

**New Zealand Health and Disability Sector
Safety Improvement Programme**

**POLICY FOR THE MANAGEMENT OF HEALTHCARE
INCIDENTS**



DRAFT

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1. INTRODUCTION

1.1 Purpose

The purpose of this document is to detail the policy that will provide a nationally consistent approach to the management of healthcare incidents. This policy directive advises clinicians and managers on how to respond effectively to all incidents that occur in the health and disability sector and provides a mechanism for national co-ordination, analysis and action.

1.2 System Purpose

The primary purpose of the New Zealand Health and Disability Services incident management system is to learn from experience and improve the systems and processes of healthcare. This will be achieved by reducing variation in incident management, identifying themes in healthcare incidents, facilitating the sharing of best practices and stimulating system wide improvements.

The secondary purpose of the system is to provide accountability to the community through an assurance that action is being taken to identify when things go wrong and to reduce the possibility of reoccurrence.

1.3 Context and Direction

There is no lack of recognition that errors and incidents occur in health care. Health care is a high risk industry and just as other high risk industries such as the nuclear power and the aviation industries have responded by implementing safety improvement systems, so too is the health industry. The purpose of such systems is to identify, investigate, analyse and act upon incidents as or before they occur to minimise the chance of the occurrence or reoccurrence of untoward outcomes of healthcare.

There are many components of a clinical governance and quality improvement system. An incident management system is but one of those components. It is essential that health and disability services develop an effective incident management system as described in this policy, but it is also important to recognise that this is not the only focus of clinical governance and quality improvement activity.

A number of organisations have an interest in improving the quality of healthcare in New Zealand. These include the Accident Compensation Corporation and the Health and Disability Commissioner. Healthcare incidents are identified and notified to these organisations in a different way from that required by this policy. It is planned that the implementation of this improved national approach to healthcare incident management will add to the national intelligence and action that has been commenced by these organisations and to which health and disability services already contribute.

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1.4
The national system

The following is a diagrammatic representation of the national incident management system that is established by this policy. The system is to be known as the New Zealand Safety Improvement Programme.

Many incidents occur in every health care organisation. As many of these incidents as possible are to be identified and notified to an appropriate person within the health and disability service, for management.

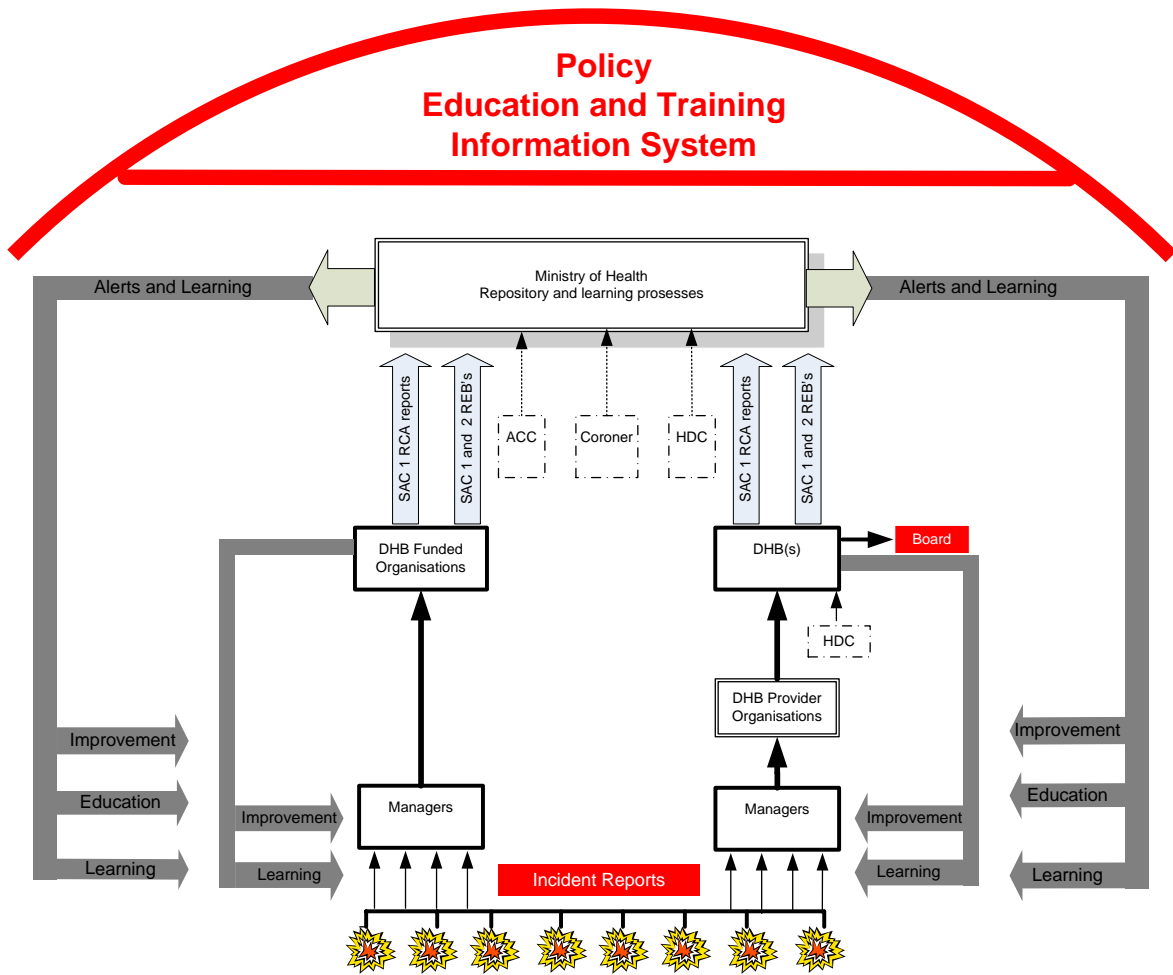
All incidents are to be reported to a central point within the health and disability organisation, where there is an organised process of aggregation, analysis and learning.

Reports from this process are to go to the Board (or other governing body) in order that the Board can discharge its responsibility for clinical governance. Learnings and improvements are to be fed back to the providers within the organisation.

Significant incidents that occur within the health and disability services (SAC 1 and SAC2) are reported to the Ministry of Health. The Ministry also receives information about health care incidents from the Health and Disability Commission, the Accident Compensation Corporation and the Coroner. The Ministry has established an organised, centralised process for national learning from incidents. This will include providing alerts to the system, national aggregation and analysis of all reported incidents from all sources and national action to affect learning and improvement across the country.

This policy, an education and training program for health and disability providers and an effective incident information system are the mechanisms for establishing and maintaining this national program.

DIAGRAM



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**1.5
Principles**

The national incident management system is based on the following principles.

- **Openness about failures** – errors are reported and acknowledged without fear of blame; the reporting of errors and incidents is encouraged
- **Open disclosure of adverse events** – patients and their families are told what went wrong and why and offered an expression of regret that an incident occurred
- **Systems focus not individuals** – the review of incidents is focussed on the systems of care rather than the individual’s contribution to the incident; human resources review processes are separate from the systems review
- **Emphasis on learning** – the system is oriented towards learning from mistakes and employs improvement methods for this purpose
- **Obligation to act** – the obligation to take action to remedy problems is clearly accepted and the allocation of this responsibility is unambiguous and explicit
- **Accountability** – the limits of individual accountability are clear; individuals understand when they may be held accountable for their actions; health services will be held accountable for reporting and improvement action
- **A “just” culture** – individuals are treated fairly
- **Appropriate prioritisation of action** – action to address problems is prioritised and resources directed to those areas where the most useful improvements are possible
- **Teamwork** – is recognised as the best defence of system failures and is explicitly encouraged and fostered within a culture of trust and mutual respect.

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**The principles
(continued)**

- **National consistency** – national learning will be possible when a consistent approach to incident management in all health and disability services is achieved
 - **National action** – national level reporting and learning processes are financially, intellectually and technically well resourced and effective.
 - **Local action** – all healthcare providers are responsible for incident management; organisations are responsible for effective systems development.
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**1.6
Scope**

This policy applies to all District Health Board provided and funded services.
The policy:

- outlines the management process for all corporate and clinical incidents.
- describes the responsibilities of organisations and individuals in relation to incident management
- defines the types of incidents that require reporting to the Ministry of Health as a Reportable Event Brief (REB)
- defines the role of the DHB Chief Executive and /or the General Manager of DHB funded services (however named) for ensuring the timely notification of incidents to the Ministry
- defines the timeframes within which incidents and the results of the investigation of serious incidents are to be reported
- identifies the scope of the national centralised processes for aggregation, analysis, learning and action on incidents
- outlines other policy and legislated incident reporting requirements.

This policy should be read in conjunction with The Easy Guide to Effective Healthcare Incident Management and Prevention (2008).¹

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¹ This publication is yet to be developed. It will contain step by step guidance on incident management, including different methods for investigation and review of incidents (including RCA method and Failure Mode and Effect Analysis).

**1.7
Safe reporting
culture**

Effective incident management depends crucially on developing a “reporting” culture. Without a detailed analysis of mishaps, incidents, near misses and “free lessons” there is no way of uncovering recurrent error traps or of knowing where the “edge “ is until patients and / or staff fall over it. The absence of such a reporting culture can result in catastrophic incidents and systemic failures.

Trust is a key element of any reporting culture and this in turn requires the existence of a “just” culture - one possessing a collective understanding of where the line should be drawn between ‘blameless’ and ‘blameworthy’ actions. Engineering a just culture is an essential early step in creating a safe culture and a safe healthcare system.

The reporting of incidents by clinical and other staff is not mandatory. It is neither possible nor advised to mandate reporting at this level. However, once a SAC 1 or SAC 2 incident (as defined later in this policy) has been identified and reported within a health or disability service, there is a mandatory requirement for the Chief Executive of the DHB or General Manager of another health service, to notify that incident to the Ministry.

**1.8
Requirement to
implement**

Compliance with this policy is mandatory for all District Health Board staff and for all other providers of health and disability services. Health and disability service providers are required to have a local policy and systems in place to implement this national policy. The one local policy will replace all current policies that relate to incident management, reportable events and serious and sentinel events.

2. DEFINITIONS of TERMS

The following are definitions of terms used in this document.

Adverse event

An incident in which harm resulted to a person receiving health care.²

Apology

A key aspect of open disclosure is saying sorry or offering an apology to the patient and their family / whanau / carer following an adverse event. An apology is an expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter whether or not the apology admits or implies an admission of fault in connection with the matter.

Clinician

A health practitioner or health service provider regardless of whether the person is registered under a health registration act. “Clinician” includes medical practitioners, nurses and allied health professionals.

Classification

The process of capturing relevant information about an incident, to ensure the complete nature of the incident, including causative and contributory factors from a range of perspectives, is documented and understood.

Complaint

An expression of dissatisfaction by a complainant. In many instances, complaints are incidents that have occurred in a health service, but that have been reported by a patient, carer or family / whanau member.

District Health Board (DHB)

The 21 District Health Boards provide the operational framework for the provision of public health and disability services in New Zealand. They are principally concerned with the provision of health services to residents within the geographic area covered by that DHB.

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² Runciman W “Shared meanings: preferred terms and definitions for safety and quality concepts.” MJA 2006; 184 (10 Suppl):S41 – S43

Error

The failure of a planned action to be completed as intended (ie error of execution) or the use of a wrong plan to achieve an aim (ie error of planning). Errors may be errors of commission or of omission and usually reflect deficiencies in the systems of care.³

Hazard

A source or situation with a potential for harm in terms of human injury or ill health, damage to property, damage to the environment or a combination of these.

Incident

An event or circumstance during health care, which resulted in unintended or unnecessary harm to a person and / or a complaint, loss or damage.⁴

Incident category

A high level grouping of incidents. There are two incident categories:

1. Clinical incidents
2. Corporate incidents. These include
 - a) staff, visitor and contractor incidents
 - b) service, finance and environment incidents.

Incident investigation

The management process by which underlying causes of undesirable events are uncovered.⁵

Incident management

A systematic process for identifying, notifying, prioritising, investigating and managing the outcomes of an incident and acting to prevent recurrence.

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³ Runciman W “Shared meanings: preferred terms and definitions for safety and quality concepts.” MJA 2006; 184 (10 Suppl):S41 – S43

⁴ Runciman W “Shared meanings: preferred terms and definitions for safety and quality concepts.” MJA 2006; 184 (10 suppl):S41 – S43

⁵ Woloshnowych M, Rogers S, Taylor-Adams S, Vincent C. The investigation and analysis of critical incidents and adverse events in healthcare. Health Technology Assessment, 2005 9 (9): vii.

Incident type

A subcategory of an incident category. For example, falls and medication errors are clinical incident types. There can be more than one incident type associated with each registered incident.

MDS

Minimum Dataset. The minimum number of data items to be captured for an incident notification.

Ministry

The Ministry of Health.

Near miss

An incident that did not cause harm.⁶ A “near miss” only occurs when the sequence of events that could have resulted in harm has been interrupted.

Notifier

Any person who identifies an incident and reports it by completing either a paper or an electronic form. This should include consumers .

Notification

The process of reporting an incident or near miss for any of the incident categories using either a paper or an electronic form.

Open Disclosure

The process of open discussion with the patient or other injured person (eg staff member) and their support person/s of incidents that result in unintended harm to a patient while receiving health care and the associated investigation and recommendations for improvement.

Reportable Event

Any incident that must be reported to the Ministry for (national) aggregation, analysis and action. This includes both clinical and corporate SAC 1 and SAC 2 incidents and also any matter that requires direct notification to the Ministry under existing legislative reporting requirements or Ministerial policy directive. All Reportable Events require a REB.

Reportable Event Brief (REB)

The method (form) used for reporting defined health care incidents to the Ministry of Health.

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⁶ Runciman W “Shared meanings: preferred terms and definitions for safety and quality concepts.” MJA 2006; 184 (10 suppl):S41 – S43

Root Cause Analysis (RCA)

A method used to investigate and analyse a SAC 1 incident to identify the root causes and factors that contributed to the incident and to recommend actions to prevent a similar occurrence.

Safety

Freedom from accidental injuries.⁷

Severity Assessment Code (SAC)

A numerical score given to an incident, based on the consequence or outcome of the incident and the likelihood that it will recur. A matrix is used to stratify the actual and/or potential risk associated with the incident (Appendix A).

System

A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.⁸

⁷ Institute of Medicine "To Err is Human: Building a safer health system" National Academy Press 1999

⁸ Op cit

3. THE INCIDENT MANAGEMENT PROCESS

Introduction

There are nine key steps to effective incident management:

- 1 Identification
- 2 Immediate action
- 3 Notification
- 4 Prioritisation
- 5 Investigation
- 6 Classification
- 7 Analysis
- 8 Improvement action
- 9 Feedback.

Health and disability services are required to ensure that local policy and practice reflects this policy such that all steps for managing incidents are taken.

Step 1 - Identification

The first step in managing incidents is recognising and identifying them. This will only be achieved in a culture and environment that allows this to happen without fear of retribution and in an environment that does not see incidents as an acceptable part of health care delivery. Each health service will need to foster this culture. Staff will need to understand what an incident is and how it differs from a recognised complication of care.

Incidents may be identified through a number of methods. These include for example direct observation, facilitated discussion, complaints, coroner's reports, staff meeting discussions, audits and/or chart reviews. They may be identified at the time they occur or at any time after the event.

Step 2 – Immediate action

Following identification of an incident it may be necessary to take immediate action to mitigate the harmful consequences of the incident. Such action would potentially include support for the person involved (patient, staff member, visitor or contractor), their family and/or the staff involved in the incident.

Immediate action may also be needed to make the local environment safe. This may involve for example the need for removal of a hazardous substance, the removal of malfunctioning equipment or supplies, or it may involve gathering basic information about a chain of evidence or notifying police and/or security.

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**Step 3 –
Notification**

In the event of serious harm to a staff member (SAC 1 or SAC 2 incident), where possible the scene of the incident should be secured by the person in charge of the workplace and notified accordingly to Health and Safety.

Staff are expected to notify all identified incidents, near misses and complaints in their local health service incident information management system. Clinical incidents should be documented in the patient's health record.

Step 3.1 Incident notification - by the notifier

- Incident notification must occur as soon as practical and preferably is to occur by the end of the notifier's work day
- The incident notifier can be either identified or anonymous, except in the case of workplace injury notification
- Notification can be either electronic or paper based
- Every notification should be directed to a clinical or non-clinical manager, as appropriate
- It is important for notifiers to give as much information as possible to assist further review and management of the incident and to allow optimal classification of incidents and comparison of data.⁹
- Patients and /or their carer/s /family / whanau should be provided with information on how to notify an incident.
- The notifier is to undertake an initial assessment of severity of the incident using the SAC Matrix (Appendix A) and give their opinion of how the incident may have been prevented. If an incident is notified by a consumer, the manager to whom the incident has been notified is responsible for allocating the SAC score.

Step 3.2 Incident notification - by the manager

Managers who receive incident notifications need to:

- reassess the SAC score according to the actual incident or near miss based on the information provided
- take immediate action if required
- discuss with the notifier (if the notifier is identified) any variation in the allocated SAC score
- complete a REB if required
- escalate as required.

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⁹ The minimum dataset (MDS) required for each incident category will be determined by June 2009 at which time this policy will be updated.

Step 3.3 Notification to the patient (open disclosure)

When an actual clinical incident occurs to a patient, an integral component of the notification process is to acknowledge the occurrence of the incident to the patient and their support person as appropriate, and to inform them of the type of investigation that will be undertaken. The notification process will depend on whether a low or high level response is required. The notification to the patient and their support person must occur in an open and timely manner.

An apology for any harm suffered is also given at this stage. Further information is later provided.

Step 3.4 Incident notification to clinical unit and Chief Executive

The relevant clinical units are to be notified of incidents that occur within their areas in a timely manner. All SAC 1 and SAC 2 incidents must be reported to the Chief Executive using a Reportable Event Brief.

Step 3.5 Incident notification to the Ministry of Health

All SAC 1 and SAC 2 incidents must be reported to the Ministry using a Reportable Event Brief. The process for reporting to the Ministry is provided in Section 4 of this document.

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**Step 4 -
Prioritisation**

All incidents are prioritised to ensure that the appropriate action is taken on each incident. Prioritisation involves the standardised, objective measure of severity of each incident or near miss.

The Severity Assessment Code (SAC) is the method used by any person who has identified an incident, to prioritise that incident.

The score is ascertained by rating the consequence of the incident and its likelihood of (re)occurrence. While there is necessarily a level of subjectivity / judgement involved in this assessment it provides a more uniform yardstick, from a systems perspective, by which to prioritise or guide actions. It is recommended that the SAC is determined at least twice, by different people to ensure greater reliability of the score.

It should be noted that the SAC score is also of value for incidents that did not actually result in an adverse event, such as close calls. This is a valuable feature as close calls generally occur more frequently than actual adverse events and provide an opportunity to improve the system without having had to experience a poor consequence.

All SAC 1 and SAC 2 incidents are notified immediately to the Chief Executive of the organisation and then to the Ministry.

Step 4.1 Severity Assessment Code scoring process

The SAC score is to be applied to all incidents whether they are of a corporate or a clinical nature. The SAC matrix is the method by which the SAC score is derived (Appendix A). The 4 SAC process steps are:

- Step 1: Determine the consequence of the incident using the definitions provided
- Step 2: Determine the likelihood of recurrence of this incident using the definitions provided. This analysis will require knowledge of the facility or health service in which the incident occurred
- Step 3: Allocate a SAC score to the incident using the SAC matrix
- Step 4: Determine the appropriate action to be taken using the table provided.

Each incident is assessed for the actual consequence and the potential consequence. The potential consequence is the worst case scenario for the incident being assessed.

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**Step 5 –
Investigation of
the incident**

Investigation of the incident is an important component of any safety program. All incidents notified require some form of review or investigation. Such investigations or reviews must focus on identifying the systems issues related to the incident and not on matters of individual competence or performance.

5.1 Levels of investigation

All notified incidents are reviewed to assess the level of investigation required. Step 4 in the SAC score (at Appendix A) guides the level of investigation.

Health and disability services must:

- assign appropriate levels of responsibility for investigation of and action on all incidents
- have policies and procedures in place for the investigation of incidents
- have training programs in place for incident management, including investigation and review
- have appropriately trained staff to support staff involved in investigations.

The following levels of investigation are required.

SAC 1 Incidents

- All SAC 1 incidents must be investigated thoroughly.
- The Root Cause Analysis method should be used for the investigation of SAC 1 incidents.
- A final report from the investigation must be provided to the Ministry within 70 days of the notification of the incident within the organisation, for the purpose of national analysis and learning
- The template for reporting contained in this policy must be used
- It may be appropriate and more efficient for health services to conduct an investigation of several similar SAC 1 incidents together. The decision to do this will be at the discretion of the organisation. The rationale for the decision however, must be provided in the final report provided to the Ministry.
- It may also be more appropriate to investigate corporate SAC1 incidents using a different investigation method from an RCA. This decision will also be at the discretion of the organisation.
- The organisation must implement processes from which the organisation can learn from the incident investigation

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**Step 5 –
Investigation of
the incident**

(continued)

SAC 2 Incidents

- All SAC 2 incidents require a detailed investigation
- Ongoing monitoring of trended aggregated incident data may also identify and prioritise issues requiring a practice improvement project
- Responsibility for the investigation of the incident must be assigned to a designated senior manager, and clinician if appropriate.
- Investigation should be completed within 70 days
- The report from this investigation must be sent to the Ministry of Health.

SAC 3 and SAC 4 Incidents

- It will not be possible to review all SAC 3 and SAC 4 incidents individually. It will probably be more efficient and appropriate to review them in common incident types.
- The review of these incidents should be undertaken at the local level and responsibility for their management must be assigned
- Any financial loss must be reported to senior management
- As well as review at the local level, monitoring of trended aggregated incident data may also identify and prioritise issues requiring a practice improvement project
- Investigation of SAC 3 and SAC 4 incidents may involve interviews with staff, the patient and / or the family / whanau involved, review of policies and procedures, patient record review, review of clinical and other performance indicators or other relevant material
- Review should be completed, where possible, within 28 days.

5.2 Investigations and individual performance

Investigations conducted under this policy should not address issues of individual performance. Where a question of individual performance or competence arises, it must be managed through the organisation's performance management system. An incident involving:

- a criminal act
- the use of drugs or alcohol by the health provider
- a deliberate unsafe act
- deliberate patient harm

needs to be referred to the Chief Executive and managed in accordance with DHB human resources policy.

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**Step 5 –
Investigation of
the incident**

(Continued)

5.3 Investigation of incidents across DHB and health service boundaries

Some incidents will involve a number of health and / or disability services eg a primary care provider and an acute hospital or perhaps a rest home and an acute hospital. Responsibility for managing the review of clinical incidents across health service boundaries must be assigned. In some instances this will be a senior clinician, in others it may be a senior administrator. The responsibility for managing cross boundary corporate incidents rests with the most appropriate area manager.

**Step 6 –
Classification**

Incident classification is the process of capturing relevant information about an incident to ensure that the complete nature of the incident, including causative and contributory factors from a range of perspectives, is documented and understood. Classification is the first step in the analysis of incidents; to identify new and previously unsuspected hazards, discover trends, or to develop strategies to decrease adverse events and patient harm. Neither the act of reporting nor the collection of data will accomplish these objectives unless the data are analysed and recommendations are made for change.

Classification can be undertaken down to many levels. The requirement to classify down to any particular level is dependent on the severity of the incident and therefore the need to know more detail, from which the system can better learn. An incident can only be fully classified after the incident has been investigated and the causative and contributory factors are better understood.

Different incident information systems have different classification systems. At present there is no one or recommended classification system in the New Zealand health and disability sector. A process for identifying an appropriate classification system for the sector has commenced.

This policy will be updated in the future to reflect the chosen classification system and the requirements for classifying each level of incident.

Standard classification systems allow comparison of data across incident type, risk level and causation. The information provided through classification will be included in reports available to managers. This will assist them in developing strategies based on trended data to understand cumulative risk and to minimise the recurrence of such incidents in their area of responsibility.

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**Step 7 –
Analysis**¹⁰

The purpose of analysis is to understand how and why the incident occurred, and to identify ways of improving the systems of care and preventing recurrence. Analysis must take place at a number of levels in the system; at the level at which the incident occurred (for example the ward); at the organisational level and at the national level. See diagram in Section 1.4. Different data are analysed and different action is expected at these various levels.

At a minimum, the incident reporting process should allow the **identification of** new and unsuspected **hazards**, such as previously unrecognised complications with medications. The simplest way of identifying hazards is by direct human review of incoming reports.

A summary analysis of the **frequency** of incidents can also be made. Other descriptive summaries can also provide valuable information for analysis. Calculating frequency permits prioritisation for the allocation of resources.

Trend analysis, obtained by calculating and observing rates of events over time, can identify changes that suggest new problems (or, if improving, that safety measures are working). Trends can also be detected using statistical control methods. A cluster of events that suddenly arises suggests a need for inquiry and immediate action.

On a more sophisticated level, data can be subjected to an **analysis of correlations** to evaluate the strength of the relationship between two variables or cofactors.

With a large number of reports, **estimations of risk**; the probability of recurrence of a specific type of adverse event or error and average severity of harm can also be calculated.

When many factors are classified and coded along with the event, a more complex set of correlations and relationships among the factors can be considered and tested in the database eg **causal factors** such as communication, workloads, teamwork, equipment, environment, staffing and the like.

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¹⁰ The WHO Draft Guidelines for Adverse Event Reporting and Learning Systems 2005

**Step 7 –
Analysis**

(Continued)

The ultimate aim of reporting is to lead to systems' improvements by understanding the **systems failures** that caused the error or injury. At the organisational level, this requires the investigation of the incident to uncover the contributing factors and system design problems. The national level system must receive this level of information in order to identify common and recurring systems failures.

DHBs and other health and disability services are responsible for analysis and action at the health organisation level; the Ministry is responsible for analysis and action at the national level.

**Step 8 –
Improvement
action**

The investigation of healthcare incidents and the analysis of the results of those investigations is the easy part of the incident management process. The next step that is required is action: the implementation of recommendations from the investigations and reviews and the development of better systems to ensure improved practice.

A suitable timeframe for the implementation of recommendations must be documented in local policy and those responsible for action identified and held accountable for the action. Senior management is responsible for deciding whether recommendations are accepted and approved and for the allocation of appropriate resource to the implementation of those recommendations. "Senior management" means any senior person with a management role and includes, doctors, nurses and allied health professionals.

The Chief Executive is required to sign off the recommendations of an RCA that is performed on a SAC 1 incident. A senior manager should record the acceptance of recommendations to ensure that the recommendations are appropriate for implementation.

Ongoing monitoring is required to ensure recommendations are addressed in a timely manner and to evaluate the success of any action taken to achieve improvement.

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**Step 9 –
Feedback
following
investigation**

Feedback is an important component of a successful incident management program. Local policy should take into account appropriate feedback to the following individuals and groups

9.1 Feedback to patients and/or support person (open disclosure)

Information given to patients, their support person(s) and family / whanau must be timely, accurate and given in a manner that is acceptable to them. Further guidance on this is provided in the section of this policy on Open Disclosure.

9.2 Feedback to staff

Feedback should also be provided to all staff on the results / outcomes of investigations and in a timely manner. Staff involved in the incident need to be informed of the recommendations arising from any investigation. For a SAC 1 incident the feedback is to be based on the final RCA report. The RCA report should therefore be provided to the relevant clinical team and presented at relevant staff meetings.

Regular reports on trended aggregated data and outcomes of RCAs are to be provided to ward staff / clinical and management teams. Feedback needs to include the changes made and improvements achieved as a result of these changes.

4. REPORTABLE EVENT BRIEFS

4.1 Purpose

The Reportable Event Brief (REB) system is designed for the reporting of specific health care incidents to the Ministry of Health. This ensures that the Ministry receives information about incidents that occur in the sector so that national aggregation, analysis and action can take place.

4.2 REB reporting requirements

All actual SAC 1 incidents, both clinical and non-clinical, are required to be notified to the Ministry, via a REB, within 24 hours of notification in the DHB or other health and disability service. See the SAC Matrix in Appendix A for further guidance on SAC score.

The Chief Executive or delegate is responsible for notifying the Ministry when there are incidents which have the potential to become matters of public interest.

The following list is a guide (only) to the types of incidents that would generally warrant prompt advice to the Ministry as a REB. The SAC matrix should be used to determine the actual events that are reported.

Clinical

- Death of a patient unrelated to the natural course of illness
- Procedures involving the wrong patient or body part
- Suspected suicide of a person (including a patient or community patient) who has received care or treatment for a mental illness from the relevant health services organisation where the death occurs within 7 days of the person's last contact with the organization or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation
- Suspected homicide committed by a person who has received care or treatment for mental illness from the relevant health services organisation within six months of the person's last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation
- Retained instruments
- Unintended material requiring surgical removal
- Intravascular gas embolism resulting in death or neurological damage
- Blood transfusion resulting in significant haemolysis
- Medication error leading to death
- Maternal death or serious morbidity associated with labour or delivery
- Infant abduction or discharge to wrong family.

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REB reporting requirements

(continued)

Non-clinical

- Suspected suicide or attempted suicide by a staff member
- Unexplained death of a staff member while on work duties
- Fire, bomb or other threatening activities in the health facility
- An incident involving assaults on, and or abuse of, patients including children and other vulnerable patients
- Complete loss of service ie power or water failure
- Criminal activity in or related to the workplace
- Large fraud.

4.3 Mandated reporting- legal and policy requirements

Any matter that requires direct notification to the Ministry under existing legislative reporting requirements or Ministerial policy directive, regardless of its SAC rating also requires a REB. These include;

Event related to	Reported to
Serious Harm to employees	Department of Labour
Misadministration of radioactive materials	National Radiation Laboratory
Electricity related incidents causing injury, death or electrically initiated fires	Energy Safety Service, Ministry of Consumer Affairs
Gas accidents	Energy Safety Service, Ministry of Consumer Affairs
Serious issues involving quality of medicines	Compliance Team at Medsafe, Ministry of Health
Medical devices that caused or could have caused injury to the patient or device user	Compliance Team at Medsafe, Ministry of Health
Explosive events	Dangerous Goods Inspector
Deaths reported to the Coroner	Coroner
Public health emergencies	Ministry of Health
Communicable diseases	Ministry of Health

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**4.4
REB reporting
process**

The REB reporting process is as follows;

- A REB is completed
- A SAC score is to be applied to all incidents reported via the REB system
- The Chief Executive is responsible for confirming the SAC score assigned to each REB
- The REB is then emailed or faxed to the Ministry within one working day of the incident being notified in the health service.
- REBs must be forwarded under the signature of the CE or nominated delegate and dated
- If the issue is urgent, the District Health Board or other health organisation is to provide telephone advice to the Ministry
- All REBs involving suspected suicide or suspected homicide by patients of mental health services must be referred to the DHB Director of Mental Health Services for review of the SAC rating prior to submission of the REB to the Chief Executive.
- All REBs should be kept in a secure location.

**4.5
Information
required in the
REB report**

- The REB must state the incident type and the reason for reporting to the Ministry
- The REB must be de-identified (of patient and individual health provider) and treated as confidential
- The REB is to contain facts, initial analysis and actions to be undertaken. Opinion and subjective comment are to be avoided
- The REB must contain sufficient information to identify the severity of the incident and the background facts that are known at the time of reporting. It is important to provide all relevant information necessary to ensure the appropriate management of the issues
- Attachments such as medical records, pathology or autopsy reports and other patient identifying reports are **not** to be forwarded with the REB.

The Reportable Event Form is provided at Appendix B

5. RESPONSIBILITIES FOR INCIDENT MANAGEMENT

Introduction Incident management is everyone's responsibility within the health system.

Effective incident management requires a whole of organisation approach with clear points of accountability for reporting and feedback lines at all levels of the organisation. This incorporates individual roles and responsibilities and those of organisations and the Ministry of Health.

All staff All staff are responsible for:

- notifying all incidents they identify
- participating in the investigation of incidents as required
- participating in the implementation of recommendations made
- encouraging colleagues to notify incidents that have been identified.
- working safely to minimise the occurrence of incidents.

Health and disability service provider organisations All health and disability service provider organisations are responsible for:

- implementing a local policy that is consistent with this policy for the management of healthcare incidents, including responsibilities of key personnel
- ensuring an effective incident management system is in place for investigating and actioning recommendations for all incidents
- ensuring monitoring and risk rating of all incidents
- reporting all SAC 1 and SAC 2 incidents within one working day of notification within the DHB to the Ministry by submitting a written REB
- conducting a detailed investigation (preferably a root cause analysis (RCA)) of all SAC 1 incidents
- providing investigation reports and key findings from these investigations to the Ministry within 70 calendar days of first notification as per the template provided in this policy
- undertaking local actions to ensure appropriate incident management and preventing recurrence of incidents
- reporting trended incident data and outcomes of SAC 3 and SAC 4 incidents to the Ministry, as required
- ensuring appropriate resources are available for effective incident management and patient safety initiatives
- implementing policies and local practices that support staff, including staff training on incident management
- encouraging an environment where incident notification and active management of incidents is fostered.

Continued on next page

District Health Boards

District Health Boards are responsible for:

- all of the above
 - the inclusion of a requirement to implement this policy in all contracts with funded health and disability services. This requirement will include appropriate performance indicators
-

Ministry of Health

The Ministry of Health is responsible for:

- establishing and maintaining a centralised national system for
 - receiving and monitoring incidents reported to the ministry
 - undertaking hazard identification and taking appropriate action
 - undertaking trend and cluster analysis
 - developing summaries and descriptions of incidents and their correlations
 - undertaking risk, causal and system analysis
 - developing national policies and strategies to minimise system errors across the country
 - disseminating lessons learned from incident management
 - identifying education needs emerging from incident management
 - providing advice to the system in response to specific queries about incident management and in response to analysis of incidents
 - providing information and reports to the Quality Improvement Committee on trends analysis and issues for all SAC categories, for their input and advice
 - providing advice and regular reports to the Minister for Health on issues and trends and providing information on lessons learnt from the incident management process
 - providing information and reports to health and disability providers on trend analysis and issues for all reported SAC categories, indicating individual providers' trends and national and peer group comparisons
 - publishing an annual report on the management of health care incidents for the community.
-

The QIC

The Quality Improvement Committee is responsible for:

- receiving reports from the Ministry about incident trends and emerging issues and providing advice to the Ministry on appropriate actions to be taken.
-

6 THE OPEN DISCLOSURE OF ADVERSE EVENTS

Introduction

One of the key features of the New Zealand Health and Disability Sector incident management system is the open disclosure of adverse events. Open disclosure in simple terms, is about being honest with patients and their family / whanau about an error that has occurred during their treatment, expressing regret that it occurred and assuring the patient that all efforts will be made to prevent a similar errors from affecting another person.

6.1

The principles

The principles of open disclosure include:

- **Openness and timeliness of communication** – when things go wrong, the patient and their support person should be provided with information about what happened, in an open and honest manner at all times. This may involve provision of ongoing information.
 - **Acknowledgement** – acknowledge that an incident has occurred and initiate open disclosure
 - **Expression of regret** – as early as possible, the patient and their support person should receive an apology for any harm that resulted from an incident
 - **Recognition** of the reasonable expectations of patients and their support person: to be fully informed of the facts surrounding an adverse event and its consequence, treated with empathy, respect and consideration and provided with support in a manner appropriate to their needs
 - **Staff support** – the environment should support staff to recognise and report incidents and support them through the open disclosure process
 - **Integrated risk management and systems improvement** – a commitment to reviewing the systems that led to the incident and mitigating the risk of recurrence
 - **Good governance** – the DHB considers how to prevent recurrence, implement changes and review the effectiveness of these changes
 - **Confidentiality and privacy** – of all involved is maintained as far as possible.
-

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6.2
Initial contact

Contact with the patient and / or their family / whanau should be made in a timely manner. It is expected that there will be contact with the patient / staff member / family / whanau as soon as possible after the event; that is, at least within 24 hours of the event becoming known. All communication must be conducted empathetically and professionally.

The incident should only be discussed with the carer / family / whanau if requested by the patient / consumer.

Staff meeting with patients or their family / whanau should:

- acknowledge that an event has occurred and ensure that the patient / family / whanau have a health service contact name and number for further contact
- express appropriate concern and condolences
- advise, where appropriate, the actions that will be taken to
 - remedy any harm suffered by the patient or to prevent harm occurring to the patient because of the event.
 - explain the process for investigation of the events and planned contact time lines and process.
- ensure that they have access to support systems, services and processes.

6.3
Education and training for staff

The practice of open disclosure can prove to be quite complicated and does not come naturally to many people. A national training programme will be provided to DHB staff to ensure an adequate level of competence in open disclosure is achieved in all DHB. DHBs and other health and disability providers will need to provide ongoing training and support for staff who need to be involved in the open disclosure of adverse events.

7. NATIONAL REPOSITORY and ACTION

Requirements

Health care organisations and individuals benefit from reporting incidents if they receive back useful information that is developed through the aggregations and analysis of similar cases from several institutions.

If an event and the results of the investigation and analysis of that event are not reported to a body external to the health service, the lessons learned cannot be disseminated beyond the walls of the service. The opportunity to generalise the problem is lost and the opportunity to develop more powerful and generalisable solutions is missed.¹¹

It is important to note that reporting in itself does not improve quality or safety. This national system requires the expert analysis of reports and dissemination of lessons learned if the reporting to the system is to influence quality and safety. The national system must produce a visible, useful response to justify the resources expended in reporting. The response process is just as important as the reporting process.

The Ministry of Health will be responsible for establishing the national processes for reporting and learning that have been identified throughout this policy document.

In summary the national centralised processes and system will:

- establish a management and governance structure for the national learning system
 - accept reports from health and disability provider organisations
 - identify immediate recognisable hazards
 - issue alerts to health and disability providers
 - combine and analyse the data and information received from the HDC, the Coroner, the ACC and all health and disability services
 - identify strategies for improvement nationally
 - liaise with other national organisations and facilitate cooperative learning and action.
-

¹¹ WHO Guidelines 2003

Analyse all incidents against ACTUAL and POTENTIAL outcomes			
CLINICAL CONSEQUENCE	Major	Moderate	Minor
CLINICAL CONSEQUENCE	Major	Moderate	Minor
<p>Serious</p> <p>Unexpected patient(s) death resulting from the process of health care, which is unrelated to the natural course of the illness and differs from the expected outcome of a patient's management</p> <p>Or any of the following events:</p> <ul style="list-style-type: none"> Inpatient suicide Wrong patient, wrong site or wrong invasive procedure events Retained equipment / swabs etc requiring surgical removal Misadministration of radioactive materials Patient / infant abduction / discharge to the wrong family <p>Any investigation commenced by police related to patient abuse (eg rape)</p> <ul style="list-style-type: none"> Haemolytic blood transfusion Maternal death or serious morbidity associated with labour or delivery 	<p>Major</p> <p>Major permanent disability or loss of function (sensory, motor, physiologic or psychological) unrelated to the natural course of the illness and differing from the expected outcome of patient management</p> <p>Or any of the following:</p> <ul style="list-style-type: none"> Disfigurement as a result of the incident Suicide of an outpatient known to the mental health service within 7 days of contact with the service Patient at risk absent against medical advice Absconded mental health patient Threatened or actual physical or verbal assault of patient or staff requiring external or police intervention 	<p>Moderate</p> <p>Permanent reduction in bodily functioning (sensory, motor, physiologic, or psychological) unrelated to the natural course of the illness and differing from the expected outcome of patient management</p> <p>Or any of the following:</p> <ul style="list-style-type: none"> Increased length of stay as a result of the incident Surgical intervention required as a result of the incident 	<p>Minimal</p> <p>No injury or increased level of care or length of stay</p>
<p>Staff: Death of staff member related to work incident or suicide, or hospitalisation of 3 or more staff</p> <p>Events involving an explosion</p> <p>Visitors: Death of visitor or hospitalisation of 3 or more visitors</p> <p>Services: Complete loss of service or output</p> <p>Financial: loss of assets replacement value due to damage, fire etc > \$1M, loss of cash/investments/assets due to fraud, overpayment or theft >\$100K</p> <p>Environmental: Toxic release off-site with detrimental effect. Fire requiring evacuation</p>	<p>Staff: Permanent injury to staff member, hospitalisation of 2 staff, or lost time or restricted duty or illness for 2 or more staff</p> <p>Visitors: Hospitalisation of up to 2 visitors related to the incident / injury</p> <p>Services: Major loss of agency / service to users</p> <p>Financial: loss of assets replacement value due to damage, fire etc \$100K-\$1M, loss of cash/investments /assets due to fraud, overpayment or theft \$10K-\$100K</p> <p>Environmental: Off-site release with no detrimental effects or fire that grows larger than an incipient stage</p>	<p>Staff: Medical expenses, lost time or restricted duties or injury / illness for 1 or more staff</p> <p>Visitors: Medical expenses incurred or treatment up to 2 visitors not requiring hospitalisation</p> <p>Services: Disruption to users due to agency problems</p> <p>Financial: loss of assets replacement value due to damage, fire etc \$50K to \$100K or loss of cash/investments /assets due to fraud, overpayment or theft to \$10K</p> <p>Environmental: Off-site release contained with outside assistance or fire at incipient stage or less</p>	<p>Staff: First aid treatment only with no lost time or restricted duties.</p> <p>Visitors: Evaluation and treatment with no expenses</p> <p>Services: Reduced efficiency or disruption to agency working</p> <p>Financial: loss of assets replacement value due to damage, fire etc to \$50K</p> <p>Environmental: Off-site release contained without outside assistance</p>
<p>Staff: Death of staff member related to work incident or suicide, or hospitalisation of 3 or more staff</p> <p>Events involving an explosion</p> <p>Visitors: Death of visitor or hospitalisation of 3 or more visitors</p> <p>Services: Complete loss of service or output</p> <p>Financial: loss of assets replacement value due to damage, fire etc > \$1M, loss of cash/investments/assets due to fraud, overpayment or theft >\$100K</p> <p>Environmental: Toxic release off-site with detrimental effect. Fire requiring evacuation</p>	<p>Staff: Permanent injury to staff member, hospitalisation of 2 staff, or lost time or restricted duty or illness for 2 or more staff</p> <p>Visitors: Hospitalisation of up to 2 visitors related to the incident / injury</p> <p>Services: Major loss of agency / service to users</p> <p>Financial: loss of assets replacement value due to damage, fire etc \$100K-\$1M, loss of cash/investments /assets due to fraud, overpayment or theft \$10K-\$100K</p> <p>Environmental: Off-site release with no detrimental effects or fire that grows larger than an incipient stage</p>	<p>Staff: Medical expenses, lost time or restricted duties or injury / illness for 1 or more staff</p> <p>Visitors: Medical expenses incurred or treatment up to 2 visitors not requiring hospitalisation</p> <p>Services: Disruption to users due to agency problems</p> <p>Financial: loss of assets replacement value due to damage, fire etc \$50K to \$100K or loss of cash/investments /assets due to fraud, overpayment or theft to \$10K</p> <p>Environmental: Off-site release contained with outside assistance or fire at incipient stage or less</p>	<p>Staff: No injury or review required</p> <p>Visitors: No treatment required or refused treatment</p> <p>Services: No loss of service</p> <p>Financial: No financial loss</p> <p>Environmental: Nuisance releases</p>

STEP 2 – Likelihood Table

Probability Categories	Definition
Frequent	Is expected to occur again either immediately or within a short period of time (likely to occur most weeks or months)
Likely	Will probably occur in most circumstances (several times a year)
Possible	Possibly will recur – might occur at some time (may happen every 1 to 2 years)
Unlikely	Possibly will recur – could occur at some time in 2 to 5 years
Rare	Unlikely to recur – may occur only in exceptional circumstances (may happen every 5 to 30 years)

STEP 4 – Action required Table

ACTION REQUIRED

- 1 = Extreme risk – immediate action required – A Root Cause Analysis (RCA) investigation should be commenced. Reportable Event Form (REF) must be forwarded to the Ministry of Health
- 2 = High risk – senior management attention needed – Notification to the MoH and / or RCA investigation is to be undertaken at the discretion of management. If RCA not undertaken, aggregate then undertake a practice improvement process
- 3 = Medium risk – management responsibility must be specified – Aggregate data then undertake a practice improvement process. **Exception** – all financial losses must be reported to senior management
- 4 = Low risk – manage through routine procedures – Aggregate data then undertake a practice improvement project

NB – An incident that rates a SAC of 3 or 4 should only be reported to the MoH if it is likely to attract external attention or requires notification under existing MoH legislative reporting requirements (and has not been reported via other mechanisms) – do not re score the SAC

STEP 3 – SAC Matrix

CONSEQUENCE LIKELIHOOD	Serious	Major	Moderate	Minor	Minimal
Frequent	1	1	2	3	3
Likely	1	1	2	3	4
Possible	1	2	2	3	4
Unlikely	1	2	3	4	4
Rare	2	3	3	4	4

<Organisation Name>
District Health Board name if relevant
REPORTABLE EVENT BRIEF

APPENDIX B

Incident ID number

1. SEVERITY ASSESSMENT CODE <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 All SAC 1 and 2 incidents are to be reported to the Ministry of Health using this form. Incidents rating a SAC of 3 or 4 should only be reported to the Ministry if the incident is considered by the organisation's CEO to be of importance to the Ministry	
2. THIS INCIDENT IS: (Tick one box -Refer to SAC matrix for clarification)	
Clinical <input type="checkbox"/>	OR Corporate <input type="checkbox"/>
3. IF NOT SAC 1 or 2 what is/are the reason(s) this incident is being reported: (choose all that apply)	
Mandatory reporting <input type="checkbox"/>	Potential for media interest <input type="checkbox"/>
Legal significance <input type="checkbox"/>	Other (please specify) <input type="checkbox"/>
Possible national implications <input type="checkbox"/>	

Date of Incident:

Time of incident:

SYNOPSIS: (A brief overall summary of incident. Avoid chronology)

DESCRIPTION OF INCIDENT (4-6 dot points. What is known about the incident at the time of this report?)

ACTION TAKEN: (4 – 6 dot points)

FURTHER PLANNED ACTION:

CONTACT NAME:

Position:

CONTACT NUMBER:

Location

The incident involved (Tick one or more boxes. For clarification of these terms, refer to the SAC matrix)

Staff Patient Visitor Service Environmental Financial

This Reportable Events Brief has been approved for transmission by the organisation's Chief Executive, on <date>

The accuracy and content of the document is endorsed.

Email or fax this form to The Ministry of Health.

(The fax numbers and email address will be provided to health and disability services at a later date.)

APPENDIX C

Root Cause Analysis Report Template

Reference details

Facility	
----------	--

Incident details

Incident details	Date of Incident: Organisational incident identifier:
------------------	--

Reporting details

RCA	Date RCA team commissioned: Date RCA signed by Chief Executive Officer: Date RCA submitted to Ministry of Health: Feedback to facility:
-----	--

Organisational contact details	Name: Position: Telephone: Email:
--------------------------------	--

Other service involved	Name: Contact details:
------------------------	---------------------------

Description of the incident (ensure that this is factual and clearly describes what happened)	
---	--

Describe the outcome of the event (include information such as referral to the Coroner, impact on family etc)	
---	--

Summarise the team findings	
-----------------------------	--

Contributing factors and root causes table

The following format is to be used for the (approximately) 4 causation statements that are developed at the conclusion of the RCA

Causation statement 1 (2, 3 and 4)	Write the causation statement here	
	If yes, describe the issue and how it appeared to contribute	
	Were there issues related to patient assessment	YES <input type="checkbox"/> NO <input type="checkbox"/>
	Were there issues related to staff training or competency	YES <input type="checkbox"/> NO <input type="checkbox"/>
	Was equipment (or the use of lack of use) involved	YES <input type="checkbox"/> NO <input type="checkbox"/>
	Was a lack of information or misinterpretation of information a factor	YES <input type="checkbox"/> NO <input type="checkbox"/>
	Was communication a factor	YES <input type="checkbox"/> NO <input type="checkbox"/>
	Were appropriate policies or guidelines or lack thereof a factor	YES <input type="checkbox"/> NO <input type="checkbox"/>
	Was the failure of a safety mechanism or barrier designed to protect the patient/staff a factor	YES <input type="checkbox"/> NO <input type="checkbox"/>
	Were specific patient issues a factor	YES <input type="checkbox"/> NO <input type="checkbox"/>

Continued on next page

Implementation action plan

Action 1	Description of action	Person responsible	Outcome measure	Measure date	Management agreement YES/NO	Management notes if NO

Action 2	Description of action	Person responsible	Outcome measure	Measure date	Management concur YES/NO	Management notes if NO

Action 3	Description of action	Person responsible	Outcome measure	Measure date	Management concur YES/NO	Management notes if NO

Further required actions are to be documented using this format.
