

TOWARD CLINICAL EXCELLENCE: LEARNING FROM EXPERIENCE

A Report to the Director-General of Health

**From the Sentinel Events Project
Working Party**

Published In September 2001
By the Ministry of Health
PO Box 5013, Wellington, New Zealand

ISBN 0-478-26216-7 (book)
ISBN 0-478-26215-9 (Internet)
HP3474

This document is available on the Ministry Of Health's Web site:
<http://www.moh.govt.nz>



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EXECUTIVE SUMMARY

This report is the culmination of the deliberations of the Working Party for the Sentinel Events Project. The Working Party makes recommendations to the Director-General of Health on the feasibility of implementing a mandatory event reporting system for health and disability services and related matters.

The Working Party believes it is feasible and highly desirable for New Zealand to implement a mandatory event reporting system for health and disability services. This report sets out a framework and systematic process for reporting investigations of Sentinel Events to an independent central agency, which will then evaluate them, and for identifying strategies that enable learning at a national level.

It is recommended that a pilot be undertaken before fully implementing the system. Other recommendations cover the education and support requirements for implementing a reporting system. As far as possible, this report identifies the cost and benefits of implementing such a system. The proposed system complements existing activities to improve the safety and quality of health and disability services for consumers.

Before finalising these recommendations the Working Party read widely and consulted with the health and disability sector. The Working Party believes it has addressed the issues raised in submissions. However, it recognises the Sentinel Events Reporting System will be the subject of ongoing concern until it demonstrates to all parties that it can improve the safety of services and that its level of confidentiality supports that goal.

The vision of the Working Party

The Working Party wants to create an environment within health and disability services that, locally and nationally:

- supports and encourages self-learning from analysing Sentinel Events
- promotes the redesign of systems as the main method for improving safety
- supports a culture where every health care worker takes personal responsibility for consumer safety and where the action of discovering and reporting problems, mistakes and close calls is rewarded, not punished.

If this environment is achieved, the Working Party believes that serious failures of standards of care will be uncommon. In addition, any instance of such failure will not be repeated in other parts of the country. As a result, consumers will have confidence that health and disability services can actively recognise, manage and learn from Sentinel Events. Moreover, the economic costs of failure will diminish, freeing up resources for service delivery.

The Working Party believes there is considerable support among health professionals for a confidential, fair, systems-focused method of investigation and reporting. Now is the time to build on that support.

Health care workers do not function in isolation. The root cause of problems leading to a Sentinel Event is likely to be found in the design of the system that permitted such an event.

Major recommendations

The Working Party makes the following recommendations to the Director-General of Health.

Recommendation 1

Arrange for policy work to consider rationalising the manner in which the Coroners, Health and Disability Commissioner, Police, district inspectors, Ministry of Health and Minister of Health investigate events within health and disability services. The goal is a framework that is consistent and coherent, and that meets the Government's objectives for improving the quality and safety of health and disability services.¹

Recommendation 2

Develop technical resources and guidelines to help health and disability services to achieve their own robust internal systems of event reporting, and to identify events experienced by consumers that need full investigation. The goal is to establish systems in which the factors that could lead to recurrence are eliminated, isolated or reduced.

Recommendation 3

Implement a national system (to be called the **Sentinel Events Reporting System**) that requires health and disability services to report a defined list of events (to be called **Sentinel Events**) to the Ministry of Health for review.

Recommendation 4

Advise the Minister of Health to establish an independent group (to be called the **Sentinel Events Committee**) with the status of a Ministerial Advisory Committee* for an initial period of five years. Its purpose will be to lead national efforts to make systemic improvements in the safety and quality of health and disability services in New Zealand, with a particular emphasis on eliminating, isolating and minimising the likelihood and effects of system failure.

Recommendation 5

Release a version of this report for public information and comment.

* See Appendix 9 for draft Terms of Reference.

GLOSSARY

The key terms used in this report are explained briefly below. Appendix 10 gives more information about the underlying theories of organisational accidents and learning.

Close calls

Those events that could have resulted in a **Sentinel Event** or lesser harm, but did not. The Working Party found this term had more resonance (with medical practitioners in particular) than its equivalent “near miss”, as it conveys a practitioner’s “sinking feeling in the stomach” when an untoward harmful event is averted.

Consumer

Person who receives services provided by health and disability services. This term is used in the Health and Disability Commissioner Act 1994. It includes people who might also be known as clients, patients or residents.

Health and disability services

Organisations *and* individual practitioners providing health and/or disability services to **consumers** (except where it is clear from the context that it refers to organisations only).

Incident

An undesired event that occurs within an organisation and that the organisation decides should be reported internally for quality improvement and risk management purposes.

Just culture

A culture of an organisation or sector with an atmosphere of trust rather than a total absence of blame. In this culture, people are encouraged to provide safety-related information, while there is a clear distinction between acceptable and unacceptable behaviours.

Proximate causes

The causal factors closest to a **Sentinel Event**.

Root cause analysis

A tool to identify the reason for an undesirable condition; if that reason had been corrected it would have prevented the condition. By identifying these causal factors (root causes), effective corrective actions can be formulated.²

Sometimes root causes are difficult to determine and resolve as they require fundamental change to how an organisation operates. Addressing causal factors one level below the root cause level (ie, at the level of significant contributing factors) can improve safety substantially.

Root cause analysis is used to improve safety. It is not suitable for determining direct cause-and-effect links, nor for establishing liability. The systems view of safety assumes that humans are fallible, that errors are inevitable, and that the systems within which people work must be strengthened to ensure the defences that keep people safe do not fail.

In many fields of clinical practice, relatively few protective defences/barriers intervene between danger and harm. Unlike hi-tech, well-defended systems such as aviation, the human elements of the system are often the last and most important defences.

Sentinel Events

Those events that must be reported centrally as part of the system recommended in this report. Sentinel Events result from the systems that deliver care/treatment to **consumers**.

Sentinel Events are *not*:

- events that occur as a natural consequence of the consumer's illness, disease or condition
- events that are unavoidable, expected complications of the consumer's illness, disease or condition.

Sentinel Events have a significant effect on the consumer, result in permanent disability or death, and result from management of the consumer's illness, disease or condition.

SECTION 1: INTRODUCTION

The Director-General approved the Sentinel Events Project in March 2000. It was a combined project of the Ministry of Health and Health Funding Authority.

Overview of the Sentinel Events Project

The main purpose of the Sentinel Events Project was to make recommendations to the Director-General on the feasibility of implementing a mandatory event reporting system for health and disability services. The Working Party Terms of Reference are listed in Appendix 1.

A Working Party of invited and nominated representatives was formed, with Leanne Arker as project co-ordinator, and Dr Bob Boyd, Ministry of Health and Gillian Bohm, Health Funding Authority providing sponsorship. A full list of representatives is given in Appendix 2.

Members of the Working Party read widely on its subject, undertook consultation, and reflected on the New Zealand and international experience in forming its views. A Reference Group was established in the early stages of the project. Its members were regularly consulted and informed on the issue, and received notes from Working Party meetings.

It was originally intended that this report to the Director-General of Health would be the only document distributed for consultation. However, the Working Party agreed it would be useful to obtain feedback from the health and disability sector before finalising its recommendations. Consequently, a brief consultation document *Toward Clinical Excellence: learning from experience*³ was published and distributed widely. Overall, submissions provided a remarkably consistent response on the subject. The individuals and organisations that made submissions are listed in Appendix 3.

Where possible, the Working Party has addressed concerns raised by submissions in its the final recommendations. A few concerns relating to operational detail cannot be addressed until the system is implemented. Many respondents expressed support for a confidential, just, systems-focused learning approach to the Sentinel Events Reporting System. Such support gives reason for confidence that there will be support for these recommendations from many quarters, particularly medical practitioners' professional organisations.

From the submissions and its own experience, the Working Party expects some consumer groups (and politicians) will be wary of some recommendations, particularly those that relate to confidentiality. The recommendations have been designed to address their concerns. Equally the Working Party recognises that some concerns can only be alleviated by clear evidence that the system works well in practice.

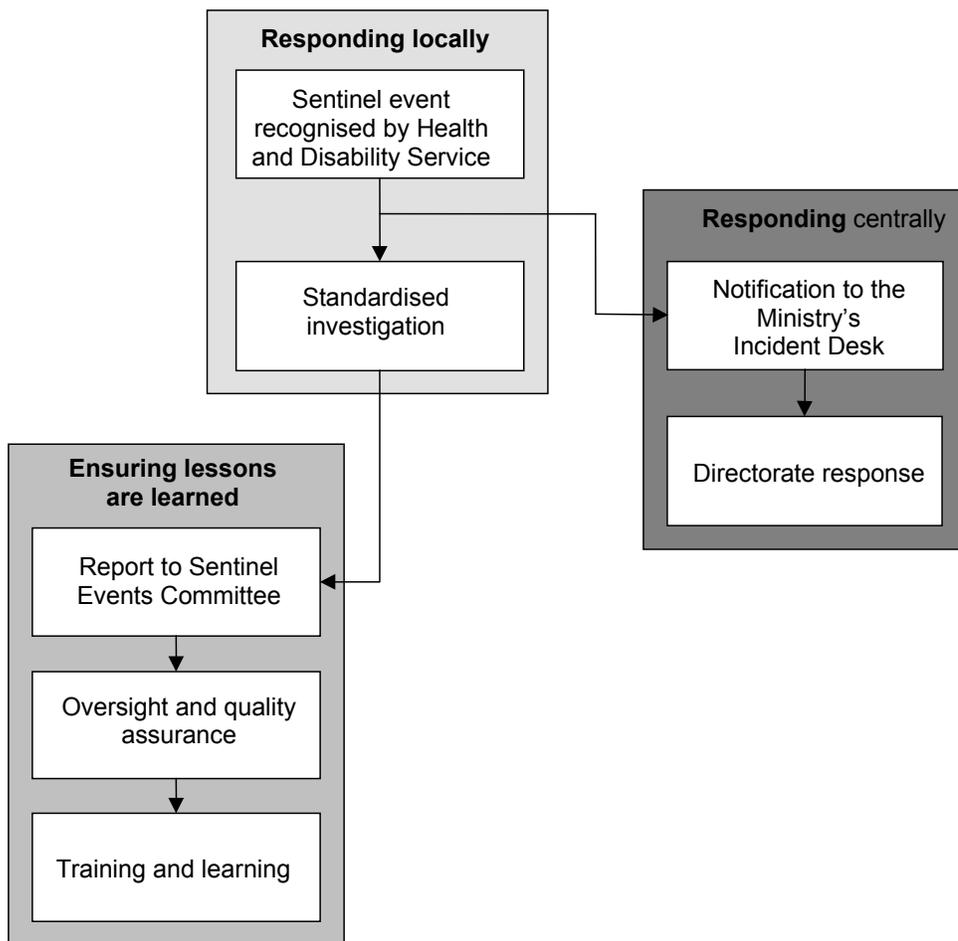
The reporting and learning framework

This report addresses three key areas of activity relating to Sentinel Events. These areas are:

1. the **local response** by health and disability services when an event occurs
2. the **role of the central agency** in reviewing actions of health and disability services and in taking immediate measures to protect the public
3. the role of a central agency in **ensuring lessons are learned** from Sentinel Events, and implementing and monitoring actions at a national level to improve safety for consumers.

Figure 1 presents an overview of this framework; each area of activity is then discussed in more detail.

Figure 1: Three key areas of activity in the reporting and learning framework



The local response to a Sentinel Event

It is generally agreed that when an unexpected, untoward event appears to result from the management of a consumer's care and treatment by health and disability services (rather than from the consumer's condition, illness or disease) the consumer wants to receive an accurate and timely explanation of what has occurred and why. Consumers want an assurance that the chances of a similar event recurring have been eliminated or significantly reduced.

The central agency's response to a Sentinel Event

The Ministry of Health (and, in the past, the Health Funding Authority) has concerns similar to those of the consumer. In its role as regulator, the Ministry of Health is concerned that, for some events, mechanisms exist to review and evaluate the actions of health and disability services in regard to:

- appropriately managing the consumer's ongoing care and treatment
- protecting other consumers at imminent risk of harm.

Its focus is both local, on mechanisms within the reporting service, and national, on mechanisms within like services.

Ensuring lessons are learned

A central agency has a role in reviewing single events, or clusters of events, and in reviewing trends to:

- determine if actions should be taken nationally to improve quality and safety in other health and disability services
- ensure that those actions are implemented and their effectiveness evaluated.

To help maintain confidence in health and disability services, it is necessary to report on these achievements to the Minister of Health, the public, and health and disability services. In this way the benefits of collective action to improve consumer safety can be acknowledged.

The current situation

A range of informal and formal mechanisms exists in each of the three key areas of activity. However, they do not always work in a consistent and co-ordinated manner. There is confusion over responsibilities; some health and disability services and events are more scrutinised than others. Another area of confusion is the threshold for inquiries and investigations. The Working Party understands that the Ministry of Health is working on this issue; the Working Party supports the Ministry's intention to clarify the parameters for the health and disability sector.

The Working Party believes that implementing a Sentinel Events Reporting System will reduce the frequency of Director-General and Ministerial inquiries because health and disability services will gain expertise in investigating events and implementing long-term solutions to improve safety.

Summary

The goal of the Working Party is to improve the ability of health and disability services to respond well to Sentinel Events, so that they analyse any such event and implement corrective action plans. To achieve a consistent response, a central agency should review the health and disability services response against accepted standards, provide feedback, analyse data and ensure that the lessons learned from Sentinel Events can be used nationally to improve safety. In short, the health and disability sector should learn from experience.

Developing the vision of the Working Party

Through its recommendations, the Working Party aims to create an environment within health and disability services that supports and encourages self-learning for the protection of consumers, health care workers, and organisations. This environment will recognise the most common cause of performance problems as the system itself, not the individuals functioning within the system.

Individuals should be disciplined for events only when their performance is negligent. While people on occasion contribute to untoward events, they are just as likely to have prevented some untoward events as they constantly monitor and react to circumstances.

Health care workers do not function in isolation. The root cause of problems leading to Sentinel Events is likely to be found in the design of the system that permitted such an event.

Health and disability services should put their greater energy into redesigning their systems to make them safer, leaving blame and discipline only for truly unacceptable behaviour.

Achieving this environment involves creating just cultures where:

- reporting all events within organisations is the norm
- staff are confident that it is safe to report Sentinel Events externally to enable national learning.

Locally and nationally, a profound culture change is needed. All health care workers from Chief Executives and District Health Boards to the newest employee should feel personal responsibility for consumer safety. The action of discovering and reporting problems, mistakes and close calls should be rewarded, not punished.

To many, this approach opposes a natural human response to blame individuals for harm. However, at some stage during their careers, all health care workers are likely to be involved in untoward events. If the only response is to blame, it is counterproductive. **It is productive to focus on the next consumer** who will be receiving care and treatment from services where there has been an untoward event, and to make systems safer for all those involved.⁴

The Working Party recommendations are intended to contribute to the effective operation of health and disability services. The Sentinel Event Reporting System will complement existing and proposed mechanisms such as the imminent Health and Disability Sector Standard. The draft Standard requires health and disability

services to implement quality and risk management systems, including proactive risk assessment and reactive internal event reporting.

Despite best efforts, health and disability services experience problems and failures. However, it is possible to achieve a system that works well in the sense that:

- effective systems for learning from problems and failures mean that serious failures of standards of care are uncommon
- serious failures do not recur within the affected health and disability services, nor are they repeated in other parts of the country
- systems are in place to minimise the occurrence of serious failures in standards of care
- attention is paid to monitoring and reducing levels of less harmful events⁵
- the need for “crisis response” is reduced and consumer confidence is in greater evidence.

Given effective tools, health and disability services can build their capacity to confidently investigate untoward events within their organisation or practice, minimising the need for crisis response and management by the Ministry of Health. The Ministry of Health’s expertise is more effectively utilised in overseeing the actions of health and disability services and in identifying and acting on the national learning opportunities from single events and from trends.

Through implementation of the Working Party recommendations, the New Zealand health and disability sector stands to gain the following benefits.

- From the data collected, the sector will understand its major risk areas and take long-term measures to reduce the risk to consumers. The high quality learning will influence international best practice.
- Consumers, health care workers, managers and policy advisors will improve safety and quality using a systems approach. The mandatory nature of the Sentinel Events Reporting System will become irrelevant; people and organisations will participate in the process because they can actively contribute to local and national learning.
- By 2005 a substantial number of actions will have been taken to eliminate, isolate or minimise risks to consumers at local and national levels. By 2010 the events reported before 2005 will not recur (or their incidence will have reduced significantly).

In contrast, in failing to implement these recommendations, the New Zealand health and disability sector would:

- ignore the significant support among national professional organisations and health and disability services for this system as one of the strategies to improve the safety and quality of health and disability services
- miss an opportunity to reduce the real risks to consumers from the delivery of health and disability services in an increasingly complex environment

- ignore the chance to provide a supportive environment for health and disability services where problems and failures can be thoroughly investigated and actions implemented to prevent their recurrence. Currently, unless legal privilege is used, any examination of events is accompanied by the risk that the information could be used to assign liability
- lose an opportunity to address the root causes of problems, which are missed through person-focused rather than systems-focused investigations. Short-term fixes that address proximate causes would continue, providing some assurance to the public that prompt action has been taken, but doing little to reduce the risk of recurrence in the long term
- continue to vilify individuals for problems, thereby diverting focus and resources away from root causes. Inevitably, events would recur, eroding public confidence in the safety and quality of health and disability services
- continue to experience the high cost of system failure in higher treatment and/or rehabilitation costs, and increased pressure on acute/rehabilitation beds. Also lost is the opportunity for the consumers involved to contribute fully to New Zealand's economic and social life
- fail to learn from overseas colleagues who are proposing and/or taking measures similar to these proposals. In 2000 the Australian Government instructed the Australian Council for Safety and Quality in Health Care to develop a national framework for adverse event monitoring, management and prevention (including incident monitoring and complaints).⁶ See also United States reports *To Err is Human: building a safer health system*⁷ and *Doing What Counts for Patient Safety: Federal actions to reduce medical errors and their impact*⁸, and *An Organisation with a Memory*⁹ (United Kingdom).

Vision of the Working Party

A Sentinel Event Reporting System, as the Working Party envisages it, will contribute to an environment where serious failures of standards of care will be uncommon. If an instance of such failure occurs, it will not be repeated elsewhere. As a result, consumers will have confidence that health and disability services can actively recognise, manage and learn from Sentinel Events. Moreover, the reduced economic costs of failure will free up resources for service delivery.

There is considerable support among health professionals for a confidential, fair, systems-focused method of investigation and reporting. Now is the time to build on that support.

In summary the Working Party's vision is:

to create an environment, local and nationally, within health and disability services that:

- supports and encourages self-learning from analysing Sentinel Events
- promotes the redesign of systems as the main method for improving safety
- supports a culture where every health care worker takes personal responsibility for consumer safety and where the action of discovering and reporting problems, mistakes and close calls is rewarded, not punished.

Presentation of the recommendations

Individual recommendations of the Working Party, along with the recommended steps to effect them, are given at the end of the section to which they relate. Appendix 4 lists all recommendations.

SECTION 2: THE LOCAL RESPONSE

Consumers state that when a harmful, untoward event appears to be the result of the **management** of a consumer's care or treatment by health and disability services, the consumer wants:

- an accurate and timely explanation of what has occurred and why
- an assurance that the chances of the same event recurring have been eliminated or significantly reduced.

This section describes how health and disability services work to achieve these goals, the problems experienced and possible steps to remedy them.

The current situation

Most organisations expect employees to report any harmful, untoward event through an internal reportable events system (often called incident reporting). Health and disability services monitor and/or minimise its effect on the consumer through observation, testing and/or therapy. The consumer and the family/whānau may be advised and an apology may be made. The consumer may be advised of the factors that contributed to the event and of the actions being taken to prevent recurrence.

Once the immediate situation is stabilised, the organisation's reportable events policy usually requires the manager of the unit involved to conduct an investigation. The manager reports on:

- the remedies that the unit has used, or that the organisation should introduce, to prevent a recurrence
- whether the unit has met mandatory or voluntary reporting requirements (see Appendix 5 for examples).

The external authority investigates the event or requests the health and disability services to conduct an internal investigation, which may involve an independent external element.

Problems with the current system

Event reporting systems rely on the ability of employees to recognise events and then report them according to the organisation's reportable events policy. Information on the effectiveness of event reporting systems within all health and disability services is lacking. However, in a 1999 review of event reporting systems among Hospital and Health Services (HHSs), the Health Funding Authority found the following major problems within most HHSs.¹⁰

- Consumers are not always advised that harmful, untoward events have occurred despite a legal requirement in the Code of Rights for consumers to be informed about matters affecting their care and treatment directly.

- Among HHSs there is a lack of agreement on which events should be fully investigated and which events could be reviewed at a lower level. Within an HHS, there may be no threshold for investigation of consumer-related events.*
- Few investigators have training in root cause analysis, making it more difficult to devise lasting solutions. Because of deficiencies in investigations, it is also difficult to provide accurate information to consumers. Thus explanations are likely to refer to proximal causes only, and apologies may be vague, misplaced or misguided.
- Few HHSs have systems to ensure that recommendations for improvements are referred to those who can decide on implementation. If actions are implemented, project management is insufficient to monitor progress, evaluate effectiveness or identify any new problems the solution may have created.
- External reporting requirements are not centrally co-ordinated. Internally reported events are not automatically flagged to ensure compliance with mandatory reporting requirements.

To help HHSs remedy some of these problems, the Health Funding Authority published the *Reportable Event Guidelines*.¹¹ While copies were distributed to HHSs and are available on request, they have not been made widely available to other health and disability services.

Some of the outstanding issues from the Health Funding Authority review were taken up as part of this Sentinel Events Project. Both parties noted the following points.

- Views differ over the criteria for an internal versus external investigation, leading to varying opinion about whether an investigation has been sufficiently robust.
- For particular events, multiple, unco-ordinated investigations may be conducted concurrently but separately, or in a varying sequence over an extended period. For example, where a death is involved, it is possible that the Coroner, Police, Ministry of Health (and in the past the Health Funding Authority), and Health and Disability Commissioner will conduct investigations.

Discussion

Quality and risk management experts agree that the most common cause of performance problems is the system itself, not the individuals within the system. While a human error may have occurred, the root cause is likely to be in the design of the system that permitted such an event. Health care workers collaborate to deliver health and disability services; they do not function in isolation.

* Legislation sets a threshold for investigating health and safety in employment events; all near misses, incidents and accidents must be investigated.

Multiple factors affect performance as well as decision-making, task prioritisation, and conflict resolution. These factors include:

- personal characteristics, attitudes and qualifications
- the composition of teams
- organisational culture and climate
- physical resources
- the condition of the consumer, which in turn influences the caregiver's activities.

Health and disability services can provide better information to consumers, external authorities, as well as to their own staff, if investigations are conducted consistently and focus on systems, not individuals. An investigation should establish the chain of events and determine the factors contributing to the event under investigation.

This information should be used to develop plans for corrective actions that aim to eliminate, isolate or minimise the effect of the factors that could lead to similar events. After implementation these plans should be monitored for effectiveness.

To be most effective and to enable trending, minimum data sets should be collected, documented and reported. Investigations should begin soon after the event while memories are fresh and where there is interest in addressing the problem immediately.

Deciding what to investigate

In the Working Party's view, health and disability services should always investigate a harmful, untoward event to identify what happened and why, and how it could be prevented from recurring. Thorough investigations take time and health and disability services may not have sufficient resources to investigate all internally reported events. Therefore it would be useful to provide services with a classification model that they can use to set a minimum threshold for investigations. Such a model will help achieve consistency within organisations and could be used to set a threshold throughout the health and disability sector.

The Health and Disability Sector Standard requires health and disability services to have a reporting process for accidents, incidents and adverse clinical events.¹² Existing documentation such as the *Reportable Event Guidelines* will assist health and disability services comply with this standard.

Internal versus external investigation

The question of whether to conduct an internal or external investigation is linked with the issue of multiple inquiries into the same event. The fundamental causes of an event are best determined by the people who were involved in it and who know the systems of the organisation; only they know the factors that contributed significantly to the event. External investigation is suitable for assessing whether health and disability services have performed according to agreed or prescribed standards or legal duty.

In cases where multiple agencies were involved, there appears to be no process for determining which agency should investigate first and how agencies could share information effectively while achieving their own goals. Multiple investigations impose a heavy burden on health and disability services. They require human and financial resources to produce information in the different formats required by each agency and to release staff to speak with investigators. Whether multiple investigations confer multiple benefits is unknown.

Piloting the model and methods

Three public hospitals and one private surgical hospital have indicated a willingness to trial the proposed classification model and investigation methodology before they are finalised and published for general use by health and disability services. Once the model is confirmed, a regional training programme will be needed for health and disability services.

The model proposed by the Working Party has the following benefits:

- it has been used successfully in social and health services in the United States
- it is easy to learn
- it is practical
- it is consistent with methods used in accident investigation by organisations such as the United States Department of Energy.^{13,14}

Recommendations

The Working Party makes the following recommendations to the Director-General of Health.

Recommendation 1

Arrange for policy work to consider rationalising the manner in which the Coroners, Health and Disability Commissioner, Police, district inspectors, Ministry of Health and Minister of Health investigate events within health and disability services. The goal is a framework that is consistent and coherent, and that meets the Government's objectives for improving the quality and safety of health and disability services.¹⁵

Recommendation 2

Develop technical resources and guidelines to help health and disability services to achieve their own robust internal systems of event reporting, and to identify events experienced by consumers that need full investigation. The goal is to establish systems in which the factors that could lead to recurrence are eliminated, isolated or reduced.

To effect this recommendation the Director-General should take the following steps.

- Develop a classification model to help health and disability services prioritise which reported events affecting consumers should be fully investigated internally. (See Appendix 6 for a draft classification model.)
- Develop a systems-focused methodology that health and disability services can use to consistently investigate events that affect consumers' care and treatment and develop action plans to eliminate, isolate, or reduce the significant contributing factors that could lead to similar events occurring. (See Appendix 7 for a worked example of the proposed model.)
- Implement a pilot project to test the classification model and investigations methodology in health and disability services, encompassing large and small, secondary and primary, and public and private settings. One outcome of the pilot should be a resource kit for health and disability services that provides them with relevant information, templates and examples.
- Implement a national learning programme to provide information regionally to health and disability services and work with individual providers to implement the classification model and investigations methodology.
- Make the *Reportable Events Guidelines* available to all health and disability services as an online publication. Have it reviewed annually and updated as necessary.

SECTION 3: THE CENTRAL AGENCY'S RESPONSE

The Working Party believes a central agency has a role in reviewing and evaluating the actions taken by health and disability services after a Sentinel Event. The components of the role are:

- ensure the health or disability service has taken emergency measures to prevent other consumers from imminent harm (if relevant)
- ensure the health or disability service has made appropriate plans to manage the ongoing care and treatment of the consumer(s)
- obtain assurances from the health or disability service that the consumer and emergency management plans have been implemented
- ensure that other health and disability services have taken emergency measures to prevent a similar event.

This section describes the current processes of review by the Ministry of Health, the problems experienced and ways to remedy them.

The current situation

The Ministry of Health provides a limited form of review on a narrow range of events. The mandatory (and voluntary) reporting requirements for health and disability services is provided in Appendix 5.

Once events are reported to the Ministry of Health, there are a variety of processes for responding to health and disability services. The services may be allowed to investigate the event and report back to the Ministry of Health, or the Ministry may conduct its own investigation or contract a third party investigation.

Problems with the current system

Under the existing system, problems relate to confusion over definitions and roles and concerns over confidentiality.

Lack of clear definitions

The events reported to the Ministry of Health cover a small fraction of the events resulting in clinical harm. Because the Health Funding Authority reporting requirement has been widely interpreted, there has been both over- and under-reporting. The trigger for reporting relates more to the ability of health and disability services to continue providing services than to the harm to consumers. Health and disability services are not always clear when issues breach licensing requirements and thus may fail to report. Timeframes for reporting also vary.

In short, there is confusion as to what events should be reported routinely, to whom and when. Because mental health services have a list of events to be reported, they are perceived to be more closely monitored than other services. There are no procedures for ensuring the Ministry of Health is notified of events reported to the Ministry of Commerce.

Roles

When events are reported, there is no agreement as to the expected roles of the health and disability services and the Ministry of Health. That is, it is uncertain who has primary responsibility for conducting the investigation and so on. Delays can result as the health and disability services and Ministry of Health negotiate their roles before each investigation can begin.

If the Ministry of Health takes an active role in the investigation, the status of that involvement is unclear. Each unit of the Ministry of Health handles situations in a different way.

Confidentiality

There is widespread concern in the health and disability sector about the confidentiality and distribution of information provided to the Ministry of Health. There is a high level of awareness that the reports may be required to be released under the Official Information Act 1982 and could be used by consumers to seek liability for events. As a result some health and disability services are reluctant or refuse to provide the Ministry of Health with information. There is evidence that information is withheld because some health and disability services do not assume the Ministry of Health will restrict knowledge about events to only those who “need to know”.

Given the uncertainty as to how the Ministry of Health uses the reported information, compliance with reporting would improve if health and disability services received feedback on their reports. There is a perception that reporting is actually one-sided monitoring; services would prefer an interactive approach where the Ministry of Health might pass on skills or knowledge forthcoming from the event and subsequent reporting.

A related concern is that, now the Ministry of Health has merged with the Health Funding Authority and gained multiple roles, reports could be misused as leverage in contract negotiations.

Discussion

Despite the problems documented above, the Working Party supports the continued role of the Ministry of Health as the central agency responsible for reviewing the response of health and disability services after Sentinel Events. However, the Ministry should expand its current focus and routinely review Sentinel Events regardless of delivery setting. The events reported for review should be clearly defined to avoid misinterpretation, and the reporting based on the severity of harm to the consumer. This approach would alleviate the existing confusion about which events to report.

Several submissions opposed the Ministry of Health’s involvement in reviewing events where staff suffered harm; they clearly stated that this was a concern of the Department of Labour and a misuse of health resources. No submissions opposed mandatory reporting and several actively supported it.

A central agency is required to conduct two types of review:

1. the review of the immediate response of health and disability services and implementation of national emergency measures
2. the review of the investigation report and corrective action plans of health and disability services, and their potential to inform national learning.

The first type of review is the focus of this section. Section 4 covers the second type of review.

The Working Party recommends a clarification of the roles and responsibilities of health and disability services and the Ministry of Health concerning the notification and initial review of events.

The health and disability services is responsible for:

- reporting the facts of the event
- advising what plans have been made to safely manage the ongoing care and treatment of the consumer(s)—ie, to prevent further harm and mitigate the harm caused (if possible)
- advising what emergency measures have been taken (if necessary) to protect other consumers for whom the risk of similar harm is imminent.

The Ministry of Health is responsible for:

- reviewing information about the event, evaluating its appropriateness and providing prompt comment to the health or disability service
- offering advice and support to health and disability services as required, consistent with the expert advice, notice of expert advisors, guidelines, standards, etc currently available from the Ministry
- ensuring that other health or disability services in which consumers may be at imminent risk take emergency measures as required to protect consumers.

Both Ministry of Health and disability and support services are responsible for providing any public assurances that action is being taken because of the event.

The Ministry of Health should have a standardised process (and minimum data set requirements) for receiving reports of Sentinel Events from all health and disability services to a central entry point. It is reasonable to expect that each unit of the Ministry of Health will review events in a similar manner. There is no need to change the current processes for confidentiality of the information provided for this purpose.

Recommendation

The Working Party makes the following recommendation to the Director-General of Health.

Recommendation 3

Implement a national system (to be called the **Sentinel Events Reporting System**) that requires health and disability services to report a defined list of events (to be called **Sentinel Events**) to the Ministry of Health for review.

To effect this recommendation the Director-General should take the following steps.

- Develop a list of Sentinel Events for mandatory notification to the Ministry of Health via the Incident Desk (see Appendix 8 for a recommended list).
- Reconsider the current requirements to report serious harm to staff in events involving mental health services consumers.
- Define the minimum data set to achieve consistent reports to facilitate evaluation and agreement on timeframes for reporting events.
- Stage the implementation of mandatory reporting of Sentinel Events across health and disability services. Begin with public and private hospitals, rest homes and continuing care services. Eventually extend coverage to all health and disability services, as defined in the Health and Disability Services (Safety) Bill.
- Allow health and disability services to report voluntarily on an event that may not meet the Sentinel Event definition if they want the Ministry to oversee an event or the event to be included in the “learning” database.

SECTION 4: ENSURING LESSONS ARE LEARNED

This section addresses the second kind of review by a central agency, the review of the investigation report and corrective action plans of health and disability services, and their potential to inform national learning.

The Working Party believes a central agency has a role in reviewing the investigation report and corrective action plans of health and disability services to:

- ensure they are robust
- request reports showing that the recommended improvements are implemented and evaluated.

Another role is to review the aggregated data from events to determine if actions should be taken nationally to improve quality and safety. If such actions are warranted, the central agency should ensure that those actions are taken and their effectiveness evaluated.

This section describes the Ministry of Health's involvement in these roles, the problems experienced and ways to remedy them.

The current situation

The Ministry of Health's reviews vary in their extent and coverage. Events of a minor and major nature are reported to a wide variety of people within the Ministry. The position or unit that the health or disability service notifies tends to depend upon who is doing the notifying, and with whom they have a primary relationship. Table 1 gives examples of the typical reporting relationships.

Table 1: Examples of reporting relationships between health and disability services and Ministry of Health

Party notifying	Party receiving notice
<i>Health and disability services</i>	→ <i>Ministry</i>
Medical practitioners	→ Chief Medical Advisor
Nurses	→ Chief Nursing Advisor
Mental health services	→ Mental Health Directorate
Chief executives and managers	→ Locality managers
Medical devices	→ Medsafe
Radiation	→ National Radiation Laboratory

Each Ministry position or unit has developed its own methods for managing investigations and protecting future consumers.

Problems with the current system

The Ministry of Health's approach lacks the consistency to determine the purpose of investigations, and thereby to ensure that appropriate investigations are conducted, and to ensure that action plans are implemented and effective.

No consistent data are collected, and events are neither logged nor tracked through a central system. However, there is currently no capacity to analyse all reported events and thus identify trends.

Discussion

In a recent report the United Kingdom National Health Service was said to lack any reliable way of identifying serious lapses of standards of care, analysing them systematically and introducing lasting change that prevents similar events in future.¹⁶ The same could be said of the New Zealand health and disability sector.

The Working Party believes that health and disability services should be required to:

- complete investigations into Sentinel Events and report the results, along with any corrective action plans, to a central agency. The purpose of an investigation should be to identify the root causes or significant contributing factors that led to the event and that, if corrected, would prevent recurrence
- report progress on implementing the action plan through to completion
- provide an evaluation, after an appropriate period, of the intervention's effectiveness.

The forthcoming information should be evaluated to determine if national learning can stem from a single event or from a series of events with similar causes. National learning might result in the development of clinical or management guidelines, changes to policy or legislation, changes to credentialing processes, and so on. To implement the national learning activities, priorities should be set and agreements sought with appropriate agencies.

From the consultation for this report, from the Working Party's experience and from the international literature, it is apparent that health and disability services in New Zealand will only provide the desirable level of information if:

- legal protection is provided to those involved in the reporting
- they have an assurance that the information will be used to improve safety nationally (and therefore producing some "reward" for the effort of reporting)
- the information is evaluated by an independent group of people with diverse skills and knowledge, eg, in clinical experience, human factors theory, organisational learning and risk analysis.

Discussed here are key components to this environment: ensuring confidentiality and privacy, providing appropriate reward for participating in investigations, ensuring the central agency operates at arms length, resolving the question of

whether to report only Sentinel Events or all close calls, and taking a broad, collective approach to national learning.

Confidentiality

Confidentiality is widely seen as a prerequisite for effective reporting. Richard Croteau, from the United States Joint Commission on Accreditation of Healthcare Organisations (JCAHO), strongly reinforced this view when he spoke to the Ministry of Health and Health Funding Authority staff in November 2000. For a long time the United States health sector has recognised that quality improvement and/or risk management activities are severely compromised if the people involved with events believe they face legal risk by participating.

The New Zealand health and disability sector is not immune from this association. Hospital managers report that insurers and indemnifiers often advise their health professional members not to co-operate with internal inquiries because such information may become available for use in legal action. Doctors in particular have failed to report incidents through public hospital systems because of the lack of legal protection.

Among those who expressed support for a national system of event reporting and learning, most predicated their support on the assurance of confidentiality for participating organisations and individuals. They will not participate in the system if the investigation reports are published, as they believe that publication could allow their organisation or the consumer to be identified even though they are not named.

The Working Party believes the need to publish an investigation report would never arise. Instead, what should be reported is the number of reports received, some aggregated data about demographic and other trends, and progress reports on the implementation of local and national action plans.

While acknowledging the above concerns in health and disability services, some members of the Working Party foresee that health and disability services may want to provide some information from local investigations to other inquiries such as those of the Health and Disability Commissioner, Coroner and Police.

The Working Party acknowledges the tension involved in resolving this issue. On the one hand is the need to provide confidentiality to encourage the receipt of full and frank information from health and disability services; on the other hand is the wish to assure the public that in return for legal protection of the information, action will be taken to improve the safety and quality of systems. The desired protection is similar to the protection offered in the civil aviation industry. Health professionals still remember how Police were able to access information provided to a mortality committee; they would not want to experience a similar situation.

The Working Party believes that giving legal protection to information created for Sentinel Event reporting does not remove any rights of consumers who suffer a Sentinel Event. They are able to complain about registered health professionals to the relevant disciplinary bodies, and about individuals or organisations to the Health and Disability Commissioner. Coroners' inquiries and Accident Compensation Corporation (ACC) claims will continue as before. Moreover, the Protected Disclosures Act 2000 offers a new safeguard; any employee who

believes a serious wrongdoing is not being addressed can disclose that concern according to the organisation's procedures and the Act.

While the Working Party has indicated the areas where protection is needed, it has been unable to fully determine the types of information that should be kept confidential. To some degree, the specific types depend on the outcome from the implementation of Recommendation 1 of this report.

Privacy

Additional concerns relate to privacy. Information about an individual consumer's care and treatment, and the health care workers involved, will be used in the investigation.

In terms of personal (and health) information, the Working Party believes there is no need for the central agency to know the names of the consumers or health professionals involved in an event. As the documentation should focus on systems, not individuals, it is anticipated that individuals would be mentioned in terms of their position or relationship (eg, child, consumer, doctor, manager, nurse, orderly, parent, physiotherapist). If the documentation produced by the health and disability services is protected, then it cannot be connected to a person or organisation.

However, to properly evaluate its reports, the independent entity reviewing the information will need to know the name of the health or disability service.

Rewards for participation

Several submissions outlined health professionals' suspicions that information reported would gain no subsequent benefit. Using information to inform national safety and quality activities would confer professional satisfaction. Professionals would want direct feedback that the information was useful in determining whether national learning was possible.

Arms-length central agency

In the view of many health and disability services, the Ministry of Health is unsatisfactory as a recipient of the results of investigations, the action plans and so on within the Sentinel Event Reporting System. Their reasoning is that the Ministry now has multiple roles, leading to perceived conflicts of interest. They are concerned, for instance, that information provided through the Sentinel Event Reporting System will be used in contract/funding negotiations. Neither do services want information about individual events passed on to Sector Funding and Performance.

Thus health and disability services see a need for an arms-length central agency to oversee the Sentinel Events Reporting System. For example, a Ministerial Advisory Committee might be established; the Committee would have or could co-opt appropriate expertise to improve clinical processes and systems.

Reporting Sentinel Events versus close calls

The two main approaches to event reporting are:

1. to report Sentinel Events according to the severity of harm to the consumer
2. to report all events, that is, close calls, incidents and accidents for analysis and trending, with specific actions for severe events.

James Reason, on a recent visit to New Zealand, summarised the properties of different types of events as indicated in table 2.¹⁷ While a specific incident may have a large chance component, many of its causal elements recur and are thus amenable to change.

Table 2: Event properties

Type of event	Volume	Costs	Contextual information*
Close calls and incidents	Moderate to high	Low to moderate	Moderate to high
Accidents	Very low	Unacceptably high	Often very high

Note: * Information that can be used for identifying upstream causal influences.

The Working Party recognises that learning may come from analysis of close calls, incidents and accidents. In several written submissions and during meetings with health professionals, there was support for a national incident reporting system similar to that operated by the Australian Patient Safety Foundation. Others commented that they would support Sentinel Event reporting only as a precursor to a more extensive reporting strategy.

The Working Party has not considered in depth the issues relating to implementation of a nationwide system of reporting close calls and incidents. After taking advice from the Civil Aviation Authority, international experts and others, it is convinced that New Zealand should begin by analysing the events in the “accident” category—that is, Sentinel Events—as there is much to be gained from this approach.

A broad approach to national learning

With the Working Party unable to ascertain how the mortality committees would relate to the Sentinel Events Committee, more work needs to be done in this area. The mortality committees will be notified of all maternal, child and peri-operative deaths. Of this group, a subset will meet the Sentinel Events definition—that is, they will be deaths in health and disability services resulting from health care management, not the consumer’s condition, illness or disease.

Although the Working Party does not know what methodologies the mortality committees will be using, it should be possible for those committees to expertly review Sentinel Events in their areas of expertise and still contribute to the Sentinel Events Committee’s database. Also as yet unknown are the activities of the national epidemiology and quality assurance committee, as knowledge about this committee came too late to consider its implications for this project.

Lack of data is a major problem in identifying high-risk areas for action and in measuring the impact of system improvements. The Working Party believe some existing data are not being used in a way that will improve safety. The organisations identified as holding data include the Ministry of Health, ACC Medical Misadventure Unit, Health and Disability Commissioner, New Zealand Health Information Service and health professionals' disciplinary bodies. If these organisations could collectively analyse their data, it might be possible to agree on priorities for national learning.

Recommendation

The Working Party makes the following recommendation to the Director-General of Health.

Recommendation 4

Advise the Minister of Health to establish an independent group (to be called the **Sentinel Events Committee**) with the status of a Ministerial Advisory Committee* for an initial period of five years. Its purpose will be to lead national efforts to make systemic improvements in the safety and quality of health and disability services in New Zealand, with a particular emphasis on eliminating, isolating and minimising the likelihood and effects of system failure.

To give effect to this recommendation the Director-General should take the following steps.

- Consider establishing the Sentinel Events Committee as a subcommittee of the National Health Epidemiology and Quality Assurance Advisory Committee being established under the New Zealand Public Health and Disability Act 2000. (Notice of this committee's establishment came too late to consider its relationship with the proposed committee.)
- Extend the Sentinel Events Reporting System (Recommendation 3) to require health and disability services to send to a central agency for review:
 - copies of the investigation reports from Sentinel Events
 - any subsequent corrective action plans
 - a report advising completed implementation of the action plan
 - a report evaluating the effectiveness of the corrective actions.Timeframes for receiving and responding to the information should also be agreed.
- Define the minimum data set for each report and action plan. Action plans will eliminate, isolate or minimise the significant factors in or causes of the event.

* See Appendix 9 for draft Terms of Reference.

- Allow health and disability services to voluntarily report events not defined as Sentinel Events so that the learning opportunities are enhanced. These events may differ from those identified in Section 3 as voluntarily reported to the Ministry of Health.
- Develop a database that will enable the information from health and disability services to be analysed for trends.
- Implement the Sentinel Events Reporting System in legislation and provide legal protection to the information from health and disability services to the Sentinel Events Committee. In developing the legislation, consider whether to make available penalties for failing to provide information to the Sentinel Events Committee or for breaching confidentiality provisions.
- Undertake policy work to devise a generic and ethical framework for determining an acceptable level of risk. The Sentinel Events Committee will need a methodology to determine when national learning actions should be undertaken and to use in recommending priorities.
- Require the Sentinel Events Committee to widely disseminate information about its activities, undertake educational activities as required and publish an annual report of its activities to the Minister of Health.
- Receive from the Sentinel Events Committee, within three years of its establishment, a report advising how a national system of close calls reporting could be implemented.
- Provide support to the Sentinel Events Committee via a secretariat based in the Ministry of Health.
- Undertake work to determine how the Sentinel Events Committee and mortality committees (peri-operative, maternal and child) should interact to maximise learning and prevent duplication.
- Task the Sentinel Events Committee with collaborating with other agencies to identify priority areas for improving safety and propose national action strategies. Initially, it is suggested that agencies to approach should include the Health and Disability Commissioner, ACC Medical Misadventure Unit, the Coroners' Council, and the Australian Council for Safety and Quality in Health Care.

SECTION 5: FISCAL AND SOCIO-ECONOMIC IMPACT

This section focuses on costs at two levels: fiscal and socio-economic costs as they relate to Sentinel Events themselves and as they relate to the proposed Sentinel Events Reporting System.

The cost of Sentinel Events

Many difficulties are associated with the process of identifying the incidence and economic impact of harmful events, even at the severe end of the scale where these events cause permanent disability and death. Although the Working Party tried to find equivalent New Zealand data to those in a United Kingdom report,¹⁸ such data are not collected, unreliable or not kept in a readily obtainable form.

Therefore, to demonstrate the impact of harmful untoward events in New Zealand, the Working Party extrapolated the findings from the Harvard Medical Practice Study and Australian Quality in Health Care Study to the New Zealand situation. The results are shown in tables 3 and 4.¹⁹ The New Zealand figures are based on 727,342 discharges from public hospitals in the 1999/2000 financial year. In calculating the economic cost of deaths the commonly accepted figure of \$600,000 was used. For simplicity \$600,000 was also used to represent the cost of permanent disability, although the Working Party is aware that costs could be higher.

Table 3: United States research into adverse events in hospitals

Event	Harvard Medical Practice Study, 1999	New Zealand extrapolation	Economic impact & financial cost
Inpatient episodes leading to harmful adverse events	3.7%	26,912	
Subset of episodes resulting in permanent disability or death	16.2%	4360*	\$2,616,000,000

Note: * It is emphasised that adverse events are not always a causal or contributory factor in these cases.

Source: Department of Health (2000) *Organisation with a Memory*.

Table 4: Australian research into adverse events in hospitals

Event	Australian Quality in Health Care Study, 1995	New Zealand extrapolation	Economic impact & financial cost
Inpatient episodes leading to harmful adverse events	16.6% (50% preventable)	120,739	
Subset of episodes resulting in permanent disability or death	3%	3622*	\$2,173,200,000

Note: * It is emphasised that adverse events are not always a causal or contributory factor in these cases.

Source: Department of Health (2000) *Organisation with a Memory*.

There is another way to gain an impression of how often mistakes occur. Although the New Zealand public's level of confidence in the health and disability sector is unknown, it could be expected to be similar to that in the United States where the 46 percent of those surveyed in 2000 reported that they or a close friend or relative had experienced a medical mistake.²⁰ A similar 1997 poll found 42 percent in this category.²¹ The cost in terms of loss of confidence in health and disability services cannot be estimated readily.

Also relevant in estimating fiscal impact are the costs of major inquiries, of which New Zealand has had several in the last 10 years. For example, the Gisborne inquiry is considered to have cost in excess of \$6 million.

The Working Party has made the following assumptions to help estimate the benefit of a Sentinel Event Reporting System.

1. The cost of inquiries into major events is unproductive in the long term. Money would be better spent on preventing recurrence of Sentinel Events.
2. The average length of stay in hospitals and the cost of inpatient admissions will fall as consumers experience fewer adverse effects from their care and treatment. As the Harvard study and similar studies have identified, where surgical patients experience avoidable adverse events, their hospital stay is extended by 2.5 days on average. Based on the figures from tables 3 and 4 and conservatively estimating that one-third of those patients are surgical patients, approximately 3190 additional bed days in New Zealand public hospitals may be attributed to adverse events.
3. Greater effectiveness will release funds for service delivery.
4. As the reporting climate improves the health and disability sector may get more innovation in service delivery and encourage health professionals to remain within and be attracted to the public health sector.

The cost of a Sentinel Event Reporting System

Although it is difficult to calculate the costs of the system, estimated here are the resources required for the Sentinel Events Committee based on sample figures given to the Working Party. These resources include:

- \$11,200 for an eight-member committee to attend four one-day meetings a year, at \$350 per member per day
- \$11,200 in paid preparation time for each committee member
- the cost of a secretariat comprising one full-time person working within the Ministry of Health.

Health and disability services will need to devote additional resources to setting up robust internal systems to comply with the Sentinel Event Reporting System. However, the United States experience is that after initial set-up costs, substantial benefits are gained in terms of quality improvement and subsequent cost reduction.

SECTION 6: CONCLUSION

This concluding section identifies the features of an effective reporting system, along with lessons to be learned from overseas experience, before concluding with a final recommendation.

Effectiveness of reporting systems

Reporting systems are effective within a safety culture, defined as a process of collective learning and constant and active awareness of the potential for harm. It is said that the four components to a safety culture are:

1. a **reporting** culture where people are prepared to report mistakes
2. a **just** culture where an atmosphere of trust encourages people to provide safety-related information, while there is not a total absence of blame and there is a clear line between acceptable and unacceptable behaviours
3. a **flexible** culture that respects the attributes of front-line staff and allows control to pass to task experts on the spot
4. a **learning** culture where there is willingness to draw appropriate conclusions from the safety information system and to implement major change when indicated.²²

During this project, the Working Party has debated the volume of Sentinel Events likely to be reported. All reporting systems suffer from under-reporting if the goal is to capture all events. Nor is reporting the only source of useful information. For example, although the United Kingdom's National Confidential Inquiry into Suicide and Homicide by People with Mental Illness offered confidentiality, its reporting rates were only around 15 percent for suicide until it was redesigned to draw on other sources of information for the initial identification of relevant incidents. Clinical information is now collected on 92 percent of relevant suicides and 93 percent of relevant homicides.²³

Thus it is correct that more events will be found through observing clinical practice or reviewing clinical records²⁴ and those strategies remain available for intensive investigation of high-risk areas. However, analysis of even one complex event can lead to major improvement where the root causes have generic application.²⁵ Therefore concerns about under-reporting are not necessarily problematic as reporting of only a few Sentinel Events may improve safety. Under-reporting caused by an inability to detect events may be a problem until clinical audit systems improve.

Lessons from overseas experience

We believe our approach and recommendations are consistent with international activities. Australia, the United Kingdom and the United States are looking to implement generic national event reporting systems.^{26,27,28} Working Party recommendations have drawn on the experience of other countries. Key features of effective overseas systems appear to be that:

- reporting requirements must be properly specified to encourage reporting

- data must be used to make broad system improvements and communicated effectively to health and disability services.²⁹

A brief review of the systems in the United States and United Kingdom follows.

Experience in the United States

The Commonwealth of Massachusetts Board of Registration in Medicine requires reporting of major events, and evaluates the response of health and disability services to the event. The response must include a thorough investigation and, when appropriate, implementation of steps to reduce the likelihood of recurrence. Reports are confidential and never used to discipline doctors. The Board may request further information if unsatisfied with reports.

The requirement for quarterly reporting ensures the Board's role is restricted to overseeing the performance of health and disability services, rather than involving the immediate management of the event. The Board issues recommendations and guidelines if reports reveal an issue that needs broad attention. Although it does not monitor whether the advice has been taken, it can prevent doctors from practising in facilities that do not have effective quality improvement programmes.³⁰

The Board has gained the trust of hospitals.³¹ Eminent writers comment that it seems to work though its full potential has not been realised due to lack of funds.³²

In the United States, the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) accredits hospitals; membership is voluntary, as is the requirement to report Sentinel Events against specified criteria. However, if members withhold reports and the event comes to JCAHO's attention, a root cause analysis report and corrective action plan is requested. The purpose of reporting is to share lessons learned with colleagues nationally.³³ The confidentiality promised by JCAHO is being legally tested on a state-by-state basis; uncertainty in this regard is one major obstacle to the programme's success.

If trends become apparent, JCAHO alerts or distributes recommendations to members. JCAHO reports that no deaths from misadministration of intravenous potassium have occurred within member hospitals since they issued a recommendation that potassium chloride be removed from wards.³⁴

The impetus for change in United States came from a non-governmental source. In 1991 the "Harvard study" identified that adverse events occurred in 3.7 percent of hospital admissions; of these adverse events, 13.6 percent led to death. Over 50 percent of adverse events resulted from medical error and were preventable.³⁵ Little action was taken to address this problem until 1999 when the Institute of Medicine (IOM) released a major report laying out a national agenda for achieving a threshold improvement in quality over the next 10 years.

Among its recommendations IOM proposed legally protected mandatory event reporting to identify and learn from errors. Reporting was to be to a federal agency, with the aim of continuing to make the system safer for consumers. IOM wants to create safety systems inside health care organisations through the

implementation of safe practices at the delivery level.³⁶ It regarded confidentiality of reported information as critical to success.

Next the United States President directed the Quality Interagency Coordination Task Force (QuIC) to evaluate IOM's recommendations and respond with a strategy. QuIC accepted and/or extended all recommendations and proposed implementation plans.³⁷ As a result, the Clinton administration proposed that a mandatory reporting system be created within three years and that electronic medication prescribing be introduced into Veterans' Administration hospitals. However, passage of the Bills into legislation has stalled.

Experience in the United Kingdom

The United Kingdom requires mandatory reporting of peri-operative deaths, maternal deaths, stillbirths, deaths in infancy, and suicides and homicides by people with mental illness. Data are confidential and committees analysing data draw on the range of events they examine. Committees make safety recommendations. However, implementation of these recommendations is voluntary. It appears that those recommendations requiring marked changes to clinical practice are least likely to be implemented.³⁸

It is critical, therefore, that when the Sentinel Events Committee recommends national learning activities be implemented in New Zealand, systems are in place to ensure they occur.

A new event reporting scheme recommended for the United Kingdom's National Health Service will cover events experienced by all consumers of publicly funded services (whether treated in a public or private setting). It will be administered by an independent body that National Health Service employees perceive as neutral. Until local reporting systems and cultures are sufficiently robust and non-punitive, an alternative "whistle blowing" system, for use only in exceptional circumstances, will operate at a regional and national level.

Other recommendations include encouraging frank self-appraisal within a culture of blame-free assessment. A single overall system for analysing and disseminating lessons from events is proposed. A central system will:

- categorise events consistently,
- enable identification of common factors or causes through analysis
- determine the actions necessary to reduce risks to future consumers
- ensure feedback is given in a way that encourages reporting.

Attention will be paid to identifying trends and setting targets to reduce identified problem areas. The Commission for Health Improvement will monitor uptake of recommendations.³⁹

Critical steps in implementation

We asked James Reason to identify the critical steps involved if New Zealand was to implement a Sentinel Events Reporting System. He gave the following advice.

1. Start.

2. Start slowly.
3. Collect data.

The Working Party believes that by starting with Sentinel Events and learning to use the Sentinel Event Reporting System, the health and disability sector can improve the safety and quality of its services for consumers. As trust in the system grows and health and disability services learn to recognise Sentinel Events, the Working Party anticipates that the level of reporting will gradually increase.

Recommendation

The Working Party makes the following recommendation to the Director-General of Health.

Recommendation 5

Release a version of this report for public information and comment.

APPENDICES

APPENDIX I: WORKING PARTY TERMS OF REFERENCE

The initial Terms of Reference were developed and accepted by the Health Funding Authority and the Ministry of Health. They were later slightly revised at the first meeting of the Sentinel Events Project Working Party. The main purpose of the Working Party was to make recommendations to the Director-General of Health on the feasibility of implementing a mandatory event reporting system for health and disability services. Its tasks are listed below.

1. Develop a framework for the reporting of adverse events or near misses occurring as part of the delivery of health care services.
2. Ensure the Working Party's deliberations take into account the requirements of the Health and Disability Sector (Safety) Bill and the associated Health and Disability Sector Standard.
3. Develop a systematic process for the analysis of reported events.
4. Determine the types of reported information that should be kept confidential in any proposed system.
5. Identify matters that would require resolution before a national reporting system could be implemented.
6. Identify the cost and benefits of implementing a reporting system compared to other approaches.
7. Advise upon the implications of not proceeding with a reporting system.
8. Consider processes for pilot testing and implementation, including describing the education and support requirements.
9. Consider any other matters that will contribute to informed debate on a national event reporting system.
10. Work with project leaders and the project co-ordinator to produce a discussion document (with recommendations) for consultation throughout the sector.

APPENDIX 2: SENTINEL EVENTS PROJECT WORKING PARTY

Project leaders

Dr Bob Boyd, Chairperson, Chief Advisor, Safety and Regulation, Ministry of Health

Gillian Bohm, Quality Improvement Analyst, Service Strategy, Health Funding Authority

Project co-ordinator

Leanne Arker, RMC (NZ) Limited

Working party members

Chris Fabling, Audit New Zealand

Dr Barry McGuinness, Partner, Aotea Hospital Johnsonville; nominated representative of New Zealand Private Hospitals Association

Dr Maree Leonard, Medical Officer of Health; Chief Medical Officer, Nelson; Hospital and Health Services Chief Medical Advisors Group

Grant Goodman, Manager, Quality and Risk Management, Taranaki Healthcare Limited; nominated representative of the Hospital and Health Services Risk Managers' Group

Jocelyn Peach, Director of Nursing and Midwifery, Quality Facilitator, Waitemata Health; member of the New Zealand Nurse Executives Group

Katharine Greig, Chief Legal Advisor, Health and Disability Commissioner

Professor Stephan Schug, Faculty of Medicine and Health Sciences; principal investigator of the New Zealand Quality on Health Care Study

Ron Law, Lecturer, Management and Employment Relations Group, Auckland University of Technology

APPENDIX 3: SUBMISSIONS

Submissions were received from the following individuals and organisations.

Organisations

Association of Salaried Medical Specialists

Auckland Healthcare

Australian and New Zealand College of Anaesthetists; New Zealand National Committee

Canterbury Health

Family Planning Association of New Zealand

Fielding Community Health Group

Health and Disability Commissioner

Health Consumer Service Trust

Health Waikato

Healthcare Otago

MidCentral Health

National Advisory Committee on Health and Disability

National Council of Women, Auckland Branch

New Zealand College of Midwives

New Zealand Institute of Medical Radiation Technology Inc

New Zealand Medical Association

New Zealand Nurses Organisation

New Zealand Society of Anaesthetists

Quality Health New Zealand, Te Taumata Hauora

Royal Australasian College of Physicians

Royal Australasian College of Surgeons

South Auckland Health; Chief Medical Officers and Clinical Directors

Southern Health

The Royal New Zealand College of General Practitioners

Wairarapa Health

Wakefield Hospital

Individuals

Dr M G (Wendy) Anderson

David Hamer, i-Management NZ Limited

Dr Jeremy G Jones, c/- Queen Elizabeth Hospital

Professor Iain Martin, South Auckland Clinical School, The University of Auckland

John Morton, c/- RMO Unit, Christchurch Hospital, Canterbury Health

Dr Kevin Smidt, Clinical Director, Medical Imaging, MidCentral Health

APPENDIX 4: RECOMMENDATIONS

The Working Party makes the following recommendations to the Director-General of Health.

Recommendation 1

Arrange for policy work to consider rationalising the manner in which the Coroners, Health and Disability Commissioner, Police, district inspectors, Ministry of Health and Minister of Health investigate events within health and disability services. The goal is a framework that is consistent and coherent, and that meets the Government's objectives for improving the quality and safety of health and disability services.⁴⁰

Recommendation 2

Develop technical resources and guidelines to help health and disability services to achieve their own robust internal systems of event reporting, and to identify events experienced by consumers that need full investigation. The goal is to establish systems in which the factors that could lead to recurrence are eliminated, isolated or reduced.

To effect this recommendation the Director-General should take the following steps.

- Develop a classification model to help health and disability services prioritise which reported events affecting consumers should be fully investigated internally. (See Appendix 6 for a draft classification model.)
- Develop a systems-focused methodology that health and disability services can use to consistently investigate events that affect consumers' care and treatment and develop action plans to eliminate, isolate, or reduce the significant contributing factors that could lead to similar events occurring. (See Appendix 7 for a worked example of the proposed model.)
- Implement a pilot project to test the classification model and investigations methodology in health and disability services, encompassing large and small, secondary and primary, and public and private settings. One outcome of the pilot should be a resource kit for health and disability services that provides them with relevant information, templates and examples.
- Implement a national learning programme to provide information regionally to health and disability services and work with individual providers to implement the classification model and investigations methodology.
- Make the *Reportable Events Guidelines* available to all health and disability services as an online publication. Have it reviewed annually and updated as necessary.

Recommendation 3

Implement a national system (to be called the **Sentinel Events Reporting System**) that requires health and disability services to

report a defined list of events (to be called **Sentinel Events**) to the Ministry of Health for review.

To effect this recommendation the Director-General should take the following steps.

- Develop a list of Sentinel Events for mandatory notification to the Ministry of Health via the Incident Desk (see Appendix 8 for a recommended list).
- Reconsider the current requirements to report serious harm to staff in events involving mental health services consumers.
- Define the minimum data set to achieve consistent reports to facilitate evaluation and agreement on timeframes for reporting events.
- Stage the implementation of mandatory reporting of Sentinel Events across health and disability services. Begin with public and private hospitals, rest homes and continuing care services. Eventually extend coverage to all health and disability services, as defined in the Health and Disability Services (Safety) Bill.
- Allow health and disability services to report voluntarily on an event that may not meet the Sentinel Event definition if they want the Ministry to oversee an event or the event to be included in the “learning” database.

Recommendation 4

Advise the Minister of Health to establish an independent group (to be called the **Sentinel Events Committee**) with the status of a Ministerial Advisory Committee[†] for an initial period of five years. Its purpose will be to lead national efforts to make systemic improvements in the safety and quality of health and disability services in New Zealand, with a particular emphasis on eliminating, isolating and minimising the likelihood and effects of system failure.

To give effect to this recommendation the Director-General should take the following steps.

- Consider establishing the Sentinel Events Committee as a subcommittee of the National Health Epidemiology and Quality Assurance Advisory Committee being established under the New Zealand Public Health and Disability Act 2000. (Notice of this committee’s establishment came too late to consider its relationship with the proposed committee.)
- Extend the Sentinel Events Reporting System (Recommendation 3) to require health and disability services to send to a central agency for review:
 - copies of the investigation reports from Sentinel Events
 - any subsequent corrective action plans
 - a report advising completed implementation of the action plan

[†] See Appendix 9 for draft Terms of Reference.

– a report evaluating the effectiveness of the corrective actions.

Timeframes for receiving and responding to the information should also be agreed.

- Define the minimum data set for each report and action plan. Action plans will eliminate, isolate or minimise the significant factors in or causes of the event.
- Allow health and disability services to voluntarily report events not defined as Sentinel Events so that the learning opportunities are enhanced. These events may differ from those identified in Section 3 as voluntarily reported to the Ministry of Health.
- Develop a database that will enable the information from health and disability services to be analysed for trends.
- Implement the Sentinel Events Reporting System in legislation and provide legal protection to the information from health and disability services to the Sentinel Events Committee. In developing the legislation, consider whether to make available penalties for failing to provide information to the Sentinel Events Committee or for breaching confidentiality provisions.
- Undertake policy work to devise a generic and ethical framework for determining an acceptable level of risk. The Sentinel Events Committee will need a methodology to determine when national learning actions should be undertaken and to use in recommending priorities.
- Require the Sentinel Events Committee to widely disseminate information about its activities, undertake educational activities as required and publish an annual report of its activities to the Minister of Health.
- Receive from the Sentinel Events Committee, within three years of its establishment, a report advising how a national system of close calls reporting could be implemented.
- Provide support to the Sentinel Events Committee via a secretariat based in the Ministry of Health.
- Undertake work to determine how the Sentinel Events Committee and mortality committees (peri-operative, maternal and child) should interact to maximise learning and prevent duplication.
- Task the Sentinel Events Committee with collaborating with other agencies to identify priority areas for improving safety and propose national action strategies. Initially, it is suggested that agencies to approach should include the Health and Disability Commissioner, ACC Medical Misadventure Unit, the Coroners' Council, and the Australian Council for Safety and Quality in Health Care.

Recommendation 5

Release a version of this report for public information and comment.

APPENDIX 5: CURRENT REPORTING REQUIREMENTS—MANDATORY AND VOLUNTARY

Health and disability services undertake a wide range of external event reporting on a mandatory or voluntary basis. These requirements are partly prescribed by legislation, partly required by contract, and partly undertaken as part of health care professionals' routine quality improvement and risk management.

Tables 5 and 6 record some but not all events that relate to the safety of services. If the recommendations of this report are accepted, there may be an opportunity to streamline notification, investigation and analysis of some of these events. There may also be opportunities, through the Learning Committee, for prioritising the development and implementation of corrective action plans.

Table 5: Events and destination for mandatory reporting

Events for which reporting is mandatory	Position or body to receive report
Breach of hospital licensing requirements	Ministry of Health— Manager, Licensing
Misadministration of radioactive materials	Ministry of Health—National Radiation Laboratory
Suicide, unexpected or sudden death, serious injury involving staff, serious injury involving another client, absence without leave of a client who may be seen as a danger to themselves or others	Ministry of Health—Director- General of Mental Health
<ul style="list-style-type: none"> • Significant risks • Significant issues (including those that could reasonably be considered to have high media or public interest) • Date conformity issues which materially reduce or affect, or are most likely to materially reduce or affect, the ability of [the provider] to meet [their] obligations under the agreement	Health Funding Authority
Events relating to the safety of electrical equipment	Ministry of Commerce— Chief Electrical Engineer
Gas accidents	Ministry of Commerce— Chief Gas Engineer
<ul style="list-style-type: none"> • Every death that appears to have been without known cause, suicide or unnatural or violent • Every death in which no doctor has given a certificate under section 25 of the Births, Deaths Registration Act 1951 • Every death that occurred while the person concerned was undergoing a medical, surgical, or dental operation or procedure or some similar operation or procedure; or that appears to have been a result of any such operation or procedure; or that appears to have been a result of the administration to the person of an anaesthetic • The death of any patient detained in an institution pursuant to an order under section 9 of the Alcoholism and Drug Addiction Act 1966 • The death of any child or young person in an institution or residence established under children and young persons legislation • The death of any special patient or patient under compulsory treatment under the Mental Health Act 1992 and amendments 	Coroner

Table 6: Events and destination for voluntary reporting

Events for which reporting is voluntary	Position or body to receive report
Perceived professional misconduct, disability or incompetence	Occupational regulation bodies eg, nursing and medical councils
Adverse medications reactions	Centre for Adverse Reactions Monitoring
Events related to the use of medical devices	Ministry of Health—Medsafe
Suspected occurrence of child abuse	Child, Youth and Family, Police
Breaches of the Code of Rights	Health and Disability Commissioner

APPENDIX 6: PROPOSED CLASSIFICATION FOR CONSUMER-RELATED EVENTS

The classification outlined in table 7 is an example of one method that health and disability services could use to determine when full investigations of internally reported events will be undertaken. It is a categorisation for consumer-related events only.*

Health and disability services may wish to start by **requiring** investigations of a limited number of categories, such as A, B and C. As the incidence of those events decreases, health and disability services may increase the categories **requiring** full investigations to include Category D and/or E.

At all times, discretion should be given to employees to fully investigate any event where they believe benefits can be gained. An example is when a procedure is almost undertaken on the wrong side or wrong body part of a consumer but the error is averted and the correct procedure is performed. This event would fit in Category H. However, if the mistaken procedure occurs, it would be a Category C event, warranting a full investigation.

Table 7: Classification model

Category	Type of event	Some examples
A	Event resulted in death	
B	Event resulted in near death	<ul style="list-style-type: none"> • Anaphylaxis • Cardiac arrest
C	Event resulted in permanent discomfort, infection, pain or harm	<ul style="list-style-type: none"> • Deafness caused by overdose of Gentamicin • Iatrogenic harm to the spinal cord secondary to intrathecal injection/lumbar puncture etc • Removal of body part after incorrect histopathological diagnosis
D	Event resulted in initial hospitalisation, or prolonged hospitalisation and caused the consumer to experience temporary discomfort, infection, pain or harm	<ul style="list-style-type: none"> • Untreated infection • Failure to diagnose all fractures following an MVA – leads to a return to theatre after initial surgery to treat the fractures detected at admission
E	Event resulted in the need for treatment or intervention. The consumer may have experienced temporary discomfort, infection, pain or harm	<ul style="list-style-type: none"> • Transfusion of incompatible blood • Skin damage from plaster casts
F	Event resulted in the need for increased monitoring of the	<ul style="list-style-type: none"> • IV fluids administered too quickly

* The Health and Safety in Employment Act 1992 requires full investigation of **all** near misses, incidents and accidents that relate to the safety of the workplace for employees, contractors, and visitors.

	consumer's condition but did not cause the consumer discomfort, infection, pain or harm	<ul style="list-style-type: none"> • Higher than prescribed dose of diuretics
G	Event reached the consumer but did not cause the consumer discomfort, infection, pain, or harm	<ul style="list-style-type: none"> • Extra IV dose of antibiotic when oral dose supposed to commence • Transfusion of group-compatible blood to the wrong person
H	Circumstance or event with the capacity to cause harm or error	<ul style="list-style-type: none"> • Illegible medication order • Alike consumer names on the same unit • Inappropriate storage of medications leading to their decreased potency

Source: Adapted from a classification used by a hospital in New York State, United States, provided by Patrice Spath in October 2000.

APPENDIX 7: WORKED EXAMPLE OF AN INVESTIGATION, ANALYSIS, REPORT AND ACTION PLAN

The event

Twelve hours after falling and hitting his head at home, a 69-year-old man presented to the Emergency Department (ED) with complaints of headache and dizziness. He was evaluated and discharged home from the ED after staff received a guarantee from the consumer that a neighbour would be available to check on him, or assist him if necessary. Apparently, the consumer did not have anyone on hand to help, and 24 hours later he was found at home unconscious. He was subsequently admitted to the hospital with a subdural haematoma that eventually contributed to his death.

The investigation

The risk manager found out about the event after receiving a telephone call from the consumer's admitting consultant. The event was identified as requiring internal investigation according to hospital policy and for external reporting to the Sentinel Events Committee. The risk manager contacted the quality improvement facilitator (QIF) with responsibility for the ED, advised her of the event, and an investigation began.

In preparing for and conducting the investigation the QIF undertook the following activities.

- She obtained a copy of the consumer's clinical record and documents/records relating to the first assessment in the ED. Part of this process was to check for relevant policies and procedures, incident reports, complaints, etc.
- She identified the staff that wrote in the clinical record and checked rosters to identify who was on duty at the time. She spoke to staff to establish whether any unrostered staff cared for the consumer (ie, staff who may have relieved for a meal break or helped out because the ED was busy).
- In a preliminary review of the record, she determined what happened during the assessment.
- She constructed a skeleton Event & Causal Factors Chart (E&CFC) as the basis for constructing an event line.
- She considered whether to complete the E&CFC by interviewing staff individually or as a group, in view of the advantages and disadvantages of each approach as listed in table 8.
- After considering the advantages and disadvantages, and knowing the staff involved, she decided that a group interview was desirable. It could also be scheduled readily as the same staff were on duty again in two days time and a group interview could be organised for the hand-over period. This was arranged.
- She considered whether anyone else should be on the investigation team. At this stage, there appeared to be no need.

- At this stage there appeared to be no need to gather physical evidence.
- The QIF held the investigation meeting and the group's analysis began.

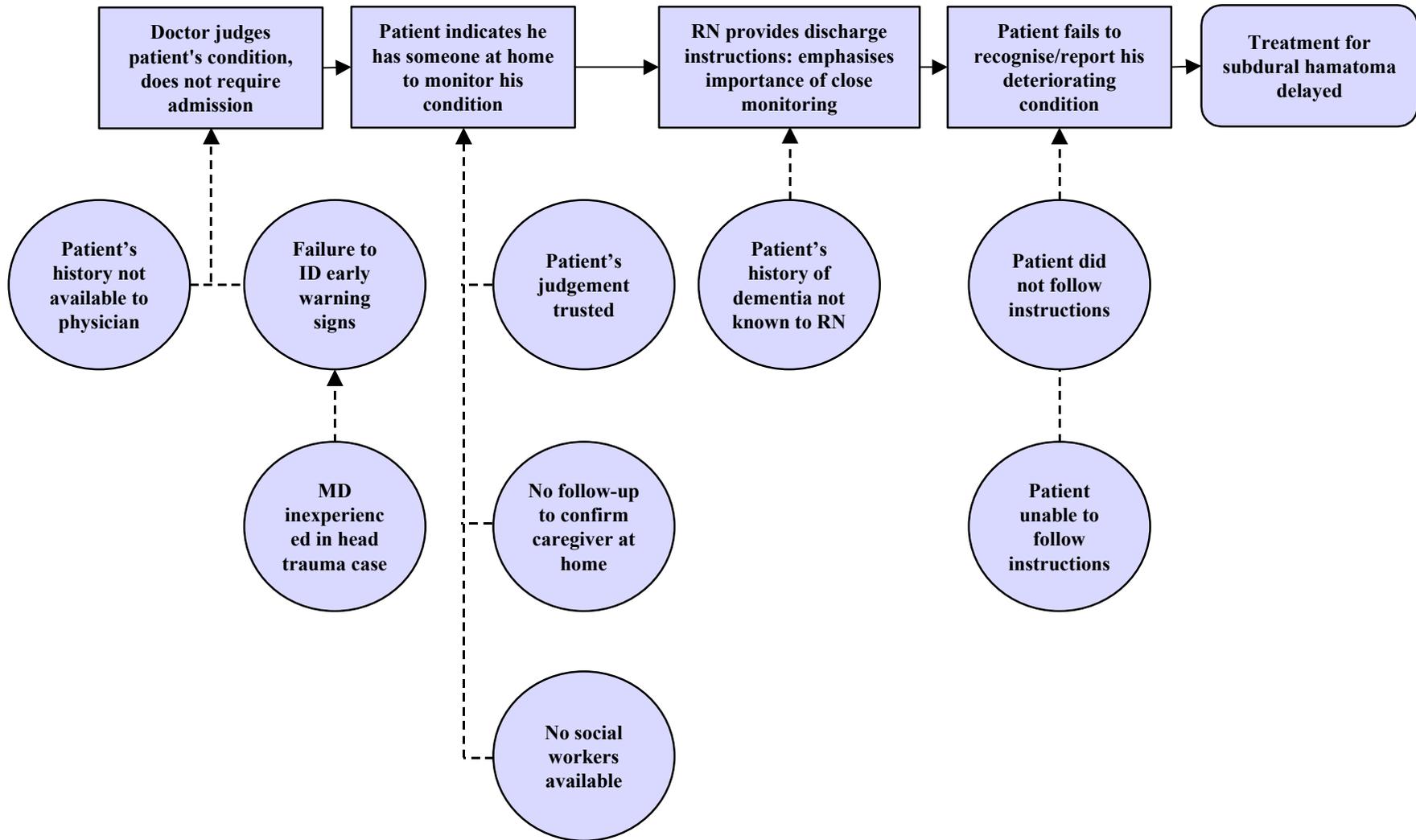
Table 8: Advantages and disadvantages of individual or group interviews

	Advantages	Disadvantages
Individual interviews	<ul style="list-style-type: none"> • Obtain independent stories • Obtain individual perceptions • Establish one-to-one rapport 	<ul style="list-style-type: none"> • More time-consuming • May be more difficult to schedule
Group interviews	<ul style="list-style-type: none"> • More efficient use of time • All involved caregivers can supplement the story; may give a more complete picture • Other people serve as memory-joggers 	<ul style="list-style-type: none"> • Involved caregivers will not have independent stories • More vocal members of the group will have a greater influence than those who are quieter • "Group think" may develop; some individual details may get lost • Contradictions in accounts may not be revealed

The analysis

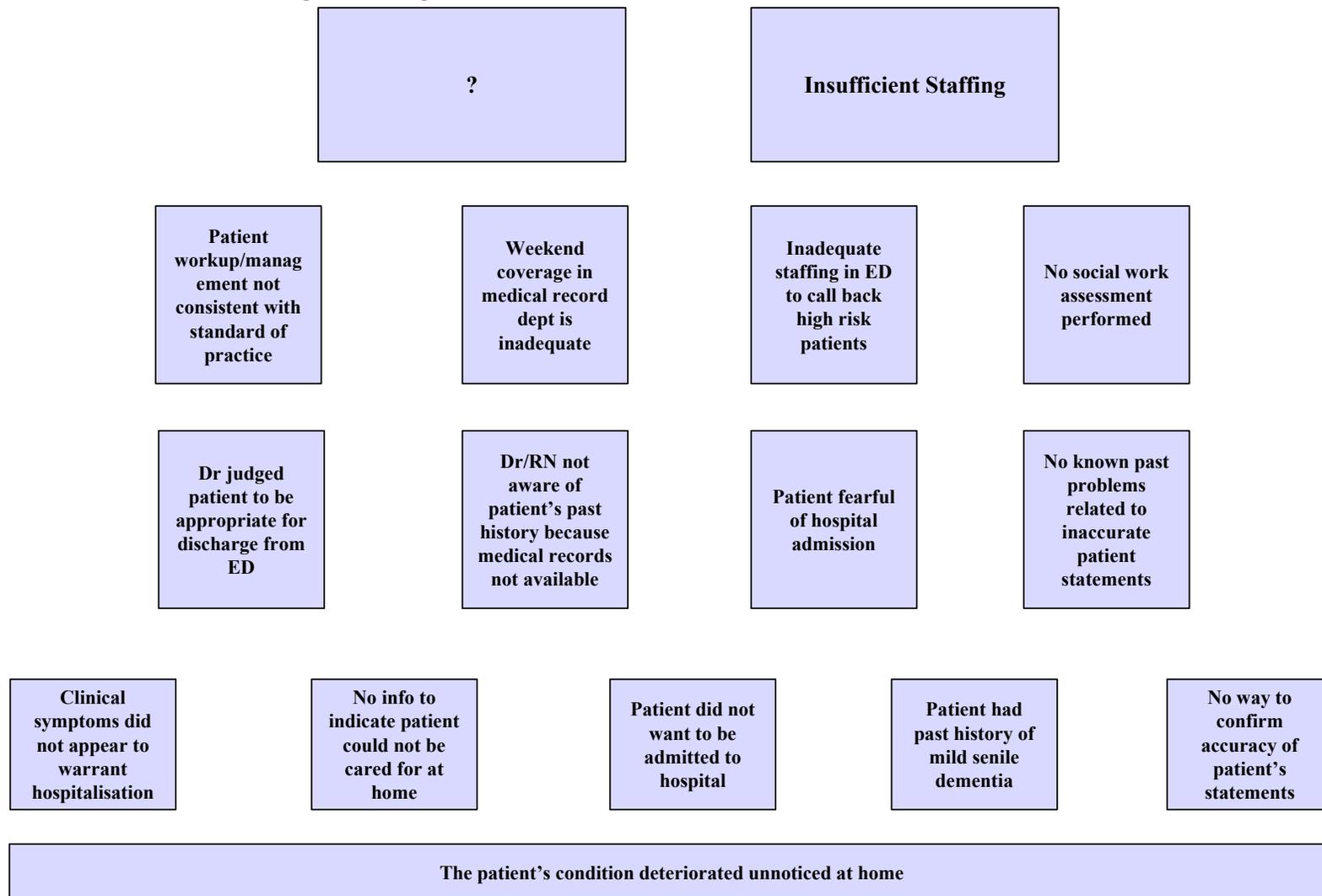
At the investigation meeting the QIF helped the team to complete an E&CFC (figure 2) to identify causal factors involved in the event.

Figure 2: Events and causal factors identified using an Event & Causal Factors Chart



With reference to the causal factors identified in the E&CFC, the group then completed a tier diagram to identify root causes (figure 3).

Figure 3: Root causes identified using a tier diagram



To doublecheck that the significant contributing factors were identified, the group decided to complete a change analysis chart (figure 4).

Figure 4: Change analysis chart

Factors that influence performance	Describe the event-producing situation	Describe the ideal or event-free situation	What is the difference?	What is the effect of this difference?
What				
When	Consumer seen in ED at 3.00pm during shift change. Social workers not available for elderly consumers with high-risk diagnosis who live alone.	Before ED discharge, social worker evaluates any high-risk elderly consumer who lives alone.	No social worker intervention.	Social worker may have identified follow-up problems.
Where				
Who				
How	Consumer's old notes not available to doctor/nurse.	Consumer's old notes available to doctor/nurse	Old notes not available.	Upon review of old notes, doctor and/or nurse may have recognised potential problems.

The group also decided to complete a barrier analysis chart (figure 5).

Figure 5: Barrier analysis chart

Loss (undesirable event, adverse outcome or injury)	Target	Barrier that should have prevented the event	Analysis: why the barrier failed to prevent the event	Probable cause of the barrier failure
Death	Consumer	Consultant review of house surgeon decision	House surgeon did not contact the consultant on call	The house surgeon was intimidated as the consultant had previously refused to review consumers for him

The group brainstormed all the possible solutions to this problem before the meeting ended. The QIF documented solutions for each significant contributing factor on an Optional Solutions Worksheet (figure 6). Only one worksheet is shown here.

Figure 6: Optional solutions worksheet

Root cause to be solved: No social work assessment performed.	
<p>List all solutions that have any chance of working</p> <p>Ensure the social worker on call for ED during day and after hours does not have arranged appointments</p> <hr/> <p>Have social worker available in ED 24 hours a day</p> <hr/> <p>Have social work and nursing staff agree a protocol for nurses to determine home support needs before at-risk consumers are discharged (with occasional on-call support from social workers for difficult cases)</p> <hr/>	<p>Evaluation Rating*</p> <p>5</p> <hr/> <p>1</p> <hr/> <p>3</p>

Note: * Ask the investigation team to rate each proposed solution and then tabulate the ratings using a scale such as:

- 5 = Top preference
- 4 = High preference
- 3 = OK
- 2 = Maybe
- 1 = Small chance
- 0 = Won't work

The QIF transferred the options to another worksheet to help evaluate them before presenting them to the investigation team for comment (figure 7).

Figure 7: Options evaluation worksheet

Desired result: No at-risk consumers go home without their home circumstances being ascertained, verified and evaluated as adequate.
(What is expected to happen if the root cause is eliminated)

Possible Solutions	Fixes root cause of the problem (Yes/No)	Creates new problems (Yes/No)	Management / staff receptive (Yes/No)	Doctor receptive (Yes/No)	Group can implement (Yes/No)	Cost (High / Low)
Protocol for nursing use	Yes	Yes*	Yes	Yes	Yes	Low
SW on call (with no routine appts) for ED 24 hours	Yes	Yes*	Yes	Yes	Yes	Medium
SW in ED 24 hours a day	Yes	Yes	No	No	No	High

Note: * While both these solutions created new problems (more pressure on staffing), there were more problems in obtaining social workers than in finding additional nursing hours. Therefore the first solution, protocol for nursing use, was implemented.

The action plan

The QIF developed an action plan for review by the investigation group (figure 8).

Figure 8: Action plan

Overall target (what is expected to occur after the root cause has been removed):		
All elderly at-risk consumers who live alone will have their social situation evaluated before being discharged home from ED or inpatient wards		
Measures to be used to evaluate target achievement	When measures are to be reported	
Draft protocol developed Protocol signed off by week 8 First audit undertaken 1 month after protocol's formal release Second audit undertaken 2 months after protocol's formal release	Week 4 Week 8 Week 12 Week 16	
Action plan steps	Responsible person / department	Expected completion date
1. Project co-ordinator appointed	QIF, ED	Week 1
2. Co-ordinator identifies and assembles representatives from social work, ED and a medical and surgical ward with a history of admitting and discharging elderly consumers who live alone	Project co-ordinator	Week 2
3. Team drafts protocol during a meeting	Project co-ordinator	Week 3
4. Draft protocol taken back to the team's areas for a first round of consultation to test for readability and feasibility	The team	Week 4
5. Revisions made and draft protocol distributed to relevant units for consultation	Project co-ordinator	Weeks 4–6
6. Team considers feedback, revises protocol if needed, and sends to manager for sign-off	Project co-ordinator	Week 7
7. Protocol formally issued and staff informed of implementation of new protocol	ED QIF	Week 8-10
8. Audit to test implementation of protocol	QIF in each area of the hospital	Week 12 Week 16
9. Any action necessary to solve any problems identified during the audits is proposed, approved, and implemented	Project co-ordinator	Ongoing

The report

Before submitting final recommendations to the Management Team, the QIF asked the Investigation Team to evaluate their choices one more time to be sure all bases were covered. Figure 9 provides a checklist of the types of questions they considered. Only when the team felt each question had been thoroughly answered did it move on to the next one.

Figure 9: Final check

	Stop: complete before proceeding	
1.	What is the overall objective and ideal situation?	<input type="checkbox"/>
2.	What is needed to get there from here?	<input type="checkbox"/>
3.	What actions need to be done?	<input type="checkbox"/>
4.	Who will be responsible for each action?	<input type="checkbox"/>
5.	How long will each step take and when should it be done?	<input type="checkbox"/>
6.	What is the best sequence of action steps?	<input type="checkbox"/>
7.	How can we be sure that earlier steps will be done in time for later steps that depend on them?	<input type="checkbox"/>
8.	What training is required to ensure that all staff have sufficient know-how to execute each step in the plan?	<input type="checkbox"/>
9.	What level of quality is desired?	<input type="checkbox"/>
10.	How will we measure the results of actions?	<input type="checkbox"/>
11.	What resources are needed and how will we get them?	<input type="checkbox"/>
12.	What checkpoints and milestones should be established?	<input type="checkbox"/>
13.	How will we follow up each step and who will do it?	<input type="checkbox"/>
14.	What are the make/break vital steps and how can we ensure they succeed?	<input type="checkbox"/>
15.	What could go wrong and how will we get round it?	<input type="checkbox"/>
16.	Who will this action plan affect and how will it affect them?	<input type="checkbox"/>
17.	How can the plan be adjusted without jeopardising its result to ensure the best response and impact?	<input type="checkbox"/>
18.	How will we communicate the plan to ensure support?	<input type="checkbox"/>
19.	What will be people's reactions be and how will we deal with them?	<input type="checkbox"/>
20.	What peripheral groups will be affected by this action plan?	<input type="checkbox"/>

The QIF finalised the report and recommendation for approval by the Management Team. Once Management Team signed them off, the action plans were implemented.

A brief article informing the staff of the changes to come was submitted for publication in the staff newsletter. Staff were informed that the changes resulted from an event being reported and were encouraged to draw attention to any problems or events that should be addressed. A report on the effectiveness of the change was published after the second audit.

APPENDIX 8: PROPOSED LIST OF SENTINEL EVENTS

The Working Party recommends that the following definition be adopted as the definition of Sentinel Events. These events must be reported to the Ministry of Health for initial review. The report of the investigation and subsequent corrective actions plans will be sent to and received by the Ministerial Advisory Committee established to ensure national learning occurs.

Sentinel Events

1. An event during care/treatment* has resulted in an unanticipated death or major permanent loss of function[†] **not related** to the natural course of the consumer's illness / underlying condition / pregnancy / childbirth.[‡]
2. The event is one of the following:
 - 2.1 surgery on the wrong consumer
 - 2.1 surgery on the wrong body part
 - 2.3 deaths or suicides of consumers while in intensive psychiatric care
 - 2.4 infant abduction or discharge to the wrong family.

This list of events has been derived and adapted from a number of sources including:

- United States Joint Commission on Accreditation of Healthcare Organisations
- Commonwealth of Massachusetts Board of Registration in Medicine
- Ministry of Health, New Zealand.

* "Care/treatment" refers to the services provided by health and disability services.

† "Permanent loss of function" means sensory, motor, physiological or intellectual impairment, not present on admission, that requires continued treatment or lifestyle change. When it cannot be determined immediately, the applicability of this process is not established until either the consumer is discharged with continued loss of function, or two weeks have elapsed with persistent major loss of functions, whichever occurs first. "Permanent loss of function" includes an increase in the level of disability where the consumer has a pre-existing disability or disabilities.

‡ "Not related" means that death or loss of function occurs due to treatment or lack of treatment of the consumer's illness, condition, pregnancy or childbirth.

APPENDIX 9: SENTINEL EVENTS COMMITTEE: TERMS OF REFERENCE (DRAFT)

The Sentinel Events Committee has the following Terms of Reference.

Role

To oversee national efforts to promote systemic improvements in the safety and quality of health and disability services in New Zealand with a particular focus on eliminating, isolating and minimising the likelihood and effects of system failure.

Tasks

- Provide advice to the Minister of Health on national strategy and priority areas for safety and quality improvement.*
- Oversee the collection of data to identify national learning opportunities and inform the professions in the health and disability sector.
- Monitor the effectiveness of national learning activities.
- Widely disseminate information on the activities of the Committee; report to the Minister of Health, professions and public at agreed intervals.

In undertaking these tasks, the Committee will:

1. Implement an effective confidential system for health and disability services to report their analysis of Sentinel Events and subsequent corrective action plans for the purpose of:
 - (a) obtaining review of the health and disability services' analysis and plans
 - (b) ensuring health or disability service has successfully implemented their action plan(s).
2. Identify opportunities for national learning to reduce the recurrence of Sentinel Events elsewhere.
3. Work collaboratively with stakeholders; in particular building on the existing efforts of health and disability services and consumers to improve the safety and quality of health care.
4. Ensure that strategies for improving safety and quality in health and disability services:
 - (a) are evidence based
 - (b) are monitored for effectiveness
 - (c) are supported by appropriate education and training.
5. Liaise with appropriate national agencies or collectives that have data relating to adverse or Sentinel Events to identify priority areas for action.
6. Co-opt members with specific expertise, and establish subcommittees and reference groups as required.

* As noted elsewhere in this report, the Sentinel Event Committee could be established as a sub-committee of the National Health Epidemiology and Quality Assurance Advisory Committee.

APPENDIX 10: ORGANISATIONAL ACCIDENT AND LEARNING THEORIES

Major events such as the nuclear accident at Three Mile Island in 1979 and the capsizing of the Herald of Free Enterprise in 1982 led to sustained, cross-disciplinary studies of the human contribution to safety. This approach departed from the traditional person-centred view of safety where the individual is blamed for making errors and must undergo education, training and/or disciplinary action. With the traditional approach, policies and procedures are also often developed in the hope of preventing others from making the same mistakes.⁴¹

Reason's theory of organisational accidents—an overview

The pre-eminent writer in the organisational accident field is James Reason. He originally developed his model in complex industrial systems to understand the relationships among various causes of accidents and to identify methods of accident prevention.⁴²

In summary, Reason's theory is that accidents are unplanned and unintentional events that result in harm or loss to personnel, property, production or anything that has some value. Barriers (physical and management) should prevent accidents or mitigate their consequences. Accidents occur when one or more barriers in a work system fail to perform or do not exist.

Human factors are important in assessing the causes of accidents. Two basic principles are important in assessing the role of human factors in an accident.

1. Nearly every accident has more than one cause.
2. Human error can be identified as a causal factor in nearly every accident.

The major human aspects that affect work performance are experience, knowledge, training, physical aptitude, fitness, behaviour, stress, fatigue, work, and shift changes.⁴³ In addition to individual human factors, contributors to accidents include institutional context, organisational factors, work environment, team factors, task factors, consumer characteristics and management factors.⁴⁴ They may include the interface between people and machinery, and equipment/design considerations.⁴⁵

Reason's model applied to the health sector

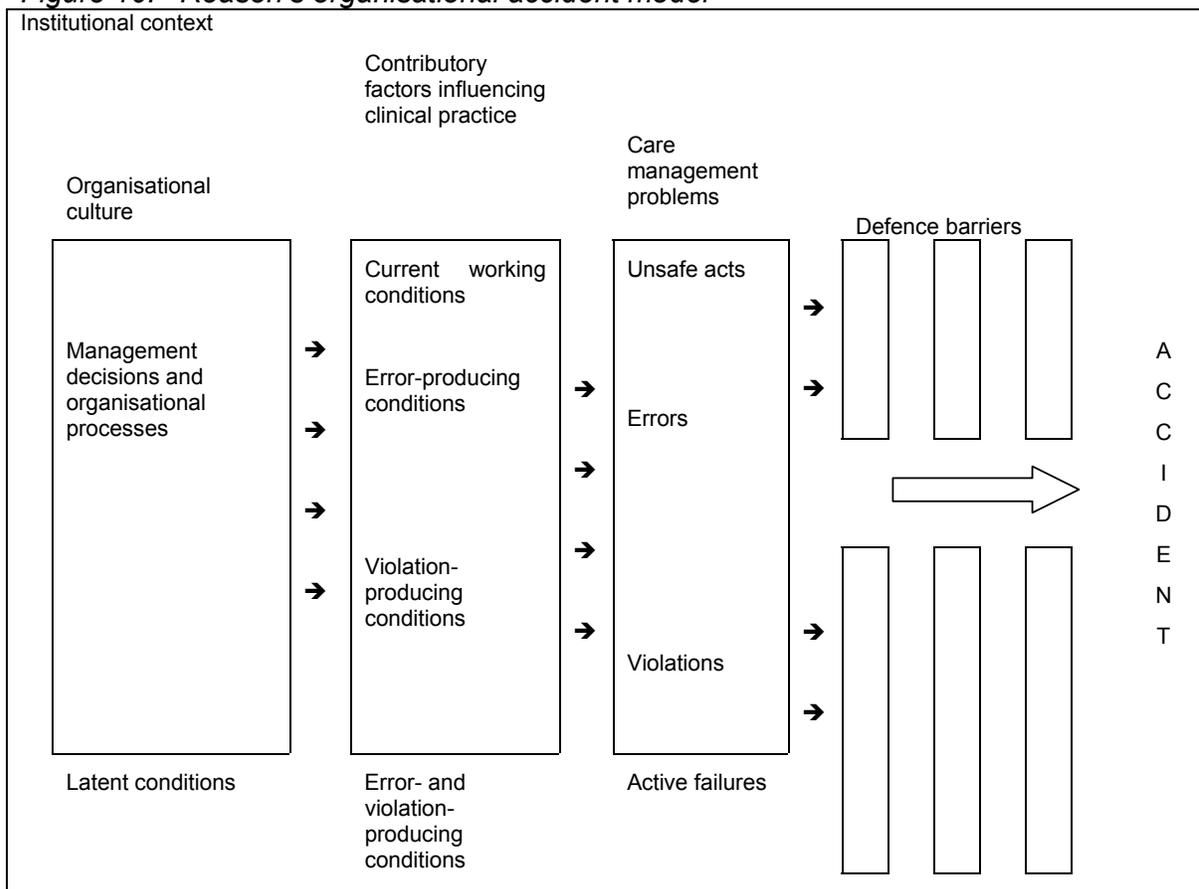
Reason's model is widely accepted in the health sector in the United Kingdom by the National Health Service,⁴⁶ in Australia by the Australian Patient Safety Foundation,⁴⁷ and in the United States.⁴⁸ Using words such as "error" and "failure", with negative connotations for health professionals, would hinder a reporting system that is focused on learning lessons from the experience of reportable events. At a motivational level, it is difficult to ask employees to participate in root cause analysis when the aim is to find fault. It is much easier to gain people's co-operation where they are asked to find solutions, and where the Director-General is relying on their unique knowledge to find those solutions.

The model is presented in figure 10, with small adaptations applicable to the health sector. It identifies:

- **latent conditions**, similar to resident pathogens in the body, which do no particular harm but form the preconditions for failure. Although they can be identified and removed before an accident occurs, doing so often requires fundamental change to the beliefs and values of senior staff and affects the organisation's culture and management processes⁴⁹
- **errors** arising primarily from information problems, eg, forgetting, lapses in attention
- **violations**, which are deviations from safe operating procedures or standards⁵⁰
- **active failures**, which are unsafe acts or omissions by staff that have immediate consequences, eg, picking up the wrong syringe.⁵¹

From research based on this model, it is known that high-risk processes are characterised by variable input, complex, non-standard, tightly-coupled and heavily dependent on human intervention. They involve hierarchical rather than team management and have tight or loose time constraints.⁵² Health services have all of these characteristics.

Figure 10: Reason's organisational accident model



Applying Reason's model to safety management

Moving from error analysis where people are assumed to be unreliable components of systems, recent research has focused on how people contribute to safety. It shows that high-reliability individuals, teams, systems and organisations can recognise trouble in time to prevent serious consequences. Analysis of information about untoward events, even minor problems, can reveal vulnerabilities that create or increase the likelihood of adverse events.⁵³

The aviation industry uses Reason's cognition theory. It regards event reporting as an important tool in safety management because workers provide information about problems.

The health sector also uses event reporting in limited areas. For example, the United Kingdom Confidential Inquiry into Maternal Deaths has helped reduce the rate of anaesthetic deaths from 12.8 per million births to 0.5 per million from 1970 to 1996.⁵⁴ In just over a decade, the overall death rate from anaesthesia in the United States dropped from 1:10,000 to 1:200,000.⁵⁵ The actions that led to this improvement were stimulated by an analysis of data from voluntary reporting and interviews by an engineer.⁵⁶ Because this approach is resource intensive and root cause investigation methods have advanced, it has commonly been replaced by reporting systems and analysis of databases.

Related to the Reason model is the idea that there is a statistical ratio between the reporting of near misses and the number of accidents. Consequently, if near misses can be reduced, accidents will be prevented. One way to reduce near misses is to report events, whether near misses or Sentinel Events, enabling systems to be improved. New Zealand's Civil Aviation Authority advises that for aviation, research shows the **Heinrich ratio**⁵⁷ to be 1 serious accident to 30 less serious accidents to 300 near misses.

Analytical techniques are used to determine the causes of an accident. The three types of causal factors are: the direct cause, contributing causes and root causes. Core analytic techniques generally used in accident investigations are:

- **events and causal factors charting and analysis (E&CF)** to trace the sequence of events and conditions surrounding an accident, as well as to determine the causal factors
- **barrier analysis** to examine the effectiveness of barriers (management and physical) intended to protect persons, property and the environment from unwanted energy transfers
- **change analysis** to examine planned or unplanned changes in a system and determine their significance as causal factors in an accident
- **root cause analysis** to identify the causal factors, including management systems that, if corrected, would prevent a similar accident. While specific methodologies may vary, any such analysis involves systematic use of information from an investigation of an undesirable event to determine the underlying reasons for deficiencies or failures.⁵⁸

Each of these techniques has strengths and limitations that should be reviewed before applying it to any given accident. However, these core techniques are generally sufficient for most accident investigations.⁵⁹

Organisational learning

Also significant to mandatory reporting is the theoretical concept that organisations can learn. It means that the safe practices of one organisation can be transferred to another, while allowing variations to suit local conditions.

- Change that is actively managed is **active learning**.
- **Passive learning** occurs where information is given but its uptake is not facilitated or its implementation is not evaluated.⁶⁰

The concept of organisational learning is related to the concept of safety culture, which requires an organisation to have its own culture, rather than being solely dependent on a few individuals.⁶¹ Two health and disability services could provide the same services, but one organisation could be safer than another because of its safety focus.

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