Waitangi between the Crown and tangata whenua (Māori) describes the principles of mana whenua, kaitiakitanga and manaakitanga: participation, partnership and nurturing relationships. These principles form the basis of interactions between Crown agencies and Māori, including health and disability services. The Code of Health and Disability Services Consumers' Rights sets out consumers' rights in relation to health and disability services, including the right to respect, information, choice, equity, dignity, effective communication, support and full involvement.

[68] World Innovation Summit for Health. 2013. *Patient and family engagement: Partnering with patients, families, and communities for health: A global imperative*. Doha: World Innovation Summit for Health. p6. URL: www.wish.org.qa/wp-content/uploads/2018/01/27425_WISH_Patient-Engagement_web-1.pdf.

[69] Health and Disability Commissioner. 2009a. Code of Health and Disability Services Consumers' Rights. Wellington: Health and Disability Commissioner. URL: www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights.

Improving consumer experience is a strategic priority for the Commission.[70] We recognise that consumer engagement is pivotal to improving safety and quality across the health and disability system. Our programme aims to help health and disability service providers build strong relationships with consumers – not just as consumers of services but as active partners in their own care. A key focus for our adverse events learning programme is to improve responsiveness to consumers affected by an adverse event and to involve consumers nationally and locally in adverse events reporting, review and learning.

Box 2: Consumers and the National Adverse Events Reporting Policy 2017

Consumer participation is one of six core Policy principles. This principle recognises that including the affected consumer's perspective in the review of an adverse event enables a broader understanding of the circumstances surrounding that event. When reviewing an adverse event, the Policy requires that providers:

1. consider the event within the context of the whole consumer experience of care or support
2. offer consumers who have been involved in an adverse event the opportunity to share their story as part of the review process
3. share review findings and recommendations with affected consumers
4. consider involving independent consumers in the review process.

The principle of consumer participation is supported in the Policy by the principles of open communication and culturally appropriate review practice. These two principles guide providers to communicate with the affected consumer in a timely, truthful and open way following an adverse event, and consider the cultural viewpoints and practices of the consumer in every stage of the adverse event review and learning process.

Source: Health Quality & Safety Commission 2017a, *op. cit*.

Consumer engagement in learning from adverse events

Consumers are engaged in safety and quality in two key ways:[71]

1. Safety management: These are the actions that help to proactively anticipate safety incidents and prevent them from occurring. They include managing safety risks, co-designing and testing safety solutions, and quality improvement processes
2. Adverse event management: These are the actions that follow adverse events, including event reporting, immediate response, event review, actions to reduce risk of recurrence and sharing learning.

[70] Health Quality & Safety Commission. 2017b. *Statement of Intent 2017–21*. Wellington: Health Quality & Safety Commission. URL: www.hqsc.govt.nz/publications-and-resources/publication/2971.

[71] Canadian Patient Safety Institute, Patient Engagement Action Team 2017, *op. cit*.

The focus of this chapter is on the latter, specifically, the benefits, challenges and key approaches to partnering with consumers affected by adverse events in the review and learning processes that follow an adverse event.

Benefits

Because consumer engagement in adverse event management is still relatively new, there are few rigorous empirical studies demonstrating the effectiveness or impact of this approach.[72] However, there is emerging evidence of benefit, as discussed below.

Consumers can recognise and report adverse events

There is evidence that consumers who have been involved in an adverse event are able to successfully identify and report adverse events,[73] including those events not captured in clinical reporting systems or medical records.[74] There is also evidence that some affected consumers are more comfortable reporting adverse events to a reporting system than directly addressing them with a provider.[75] For these reasons, some jurisdictions are exploring new technologies and developing reporting systems specifically for consumers to report adverse events (separate from consumer complaints systems or provider reporting systems).[76] There is a view that consumer reporting of adverse events may be beneficial because it minimises the time between the event occurring and reporting (ie, it allows for real-time reporting of events), thereby reducing recall bias. However, this is still an emerging area of research and evaluation of the value of consumer reporting is still in its infancy.[77] In New Zealand, consumers can make a formal complaint to the Health and Disability Commissioner about the quality of health or disability services they have received, and sometimes these complaints will relate to an adverse event. However, there is currently no formal mechanism by which consumers can report an adverse event. The Commission intends to explore options for consumer reporting of adverse events over the next three to five years, including

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72 Canadian Patient Safety Institute, Patient Engagement Action Team 2017, *op. cit.*; Sutton E, Eborall H, Martin G. 2015. Patient involvement in patient safety. Current experiences, insights from the wider literature, promising opportunities? *Public Management Review* 17(1): 72–89.

73 Khan A, Furtak SL, Melvin P, et al. 2016. Parent-reported errors and adverse events in hospitalized children. *JAMA* 170(4): e154608. DOI: 10.1001/jamapediatrics.2015.4608.

74 The Public Administration Select Committee (PASC). 2015. *Investigating clinical incidents in the NHS: Sixth report of session 2014–15.* London: PASC by authority of the House of Commons. URL: https://publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf; Weingart SN, Pagovich O, Sands DZ, et al. 2005. What can hospitalised patients tell us about adverse events? Learning from patient-reported incidents. *Journal of General Internal Medicine* 20(9): 830–6; Weissman JS, Schneider EC, Weingart SN, et al. 2008. Comparing patient-reported hospital adverse events with medical record review: do patients know something that hospitals do not? *Annals of Internal Medicine* 149: 100–8.

75 Davis, RE, Sevdalis N, Vincent C, et al. 2011. Patient involvement in patient safety: how willing are patients to participate? *BMJ Quality & Safety* 20(1): 108–14.

76 Canadian Patient Safety Institute, Patient Engagement Action Team 2017, *op. cit.*; Huerta TR, Walker C, Murray KR, et al. 2016. Patient safety errors: leveraging health information technology to facilitate patient reporting. *Journal for Healthcare Quality* 38(1): 17–23; Lawton L, Armitage G. *The role of the patient in clinical safety*. Thought paper, May 2012. London: The Health Foundation. URL: www.health.org.uk/sites/default/files/TheRoleOfThePatientInClinicalSafety.pdf; PASC 2015, *op. cit.*

77 Canadian Patient Safety Institute, Patient Engagement Action Team 2017, *op. cit.*

how any system would interface with provider reporting systems and the existing consumer complaints process.

Box 3: Stakeholder views on consumer reporting of adverse events

Stakeholders consulted in the policy review had mixed views on consumer reporting of adverse events. Some stakeholders supported it because they see consumers as having different perspectives from providers on what constitutes an adverse event and its contributing factors. Reservations about consumer reporting related to the risk of confusion with, and duplication of, the existing consumer complaints process, the challenges of making any consumer reporting system accessible to all consumers and the lack of an existing infrastructure to support a consumer adverse event reporting system.

Source: Health Quality & Safety Commission. 2016. *Ideas to improve the national reportable events policy: internal report on stakeholder consultation*. Unpublished.

Consumers can contribute unique safety information

Involving affected consumers in adverse events review and learning processes can provide 'missing' safety information.[78] This is because consumers occupy a unique position spanning the entire care journey – they interact with multiple providers and often across numerous organisations. They may be able to perceive care transition and process issues that occur before, during and after adverse events, and that are not identified by providers.[79]

Systematic reviews[80] and other studies[81] consistently demonstrate that consumers' experiences of adverse events identify a wider range of contributing factors than those identified by providers. Similarly, qualitative research has found that consumers describe adverse events and contributory factors differently to providers. Consumers more frequently identify the service quality issues that contribute to adverse events, rather than the technical or systems-wide preventable safety issues identified by providers.[82] The most common types

[78] Harrison R, Walton M, Manias E, et al. 2015. The missing evidence: a systematic review of patients' experiences of adverse events in health care. *International Journal for Quality in Health Care* 27(6): 424–42.

[79] Canadian Patient Safety Institute, Patient Engagement Action Team 2017, *op. cit.*; Etchegaray JM, Ottosen MJ, Aigbe A, et al. 2016. Patients as partners in learning from unexpected events. *Health Services Research* 51(6), Part II: 2600–14.

[80] Guijarro PM, Andrés JMA, Mira JJ, et al. 2010. Adverse events in hospitals: the patient's point of view. *Quality & Safety in Health Care* 19: 144–7. DOI: 0.1136/qshc.2007.025585; Harrison et al 2015, *op. cit.*; Lang S, Garrido MV, Heintze C. 2016. Patients' views of adverse events in primary and ambulatory care: a systematic review to assess methods and the content of what patients consider to be adverse events. *BMC Family Practice 17*: 6. DOI: 10.1186/s12875-016-0408-0.

[81] Davis RE, Sevdalis N, Neale G, et al. 2013. Hospital patients' reports of medical errors and undesirable events in their health care. *Journal of Evaluation in Clinical Practice* 19(5): 875–81; Walton MM, Harrison R, Kelly P, et al. 2017. Patients' reports of adverse events: a data linkage study of Australian adults aged 45 years and over. *BMJ Quality & Safety* 0: 1–8. DOI: 0.1136/bmjqs-2016-006339.

[82] Lang et al 2016, *op. cit.*

of issues identified by consumers relate to communication, continuity and coordination of care, and medication errors.[83]

Involvement in the review and learning process can be restorative

Qualitative research has found that consumers affected by adverse events believe they should be involved in the event review process.[84] Providers who have involved consumers in review and learning describe the process as being empowering for those affected,[85] because it has the potential to help alleviate psychological trauma[86] and maintain or restore consumers' trust in providers and the system.[87] Open discussions with health practitioners directly involved in an adverse event can provide a forum for affected consumers to voice their experience where they are carefully listened to, given a genuine apology and supported in recovery.[88]

> 'Involving consumers has great potential to both meet their needs and improve the quality and safety of health care.'[89]

See also Box 11, which describes one provider's experience of engaging with consumers in adverse events review processes.

[83] Bishop A, Cregan BR. 2015. Patient safety culture: finding meaning in patient experiences. *International Journal of Health Care Quality Assurance* 28(6): 595–610; Harrison et al 2015, *op. cit.*; Lang et al 2016, *op. cit.*

[84] Etchegaray JM, Ottosen MJ, Burress L, et al. 2014. Structuring patient and family involvement in medical error event disclosure and analysis. *Health Affairs* 33(1): 46–52; Guijarro et al 2010, *op. cit.*

[85] Stevens D. 2010. Quality lines. *Quality & Safety Health Care* 19: i. 42.

[86] Etchegaray et al 2014, *op. cit.*

[87] Walton M, Smith-Merry J, Harrison R, et al. 2014. Using patients' experiences of adverse events to improve health service delivery and practice: protocol of a data linkage study of Australian adults age 45 and above. *BMJ Open* 4: e006599. DOI: 10.1136/bmjopen-2014-006599.

[88] Moore J, Mello MM. 2017. Improving reconciliation following medical injury: a qualitative study of responses to patient safety incidents in New Zealand. *BMJ Quality & Safety* 0: 1–11. DOI: 10.1136/bmjqs-2016-005804.

[89] Etchegaray et al 2016, *op. cit.* p50.

Box 4: Stakeholder views on the importance of consumer engagement in learning from adverse events

Stakeholders consulted during the Policy review wanted a stronger focus on consumers in the adverse events review and learning process. Many recognised the differences between how consumers and providers define, describe and interpret an adverse event. In particular, they recognised consumers take a longer-term perspective over the whole continuum of the care journey, rather than focusing solely on the event itself.

Feedback from consumers, including the Commission's consumer network,* emphasised the need to listen to consumers, acknowledge and apologise, and reassure that action has been taken to change the system and prevent the harm occurring again. Consumers also highlighted the need to consider emotional harm and the impact of an adverse event on the consumer and their family and whānau.

* The consumer network is a group of consumers who support the Partners in Care programme, and the Commission more broadly, to increase consumer involvement in New Zealand's health and disability sectors.

Source: Health Quality & Safety Commission 2016, *op. cit*.

Box 5: Reasons for engaging consumers in learning from adverse events

- Consumers can successfully identify adverse events when they occur, including those not identified by providers.
- Consumers offer a unique perspective on an adverse event, including an integrated view of the system that spans their entire care or support journey.
- Consumer insights into the circumstances of an event can shed greater light on what happened and lead to a deeper analysis of underlying causes.
- Consumers encourage providers to think about alternative perspectives and can provide insights into possible improvements and solutions to prevent further events.
- Involvement in the review of an adverse event can be healing and restorative for the consumer involved.
- It's the right thing to do – 'Nothing about me, without me'.

Challenges

Some of the challenges for consumer engagement in health care and disability support more generally are also challenges for consumer engagement in learning from adverse events. These challenges relate to shifting the culture of care – from a provider-centred mindset, focused on individual services delivered by professionals, to one of integrated, collaborative care – and the practicalities of engaging with consumers.[90] See Box 6.

[90] Canadian Patient Safety Institute, Patient Engagement Action Team 2017, *op. cit.*

Box 6: General challenges for consumer engagement

Shifting the culture

Providers may be concerned that:

- consumer perspectives might differ from their own and lead to unwanted change
- consumers might not have the required knowledge to participate meaningfully
- consumers might lose confidence in the organisation if they learn about challenges with care processes
- consumers may not respect privacy and information confidentiality.

Consumers may be reluctant to engage because:

- they view providers as the experts and feel they should defer to their advice and direction
- they may fear that responsibility and accountability will be shifted to them
- they may feel they do not have the confidence, knowledge and ability to engage
- they may fear that their engagement will be seen as a token gesture and their input not used to make decisions.

Putting engagement into practice

- Competing priorities
- High demands on providers at the point of care
- Pressures to increase efficiency
- Inadequate provider time, resources and expertise to support consumer engagement
- Lack of provider and consumer knowledge, skills and experience in consumer engagement
- Lack of diversity in consumers engaged (ie, not representative of populations served)
- Working within the constraints of a consumer's volunteer time
- Identifying opportunities for meaningful engagement
- Sustaining provider and consumer interest in the work over time
- Bureaucracy and technicalities (eg, sharing information)

Source: Canadian Patient Safety Institute, Patient Engagement Action Team 2017, *op. cit*.

There are also challenges that relate directly to engaging affected consumers in adverse events review and learning.

Not all consumers want to be involved in a review process because of the potential for further emotional harm and distress, or because they don't feel comfortable speaking up. Consumers who have been involved in an adverse event may fear that speaking up could damage their relationship with providers, upset staff or compromise the quality of their care.[91] They may find it difficult to confront or challenge providers about managing care-safety issues.[92] They may be concerned about being seen as challenging or difficult and

[91] Berger Z, Flickinger TE, Pfoh E, et al. 2014. Promoting engagement by patients and families to reduce adverse events in acute care settings: a systematic review. *BMJ Quality & Safety* 0: 1–8. DOI: 10.1136/bmjqs-2012-001769; Sutton et al 2015, *op. cit.*

[92] World Health Organization. 2013. Exploring patient participation in reducing health-care-related safety risks. Copenhagen, Denmark: WHO Regional Office for Europe. URL: www.euro.who.int/__data/assets/pdf_file/0010/185779/e96814.pdf.

may be more comfortable when they don't have to speak directly to a provider about their concerns.[93]

Box 7: Stakeholder views on the challenges for consumer engagement in learning from adverse events

Stakeholders consulted during the Policy review voiced concerns about the confidentiality and sensitivity of adverse events review and learning processes. They emphasised the need for careful procedures and safeguards to protect the interests of both consumers and providers throughout the process.

Stakeholders particularly identified the risk of blame and harm to providers. Preventing such harm requires education and upskilling to give providers the knowledge, confidence and skills for managing consumer input effectively.

Source: Health Quality & Safety Commission 2016, *op. cit.*

For the reasons described above, it can be difficult to engage affected consumers in review and learning processes. Research shows that the most vulnerable consumers (eg, the elderly and those with English as a second language) are most often excluded because they are typically harder to engage.[94] This makes it more difficult to obtain consumer perspectives that are representative of the population[95] and, consequently, safety improvements may not benefit those consumers most at risk. In this situation it can be valuable to have an independent consumer providing a consumer perspective in the review process.[96]

Providers may fear being blamed or that personal complaints will be made against them.[97] They may be sceptical about an affected consumer's ability to contribute because they believe consumers have limited knowledge of technical/medical aspects of care as well as unfamiliarity with processes or organisational workflow.[98] Providers who have been involved

93 The Health Foundation. 2013. *Evidence scan: Involving patients in improving safety*. London: The Health Foundation. URL: www.health.org.uk/sites/default/files/InvolvingPatientsInImprovingSafety.pdf.

94 Ward and Armitage 2012, *op. cit.*

95 O'Hara JK, Lawton R. 2016. At a crossroads? Key challenges and future opportunities for patient involvement in patient safety. *BMJ Quality & Safety* 25: 565–8; Sutton E, Eborall H, Martin G. 2015. Patient involvement in patient safety. Current experiences, insights from the wider literature, promising opportunities? *Public Management Review* 17(1): 72–89.

96 Canadian Patient Safety Institute, Patient Engagement Action Team 2017, *op. cit.*; Etchegaray et al 2014, *op. cit.*

97 Fleetcroft R, Howe A. 2015. Out of hours. Dangerous ideas: improving the quality of Significant Event Audit by involving the patients. *British Journal of General Practice* 65(630): 30. DOI: 0.3399/bjgp15X683197; Hrisos S, Thomson R. 2013. Seeing it from both sides: Do approaches to involving patients in improving their safety risk damaging the trust between patients and healthcare professionals? An interview study. *PLOS ONE* 8(11): e80759. DOI: 10.1371/journal.pone.0080759.

98 Etchegaray et al 2016, *op. cit.*

in an adverse event may fear being re-traumatised as a result of the details of an adverse event being shared and openly scrutinised by their colleagues.[99]

To mitigate the risks of damage to consumer-provider relationships and causing further trauma for both parties, the literature emphasises the importance of shifting the focus away from a 'blame culture' to a 'safety culture'.[100] This means supporting both parties equally throughout a review process, encouraging a collaborative mutual-learning approach and building trust with the common goal of enhancing safety.[101] Providers and affected consumers need to be educated about the importance, benefits and challenges of involving consumers in adverse event review and learning,[102] and supported to work together.

Guide to engaging with consumers following an adverse event

Systematic reviews and expert commentary highlight the lack of an agreed theoretical basis or comprehensive framework to guide consumer engagement in adverse events reporting, review and learning processes.[103] However, findings from qualitative research identify factors that are known to be important.

- Consumers affected by adverse events want to be told about the event soon after it occurs, they want to be able to choose their level of involvement in the review, they want follow-up conversations about the outcomes of the review[104] and they want to be emotionally supported.[105]
- Affected consumers value being listened to carefully, having an opportunity to talk to the providers involved in the event and receiving an authentic apology.[106]
- Engaging affected consumers early and in person is best to minimise problems with recalling details of the event and maximise willingness to participate.[107]
- Open-ended questions, or a combination of closed and open-ended narrative approaches, yield richer and more useful responses[108] about an adverse event than narrow, pre-defined categories.[109]

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99 Canadian Patient Safety Institute, Patient Engagement Action Team 2017, *op. cit.*; Ullström S, Sachs MA, Hansson J, et al. 2014. Suffering in silence: a qualitative study of second victims of adverse events. *BMJ Quality & Safety* 23: 325–31.

100 Rafter N, Hickey A, Condell S, et al. 2015. *The Quarterly Journal of Medicine* 108: 273–7.

101 Hrisos and Thomson 2013, *op. cit.*

102 Macht R, Balen A, McAneny D, et al. 2015. A multifaceted intervention to increase surgery resident engagement in reporting adverse events. *Journal of Surgical Education* 72(6): e117–e122.

103 King A, Daniels J, Lim J, et al. 2010. Time to listen: a review of methods to solicit patient reports of adverse events. *Quality & Safety in Health Care* 19: 148–57. DOI: 10.1136/qshc.2008.030114; Rosen AK, Chen Q. 2016. *Measuring patient safety events: Opportunities and challenges.* Rockville, MD: Agency for Healthcare Research & Quality. URL: https://psnet.ahrq.gov/resources/resource/30165/measuring-patient-safety-events-opportunities-and-challenges; Ward JK, Armitage G. 2012. Can patients report patient safety incidents in a hospital setting? *BMJ Quality & Safety* 21: 685–99. DOI: 10.1136/bmjqs-2011-000213.

104 Etchegaray et al 2014, *op. cit.*

105 Guijarro et al 2010, *op. cit.*

106 Moore and Mello 2017, *op. cit.*

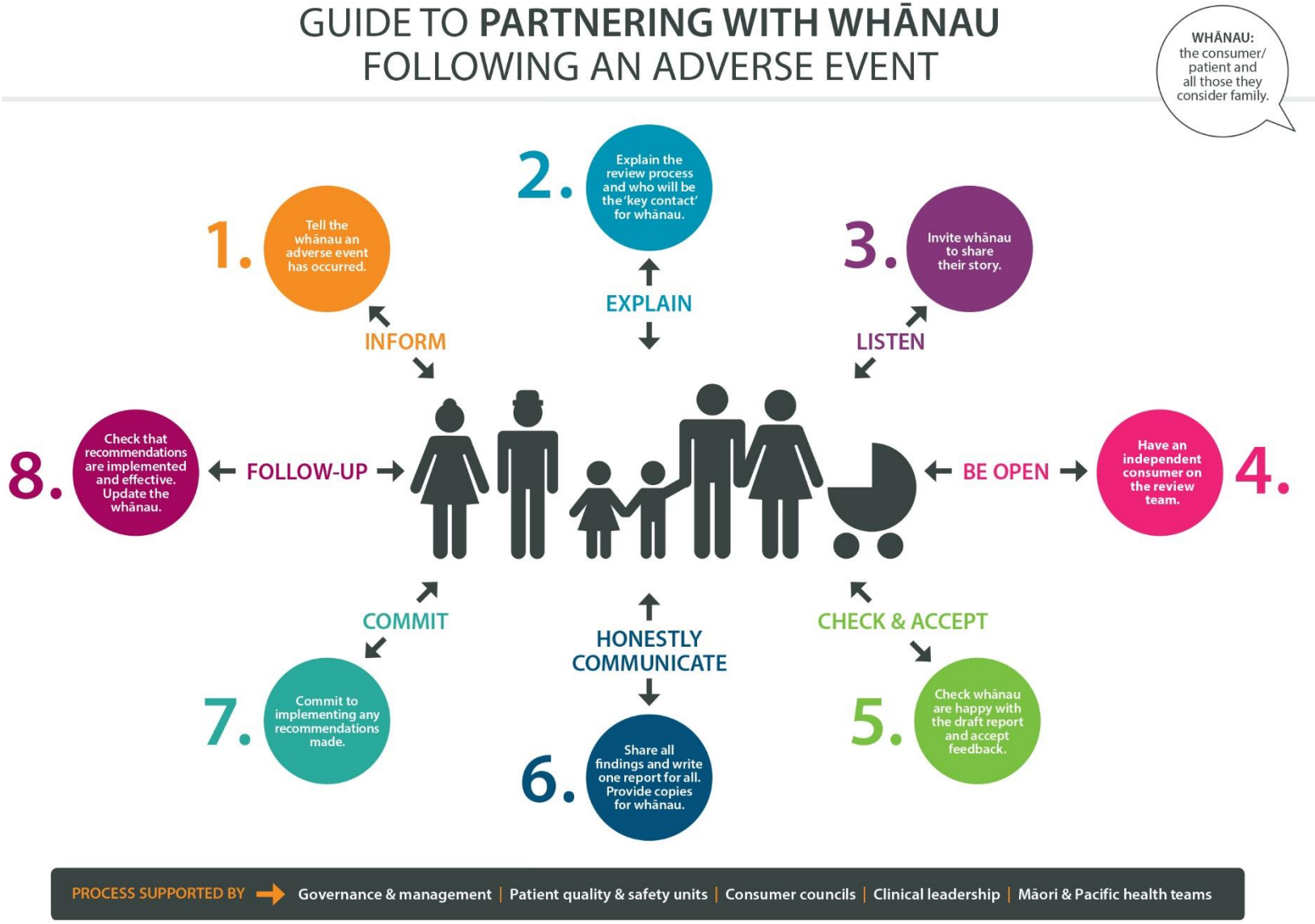
107 Etchegaray et al 2014, *op. cit.*; Rosen and Chen 2016, *op. cit.*

108 Guijarro et al 2010, *op. cit.*; Lang et al 2016, *op. cit.*

109 Sutton et al 2015, *op. cit.*

The Commission has developed a stepped guide to engaging with consumers following an adverse event (Figure 1). The eight-step process provides for ongoing, open communication between the provider and the affected consumer, and consumer input to the review.

Figure 1: Guide to engaging with partnering with whānau following an adverse event



Key steps to consumer engagement following an adverse event (see Figure 1)

Step 1: Inform the affected consumer an adverse event has occurred

Right 6 of the Code of Health and Disability Services Consumers' Rights gives all consumers the right to be fully informed, that is, to receive the information a reasonable consumer would expect to receive.[110] Consumers have a right to know when something harmful or potentially harmful has happened to them. Informing consumers honestly, fully and in a timely manner is the right thing to do.

Open communication (also referred to as 'open disclosure') is a core principle of the Policy – 'consumers are ethically and legally entitled to truthful and open communication at all times following an adverse event'.[111] Open communication is not a single conversation but a formal, ongoing process involving open discussion between an affected consumer and a provider about an adverse event or near miss.[112] It should continue until the consumer has all the information and support they need.

According to the Health and Disability Commissioner's Guidance on Open Disclosure Policies[113] open communication following an adverse event should:

- be timely (usually within 24 hours of the event occurring or the harm or error being recognised)
- be led by the provider with overall responsibility for the affected consumer's care
- include acknowledgement of the event, an explanation of what has happened and, where appropriate, what actions have been taken to prevent it happening again
- include a sincere apology.

Box 8: The importance of an apology

An apology is the provider's opportunity to say, 'We are sorry this happened to you'. It is not about allocating blame for the event but acknowledging the seriousness of the event and the distress it causes. Apologies can bring comfort to the consumer and assist with healing and resolution. An apology may also influence the consumer's decision about whether to lay a formal complaint.

Source: Canadian Patient Safety Institute. 2011. *Canadian Open Disclosure Guidelines. Being open with patients and families*. Ontario: Canadian Patient Safety Institute.

A consumer (and/or their key support people or representative) should **always** be informed about an event that has caused them harm (an adverse event). A consumer should **generally** be informed about an event that could have caused them harm but did not (a near

[110] Health and Disability Commissioner 2009a, *op. cit.*

[111] Health Quality & Safety Commission 2017a, *op. cit.*

[112] Health and Disability Commissioner. 2009b. *Guidance on Open Disclosure Policies*. Wellington: Health and Disability Commissioner. URL: www.hdc.org.nz/resources-publications/search-resources/leaflets/guidance-on-open-disclosure-policies.

[113] *Ibid.*

miss). In deciding whether to disclose a near miss to a consumer, providers should consider:[114]

- whether a reasonable person would want to know about the event
- whether an ongoing safety issue exists for the consumer, eg, if a consumer narrowly avoids being given medication intended for someone else with a similar name, it would be prudent to discuss this with them so they are aware of any ongoing safety risk related to a potential name mix-up so they can watch out for this risk in the future
- whether knowledge of the event may be relevant to future care decisions, eg, whether or not to go ahead with the same procedure on another occasion
- whether the consumer is aware of the event – if they are aware there has been a near miss, an explanation may alleviate concerns and maintain trust.
- If there is any doubt about whether to communicate a near miss to a consumer, the overarching principle should be applied that, 'it is seldom reasonable to withhold information about a consumer from that consumer'.[115]

Step 2: Explain the review process to the affected consumer

A key aspect of open communication is providing an explanation of what happened. However, this explanation is often not available until a review of the adverse event has taken place. Early communication between the provider and the affected consumer should include information about the review process, what will be involved, how long it will take, who will be the key contact for the consumer and how the consumer can be involved in the review. The consumer should be updated regularly about the progress of the review.

Affected consumers should be made aware that contributing to the review is voluntary and they should be given a choice about how much they want to be involved. Not all consumers who have been involved in an adverse event will want to be interviewed or provide feedback on the review report.

Step 3: Listen to the affected consumer's story

All consumers who have been affected by an adverse event (and/or their key support people or representative) should be offered the opportunity to tell their story of the event. Providers should start a review by interviewing the affected consumer, listening to and recording their story of what happened. This should include how the person feels about what happened, what they think may have contributed, how the event has affected them and what they think might prevent the event happening again.

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[114] Canadian Patient Safety Institute. 2011. *Canadian Open Disclosure Guidelines. Being open with patients and families*. Ontario: Canadian Patient Safety Institute. URL: www.patientsafetyinstitute.ca/en/toolsResources/disclosure/Documents/CPSI%20Canadian%20Disclosure%20Guidelines.pdf#search=open%20disclosure.

[115] Health and Disability Commissioner 2009b, *op. cit.*

Step 4: Be open to consumer perspectives in review of the event

The consumer's story should be given equal consideration with provider perspectives in analysis of the adverse event. One way of strengthening the consumer voice in the event review process is by inviting an independent consumer (see Definitions, Box 1) to be a member of the review team. This person is not an employee of the provider organisation and has not been affected by the adverse event under review. They are on the review team to provide a consumer perspective on understanding what happened and what might be done differently in the future. Box 12 describes two consumers' experiences of being on adverse event review teams.

Providers should aim for diversity and inclusion when engaging independent consumers to be part of adverse event review teams. This includes those involved reflecting the lived experiences and characteristics (eg, age groups, cultural backgrounds, socioeconomic status, education levels) of the populations served by the organisation. This also means considering and addressing the barriers that prevent different groups from participating by, for example, using a diverse range of engagement methods or culturally appropriate review practices that are sensitive to other worldviews and ways of communicating.[116]

Some organisations have 'consumer engagement specialists'. Their role is to liaise between staff, affected consumers and quality improvement specialists to help optimise consumer engagement and support improvement initiatives that stem from review learnings.[117] A consumer engagement specialist can act as a go-to person for the affected consumer to help facilitate conversations and provide support throughout the review process. 'Consumer partners' can also be useful. They are trained specifically in engaging consumers and are highly experienced in bringing the consumer voice to quality improvement teams.[118]

Step 5: Check the draft review report with the affected consumer

Providers should give the affected consumer the opportunity to check the draft review report, including findings and recommendations, and provide feedback on it. The affected consumer's feedback should be given serious consideration. While not all feedback will result in a change to the report, all feedback must be considered, and an explanation provided where feedback does not result in a change to the report.

[116] *Ibid.*

[117] *Ibid.*

[118] *Ibid.*

Step 6: Communicate all review findings to the affected consumer

The affected consumer should be given a copy of the final review report. In line with the principles of honest and full communication, providers should produce one final review report for all, including providers and consumers.

Step 7: Commit to taking action

The provider should commit to implementing any recommendations made, monitor implementation of those recommendations and check that actions taken are effective.

Step 8: Follow up with the affected consumer on actions taken

The affected consumer should be kept updated on actions taken as a result of the review. Organisational governance plays a critical role in this final stage of consumer engagement in review and learning. Governance bodies are responsible for implementing and following up review recommendations and keeping consumers updated on implementation progress.

More broadly, governance bodies have an important influence on, and responsibility for, consumer engagement throughout the reporting, review and learning process. Research shows the attitudes of boards to consumer engagement and consumer-centred care are an important driver of change.[119] Consumer representation on the organisational committees that oversee adverse events reviews would support consumer-centred approaches throughout the adverse event learning process.

Culturally appropriate review practice

This is one of six core Policy principles, stating that the cultural viewpoint and practices of affected consumers should be considered throughout the entire open communication, reporting, review and learning process. Box 9 presents stakeholders' thoughts on culturally appropriate review approaches.

[119] Health Quality & Safety Commission. 2015. *Engaging with consumers: a guide for district health boards.* Wellington: Health Quality & Safety Commission. URL: www.hqsc.govt.nz/our-programmes/partners-in-care/news-and-events/news/2213.

Box 9: Stakeholder views on culturally appropriate review approaches

Stakeholders consulted during the Policy review emphasised the need to achieve culturally appropriate consumer engagement for key populations, in particular Māori, Pacific and Asian populations. This would help quality improvements to reflect the needs of those most at risk. A range of ideas were discussed for achieving culturally appropriate review processes, including:

- having an independent consumer on the review team who is from the same cultural group as the affected consumer
- having a range of cultural advisors available to contribute to the review where appropriate
- providing cultural support to affected consumers throughout the review process
- using a wide range of review processes and engagement approaches that enable accessible communication with all populations
- considering the cultural perspectives of affected consumers and how these may influence their willingness to participate in the review process.

Source: Health Quality & Safety Commission 2016, *op. cit.*

Box 10 provides expert commentary on engaging with Māori whānau following an adverse event. Many of the ideas presented here are also relevant to engagement with other key populations. For example, the need to recognise our own values and beliefs, the influence of social biases on treatment decisions and outcomes, and the need to be flexible and skillful in responding and adapting to different cultural contexts and circumstances.

Box 10: Hui – a process for rebuilding trust for Māori whānau following an adverse event (Taima Campbell RN, MHSc (Nsg), PG Dip Bus (Māori Development), Director Hauraki Health Consulting Ltd)

All adverse events are a tragedy. Before we acknowledge and address the factors that contribute to an adverse event for Māori whānau,[120] we need to recognise that Māori are more likely to have a poor experience of many aspects of health care and have less trust in a system that consistently delivers inequitable health outcomes for them.

Inequalities or social injustice is killing people – on a grand scale.[121] The root causes can be found in the ongoing effects of our history of colonisation and, in the words of Dame Tariana Turia, 'the systematic damage incurred by decades of institutional racism'.[122] As

[120] The term 'whānau' is used instead of 'patient' or 'consumer' to describe the individual and collective recipients of health care.

[121] CSDH. 2008. *Closing the gap in a generation: health equity through action on the social determinants of health. Final Report of the Commission on Social Determinants of Health.* Geneva: World Health Organization.

[122] www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11721558

health professionals, if we are not actively involved in deconstructing racism then we are part of a health system perfectly designed to achieve imperfect results for Māori.

We may not like to think we are causing harm, but the uncomfortable truth is that our implicit and explicit biases and stereotypes regarding Māori may influence our clinical encounters and treatment decisions, resulting in adverse outcomes for whānau.[123]

While cognitive bias features in the literature regarding human factors and the impact on clinical decision-making, implicit ethnic or social biases are rarely identified as a contributing factor in adverse events.

So what corrective actions can we take? The first step, in the words of the late Michael Jackson, is to start with 'the man (or woman) in the mirror'. Culturally safe practice begins with an awareness of our own values and beliefs, and recognition that people from other cultures may not share them. It means being non-judgemental and respectful in relationships with people whose culture and worldview is different from our own; and being flexible and skillful in responding and adapting to different cultural contexts and circumstances.

When it comes to engaging and communicating with Māori whānau as part of an adverse event process, there is no 'checklist', but there are ways that are acceptable to Māori, from simple things, such as pronouncing names correctly, through to applying traditional principles and processes when holding a hui – not a meeting – with whānau.

Hui processes are embedded in the Māori worldview and are a way of Māori coming together on Māori terms. Hui start and conclude with karakia – poetic and metaphorical verses that establish our connection to Te Ao Māori (the Māori world), seeking guidance and wisdom from ancestors. Te reo Māori and tikanga Māori are essential for the hui process, providing an environment where people can express their views freely and frankly in a way that is designed to maintain the mana and integrity of everyone engaging in the discussion. Kaumatua and kuia are the 'pou' who provide wisdom and support to enable whānau and health care teams to navigate through hui and the adverse events review process.

Hui are part of the healing process. They are an opportunity for whānau to be heard and for health professionals to listen. Hui are a time for health professionals to acknowledge the mamae (the pain/ grief) of the whānau and to speak openly and sincerely about the factors that contributed to their loss. Hui are an opportunity to gain consensus on corrective actions to be taken and are a process of public accountability for following these through. Hui and other cultural processes are also a means to support whānau to re-engage with a health system they will undoubtedly need. Hui are a culturally appropriate process for all stages of the adverse events process, including being part of the journey towards rebuilding trust.

[123] www.ncbi.nlm.nih.gov/pmc/articles/PMC3993983

Future focus for consumer engagement in learning from adverse events

The focus for the adverse events learning programme over 2017–19 is on introducing the new Policy expectations for consumer involvement in review processes and supporting providers to address these expectations. The Commission will continue to develop and distribute tools and resources to support consumer engagement in reporting, review and learning. In particular, we will focus on tools and resources to support culturally appropriate review practice and independent consumer representation on adverse events review teams.

As consumer engagement becomes increasingly established in New Zealand adverse events review and learning practice, the Commission will also look to gather information on provider and consumer experiences of working together; to learn from adverse events and the impact of this approach on safety and quality across the health and disability system.

Box 11: Involving consumers in adverse events reviews – experiences and learnings from Waikato DHB (Mo Neville, Executive Director Quality and Patient Safety, Waikato DHB)

How Waikato DHB involves consumers in its adverse events review process

The adverse events review process always begins with open disclosure. If the affected consumer is an inpatient, a member of the quality team/review leader goes to the person personally, explains there will be an internal review of what happened and leaves them a leaflet that explains the process. If the consumer has been discharged, he or she is sent a letter as first contact. In both cases, the consumer is given information about the review process, advised who their key contact person is, and invited to share his or her experiences and perspectives over the telephone or in a face-to-face meeting.

The consumer meets with the review team leader, and the review team clinician if possible (eg, a nurse or a consultant clinician), to discuss the adverse event, including exploration of what the consumer thought went wrong, what could have gone better and what outcomes they are looking for from the review. The consumer's story is recorded and actively considered in all aspects of the review process. The consumer's is updated on progress at each stage of the review.

After the final review team meeting, review findings and recommendations are written up into a report and a copy of the draft report is provided to the consumer to check for factual accuracy.

The review team leader is the main point of contact with the consumer throughout the process.

The challenges

- Obtaining adequate organisational representation on the review team – clinicians involved in the adverse event can be difficult to engage, because the event and the review process can be distressing for them.
- Finding an appropriate consumer representative for the review team – there are particular skills required to successfully navigate review processes.

- Having consumer representatives on a review panel can be expensive. Waikato DHB tends to engage consumer representatives for the more complex adverse events that involve multiple departments, organisations or multiple DHBs.
- Obtaining consent to share the draft review report with the affected consumer – clinicians and staff can be reluctant to share the draft report and receive feedback on recommendations from the affected consumer.

What works well

Consumer involvement in the review process helps with healing and rebuilding trust in the system. Because the staff involved treat the consumer with compassion, give an apology in person and listen to them in a meaningful way, many consumers do get closure from the process and are less defensive or upset later on.

> '... we talk more about things from a consumer perspective; we have family meetings and we try to get them in for a face-to-face conversation. Things put in writing can seem harsh and hard. Hands being held, actively listening, and meetings, probably mean more to the family…'

Having a consumer representative on the review team:

- helps clinicians see things from another perspective. In some instances, this helps identify things that clinicians wouldn't otherwise have considered as contributing factors to the event.

  > '... spectacularly brilliant to have a lay person on the team. Wouldn't have said that a year ago…. It kept the focus on the consumer throughout the process

- provides reassurance for the consumer that the review process has some independence
- helps clinicians and staff feel less anxious about being blamed.

Key learnings

Having clear processes is important for engaging clinicians and appropriately engaging different types of consumers.

It is important to engage with consumers as early as possible after the adverse event. Early engagement reassures the consumer they can trust the provider to work to prevent the same thing happening to another family or whānau.

Box 12: Representing the consumer voice on an adverse event review – consumer representative perspectives (Sheila, Whanganui DHB; Cathie, Waikato DHB)

How do you become a consumer representative on an adverse events review team?

Sheila and Cathie became consumer representatives through quite different routes.

Cathie was asked, by a representative of the consumer's whānau, to put her name forward for the role of consumer representative. Two people were put forward and the family selected Cathie. She then met with someone from the DHB, who checked that she knew what was involved and had the capacity and capability to perform the role. Due to her professional experience, she had had some previous involvement with adverse events reviews but had never been on a review team.

Sheila is a member of Te Pukaea, Whanganui DHB's consumer council. One of Te Pukaea's roles is to represent the consumer voice on the DHB's adverse events review teams. Most Te Pukaea members have experienced a serious adverse event themselves.

> 'We have experience of trauma and some understanding of the frustrations of dealing with a corporate organisation like a DHB.'

What is the role of a consumer representative?

A consumer representative's role on the review team is usually the same as other team members. They meet to review documentation, interview staff and sometimes meet with the consumer or whānau, with a view to finding out what went wrong and making recommendations for change.

While the task and activities are essentially the same for all team members, a consumer representative makes a unique contribution to the review process. Sheila and Cathie highlighted some of the key areas in which they felt they had a particular role.

- Keeping the consumer and their care, what went wrong and how things can be improved, at the centre of the review process. Constantly reminding the review team why they're there – not just because of the event but because of what has happened to the consumer and whānau as a result of the event.

  > 'The consumer and their whānau should be at the centre of the review but can be overlooked amidst all the clinical analysis.'

- Asking the questions the family would want answered, and presenting review information in an accessible way to the consumer and whānau.

  > 'Consumer representatives see things from the consumer's perspective and enable there to be a consumer's voice within the review team.'

  > 'If we are asking, and health professionals are having to use language that we can understand, then maybe the report will be written in a way that the consumer and their whānau can understand.'

- Bringing ‘fresh eyes’ to understanding the event. Asking the basic, but sometimes hard, questions, eg, ‘why was this done?’

  ‘Consumer reps are encouraged to ask the how, what, why, where, who, when questions that the other review team members may already know the answers to, or hadn’t thought to ask because of the knowledge and experience they have within the health environment… We join a review team from our own day jobs and commitments in the community, usually without any prior knowledge of the event.’

- Looking beyond technical details to the big picture and the human factors in a consumer’s care, such as communication issues, relationship issues and gaps in care.

  ‘The consumer rep provides a perspective that tells another part of the story, which is to do with humanity, relationships, communication issues. We may see issues between departments, between various people in the hierarchy…’

- Bringing empathy for the consumer and whānau to the table. ‘You’re given the mandate to be that empathetic person.’

  ‘As community members unfamiliar with the medical world, we can share an understanding of the consumer’s reality, and what it is like to be on the receiving end of the information being communicated by health professionals.’

- Objectivity. Consumer representatives aren’t tangled up in professional hierarchies or organisational politics.

  ‘We have no vested interests in the outcome. We’re not trying to protect anybody. We’re not trying to find blame.’

  ‘The presence of a consumer, who crosses all levels of the hierarchy – or doesn’t cross any at all! – encourages everyone in the review team to feel they have a voice, and that their concerns will be listened to.’

- Adding credibility to the review process.

  ‘It added weight for the family and probably for other families. It wasn’t a closed shop.’ ‘A consumer being there just keeps it real for the patient and their family.’

What are some of the challenges?

Representing the consumer voice in the review of an adverse event has its challenges. Sheila and Cathie talked about some of the aspects they personally have found difficult.

- Dealing with challenging and sometimes very sad stories.
- Believing you can make a difference to the outcome of the review.
- Believing you have a right to question medical processes and the actions of senior medical personnel.
- Expectations that the consumer representative will ensure the outcomes the consumer and whānau want from the review are realised. The consumer representative is there

to represent a consumer perspective in the discussion but not to act as a representative for the consumer or whānau per se.
- Patronising attitudes of some team members towards the consumer and whānau.
- Significant workload involved with being part of a review team, which often has to be fitted around the consumer representative's regular job commitments.
- Working within tightly constrained review parameters, eg, not being able to look at factors outside the DHB care environment.

What are some of the rewards?

There are many rewarding aspects to being a consumer representative on an adverse events review team, not least the opportunity to reduce the chance of a similar event happening again. Some of the more rewarding aspects highlighted by Sheila and Cathie include:

- contributing to a final review report that has a strong focus on the consumer and whānau, and recommendations relevant to improving the consumer experience
- identifying contributory factors that probably wouldn't have been identified by the health professionals on the review team

  > 'I see us as asking questions that actually make a difference. And I know that some of the things I have flagged have actually been significant to the outcome of a review.'

- being able to provide positive feedback to staff on how they dealt with a traumatic event and circumstances

  > 'It is really good to be able to provide staff with positive feedback about processes and things that you can see going really well.'

- supporting staff to share their perspective when they might not otherwise have felt able to speak up

  > 'Sometimes we need to speak up for someone within that hierarchy who doesn't want to step on someone else's toes or say what they perceive to be a problem. So our presence can enable that to happen.'

Box 13: Resources to support involving consumers in adverse event review and learning

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Health Quality & Safety Commission. 2015. *Engaging with consumers: a guide for district health boards*. Wellington: Health Quality & Safety Commission. URL: www.hqsc.govt.nz/our-programmes/partners-in-care/publications-and-resources/publication/2162

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Canadian Patient Safety Institute. nd. *Communicating after harm in healthcare*. Ontario: Canadian Patient Safety Institute. URL: www.patientsafetyinstitute.ca/en/toolsResources/InformingMediaAdverseEvent/Documents/Communicating%20After%20Harm%20in%20Healthcare.pdf#search=communicating%20after%20harm.

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Grey literature for Part 2

Quality improvement in mental health (King's Fund)
www.kingsfund.org.uk/sites/default/files/field/field_publication_file/Quality_improvement_mental_health_Kings_Fund_July_2017_0.pdf

Reporting and reviewing adverse events involving users of mental health services (Health Quality & Safety Commission)
www.hqsc.govt.nz/assets/Reportable-Events/Publications/Reporting-reviewing-adverse-events-MH-Dec-2012.pdf

Mental health serious adverse events report questions and answers (Health Quality & Safety Commission)
www.hqsc.govt.nz/assets/Reportable-Events/Publications/SAE-QAs-Nov-2013.pdf

Medication Safety in Mental Health (Australian Commission on Safety and Quality in Health Care)
www.safetyandquality.gov.au/wp-content/uploads/2017/06/Medication-Safety-in-Mental-Health-final-report-2017.pdf

Review of National Reporting and Learning System (NRLS) incident data relating to discharge from acute and mental health trusts – August 2014 (NHS England)
www.england.nhs.uk/wp-content/uploads/2014/08/nrls-summary.pdf

Measurement and Monitoring of Safety Framework e-guide (The Health Foundation)
www.howsafeisourcare.com/uploads/7/6/0/0/76001935/mmsf_single_pages_7th_stg.pdf

Learning, candour and accountability: a review of the way NHS trusts review and investigate the deaths of patients in England (Care Quality Commission UK)
www.cqc.org.uk/sites/default/files/20161213-learning-candour-accountability-full-report.pdf

Reportable deaths (State Government of Victoria)
www2.health.vic.gov.au/about/key-staff/chief-psychiatrist/chief-psychiatrist-guidelines/reportable-deaths

Thematic Review of Mental Health Serious Adverse Incident Reports Relating to Patient Suicides with Recommendations & Implementation Plan (NHS UK)
www.england.nhs.uk/south/wp-content/uploads/sites/6/2016/10/thematic-review-vol1.pdf

Building a culture of improvement at East London NHS Foundation Trust. (Institute for Healthcare Improvement)
www.ihi.org/resources/Pages/Publications/Building-Culture-of-Improvement-East-ondon-NHS.aspx

Review of children and young people's mental health services (Care Quality Commission UK)
www.cqc.org.uk/sites/default/files/20171103_cypmhphase1_report.pdf

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www.cqc.org.uk/sites/default/files/20170720_stateofmh_report.pdf

Developing a national mental health and suicide prevention monitoring and reporting framework (National Mental Health Commission, Australia)
https://consultation.mentalhealthcommission.gov.au/policy-projects/framework/supporting_documents/Developing%20a%20Monitoring%20and%20Reporting%20Framework%20for%20Mental%20Health%20and%20Suicide%20Prevention%20%20NMHC%20National%20Consultation%20OctNov%202017.pdf

Serious Incident Framework – Supporting learning to prevent recurrence (NHS England)
www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf

National Standards for the Conduct of Reviews of Patient Safety Incidents (Mental Health Commission Ireland)
www.mhcirl.ie/File/final_patient_safety_review2017.pdf

Learning from adverse events through reporting and review: A national framework for Scotland (Healthcare Improvement Scotland)
www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/national_framework.aspx

Learning from adverse events: Learning and improvement summary (Healthcare Improvement Scotland)
www.healthcareimprovementscotland.org/his/idoc.ashx?docid=c3c72a83-0c2c-49d7-b25e-1ace933af418&version=-1

Procedure for the Reporting and Follow up of Serious Adverse Incidents (Health and Social Care Board, Ireland)
www.hscboard.hscni.net/download/PUBLICATIONS/policies-protocols-and-guidelines/Procedure-for-the-reporting-and-follow-up-of-SAIs-2016.pdf

Appendix 1: Themes from regional workshops held in 2017

During 2017 four regional workshops with MHA consumers were held to prioritise the work plan for the MHA quality improvement team. The themes that relate to reporting adverse events were as follows.

Incident reviews

Safety first response joint reviews.

Processes including follow up

Joint review; Uniform incident reporting; Focus on quality complaints process; Consumer advisor's role in case review; Complaint investigation processes; Debriefing; Open books to share – shared learning; Implications for practice.

Serious adverse event reviews

Include consumer, family and whānau; cross-organisation incident reviews; London Protocol; SAC rating – with mental health specific definitions; future focus feedback; DHB and NGO reviews integrated process.

There was agreement across all 20 DHBs to use the London Protocol. Now there is demand for education and training from the DHBs.[124]

[124] Feedback from the MHA quality improvement programme manager.

Appendix 2: Glossary

Patient safety terms vary widely in the literature, in different jurisdictions and even between different New Zealand agencies. Drawing on the World Health Organization draft guidelines for adverse event reporting and learning systems,[125] this report uses the following definitions.

Adverse event	An incident relating to medical management that causes harm to a patient.
Medical management	Covers all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Other sources sometimes use the terms 'sentinel event' or 'critical incident' to refer to an adverse event, but for this review we will use adverse event.
Near miss	An incident that has the potential to cause an adverse event but fails to do so because of chance or because someone stops it from happening. It is assumed that the underlying systems failures for near misses are the same as for actual adverse events.
Never event	A patient safety incident that results in serious patient harm or death and that could have been prevented by using organisational checks and balances.
Patient safety incident	Any deviation from usual medical care that causes harm to a patient or presents a risk of harm. This term includes adverse events and near misses.
Patient safety reporting systems (PSRS)	The processes and technology involved in standardising, formatting, communicating, giving feedback on, analysing, learning about and responding to reported incidents as well as in making known any lessons learned from such incidents. Other sources sometimes use 'incident reporting system' or 'reportable events system' to refer to PSRS.

[125] World Health Organization. 2005. *World alliance for patient safety: WHO draft guidelines for adverse event reporting and learning systems: from information to action*. Geneva: World Health Organization. URL: www.who.int/iris/handle/10665/69797.

In addition to the terms above, which are used in general health settings, the following terms are also used in this report. They are sourced from the mental health and addiction quality improvement programme charter.

Addiction	Addiction relates to alcohol and other drug use and/or problem gambling. It refers to a maladaptive pattern of substance use, or problem gambling, that leads to a clinically significant impairment or distress. Substance use disorders and pathological gambling disorder are characterised by difficulty in control, tolerance, withdrawal and salience, and they are considered chronic relapsing conditions.
Adverse events	An adverse event is an event with negative reactions or results that are unintended, unexpected or unplanned (often referred to as 'incidents' or 'reportable events'). In practice this is most often understood as an event that results in harm to a consumer.
Consumer	Tangata whaiora/service user/consumer/person seeking wellness/patient
District health board (DHB)	DHBs are responsible for providing or funding the provision of health services in their district.
Family and whānau	Family and whānau are not limited to relationships based on blood ties. Family and whānau can include a person's extended family, whānau, their partners, friends, advocates, guardians or other representatives.
Least restrictive care	Least restrictive care refers to practice in mental health settings that is mindful of the need to maximise both the autonomy and the safety of consumers, and to reduce or prevent practices that restrict personal freedoms and are known to cause harm, such as restraint and seclusion.
Mental disorders	Mental disorders comprise a broad range of problems, with different symptoms. However, they are generally characterised by some combination of abnormal thoughts, emotions, behaviour and relationships with others. Examples are schizophrenia, depression, and disorders due to drug abuse. Most of these disorders can be successfully treated.
Mental health	Mental health is defined as a state of wellbeing in which every individual realises their own potential, has the resilience to deal with the normal stresses of life, can work productively and/or

	make a contribution to their community, and has the opportunity to do all of these in an accepting, inclusive environment.
Non-governmental organisation (NGO)	An NGO is a citizen-based association that operates independently of government, usually to deliver resources or serve some social or political purpose.
Patient	The term 'patient' is used in this report where this is the term used in the relevant evidence review or document. The Commission recognises that people who access MHA services are better called clients, residents and consumers.
Primary care	Primary health care relates to the professional health care provided in the community, usually from a general practitioner (GP), practice nurse, pharmacist or other health professional working within a general practice.
Root cause analysis (RCA)	RCA is a method of problem solving used for identifying the root causes of faults or problems. A factor is considered a root cause if removal thereof from the problem-fault-sequence prevents the final undesirable outcome from recurring, whereas a causal factor is one that affects an event's outcome, but is not a root cause. Though removing a causal factor can benefit an outcome, it does not prevent its recurrence with certainty.
Severity assessment code (SAC)	The SAC is a numerical rating that defines the severity of an adverse event (outcome) and as a consequence the required level of reporting and review to be undertaken for the event.
Taxonomy	The practice and science of classification of things or concepts.

Appendix 3: Search strategy for Part 2

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R), Ovid Nursing Database <1946 to November Week 3 2017>, PsycINFO <2002 to November Week 2 2017>, adapted for Scopus, Embase, Cochrane

Search strategy:

1	"london protocol*".mp.
2	*medical errors/ and (reporting or monitoring).mp
3	(incident* adj3 (reporting or monitoring)).mp.
4	("learning organi*" or "organi* learning").mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, sy, dw, tc, id, tm]
5	reportable event*.mp.
6	quality improvement/ and (monitoring or reporting).mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, sy, dw, tc, id, tm]
7	safety reporting.mp.
8	(near miss* and (monitoring or reporting)).mp.
9	trigger tool*.mp.
10	(adverse adj3 (event* or incident*) adj3 (reporting or monitoring)).mp.
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12	exp mental disorders/
13	"mental health".ab,ti.
14	exp suicide/
15	exp psychiatry/
16	exp mental health services/
17	Psychiatric Department, Hospital/
18	emergency services, psychiatric/
19	hospitals, psychiatric/
20	(antipsychotic* or anti-psychotic*).mp
21	psychiat*.ab,ti.
22	12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
23	11 and 22
24	limit 23 to (english language and yr="2012 -Current")
25	remove duplicates from 24
26	(reporting system* or feedback system*).mp. and 11 [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, sy, dw, tc, id, tm]
27	(reporting system* or feedback system*).mp. and 22 [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, sy, dw, tc, id, tm]
28	27 and quality improv*.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, sy, dw, tc, id, tm]