Best practice guide to clinical incident management

Second edition – January 2023

Queensland Government

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Foreword

The *Best Practice Guide to Clinical Incident Management* has been developed as a statewide resource to support Queensland Health staff responsible for, or involved in managing, analysing and learning from patient safety incidents in healthcare settings. The aim is to foster safe and reliable care, reduce preventable incidents and improve patient safety outcomes. This revised edition of the Best Practice Guide to Clinical Incident Management (the Guide) responds to changes in methodology and approaches that have occurred in clinical incident management, nationally and internationally since it was first published in 2014.

Queensland Health is committed to improving patient safety, through the review of contemporary literature review, instigating changes to relevant legislation, promoting adherence to National Safety and Quality Health Service Standards second edition and providing strong health service leadership with a focus on creating positive safety cultures.

The health environment in which we provide care, by its very nature, poses potential risk across the spectrum of patient services. We must, therefore, learn from potential and actual patient harm scenarios, without fear of blame, if we are to reduce future harm. This new edition strongly emphasises the need to embed a *Restorative Just Culture* when responding to incidents. The framework for a Restorative Just Culture is embedded in this Guide and is central to enabling a patient-centric approach: it replaces a backward-looking determination with a forward-looking review of the clinical incident engaging participation by all stakeholders, including the staff who may be second victims, to address the harms and causes for improvements.

To further strengthen the clinical analysis process in Queensland Health, the Patient Safety Health Service Directive Guideline for Clinical Incident Management includes a new section for the development and implementation of recommendations. Ensuring the right stakeholders are involved in the development of recommendations is essential. It is also critical to ensure that the developed recommendations are effectively implemented and sustainable: a step by step process has been outlined in this edition to assist health services. Lesson learned that are well documented and widely shared will improve work processes, enhance quality and safety, and build resilient systems to prevent recurrences. With improvements and changes to Queensland Health legislation, the Patient Safety and Quality, Clinical Excellence Queensland (PSQ,CEQ) is now able to share Severity Assessment Code 1 (SAC1) clinical analysis reports with Quality Assurance Committees to establish a shared understanding of local and statewide gaps in clinical incident management and governance. This will provide enhanced opportunities for sustainable system wide improvements.

I would like to acknowledge the work of the World Health Organisation (WHO) Patient Safety Program, the Canadian Patient Safety Institute and National Health Service (NHS) in the foundational work of this Guide. Since this Guide was initially developed in 2014, there have been significant advances in the way clinical incidents are identified and reviewed to inform patient safety practice and quality improvement, both nationally and internationally. The Australian Commission on Safety and Quality in Health Care (the Commission) is recognised for their role in advancing health care standards, promoting patient safety and the development of a broad range of contemporary resources to improve the quality of health care provision.

I am pleased to be able to present this Guide as a key statewide resource to further enhance the effectiveness of clinical incident management by incorporating the practical aspects of involving the patient and family or carer, conducting an analysis, developing a report and recommendations, implementing and sustaining continuous improvements, and sharing the lessons learnt in a safe and just culture. This Guide should be read in conjunction with the Open Disclosure Guide, 2020, along with the range of Queensland Health clinical incident management resources and used in conjunction with other resources that support organisations to achieve National Safety and Quality Health Service Standards Implementation.

Kirstine Sketcher-Baker
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Introduction

Introduction and background

Everyday across Queensland Health's hospital and health services, patients receive high quality, safe and effective care from skilled clinicians that is delivered in demanding, highly complex and busy environments. However, despite our best efforts, clinical incidents do occasionally occur. These range from near misses to those that cause temporary harm to permanent harm or death to patients. When these incidents occur, it is distressing for patients, their families or carers and for the staff involved. To prevent these incidents occurring again, it imperative that the incident is reported into the RiskMan incident management system as part of a patient safety culture of incident reporting. This will enable staff to respond effectively through an investigation process including the identification and implementation of improvements.

As per the Health Service Directive Patient Safety, issued under Section 47 of the *Hospital and Health Boards Act 2011* (HHB Act), Queensland Health is required to have a clinical incident management process in place to manage all clinical incidents, and staff are mandated to report SAC1 clinical incidents. Healthcare staff are mandated to report to the PSQ, CEQ through Queensland Health's RiskMan information system within one day of becoming aware of the SAC1 event: utilising Queensland Health's incident management systems are crucial to providing safe care.

It is imperative that the patients and families or carers, and the staff who care for them are fully supported, informed, and involved when any type of health care related incident occurs. The impact associated with a clinical incident may extend for months and even years, affecting personal health, relationships and careers. Feelings of anger, frustration and complicated grieving may result[1] when communication and information is not effectively managed and where there are gaps in learning and improvement.

To purposefully manage this, disclosure processes form a key step in clinical incident management and importantly commence upon the identification of a patient safety incident. Queensland Health actively promotes the organisation-wide use of Clinician Disclosure where the treating clinician informs the patient of what has occurred, apologises and advises the patient of the next steps. In response to a SAC1 and/or SAC2 clinical incident, a higher-level response (Formal Open Disclosure) may be required, in addition to the initial step of undertaking Clinician Disclosure.

Previous theory relating to investigating incidents focused on the role of human error. Contemporary research has determined that most incidents and accidents are due to a failure within the system.[2] Adopting a systems approach to understanding incidents is the preferred framework for the analysis of clinical incidents, either retrospectively or prospectively, whilst paying attention to human factors sciences. Further to this, it is now widely understood that a culture of safety, in which staff are encouraged to report incidents and learn from them, is essential to transforming our health care environment. This can be achieved through the use of transparent reporting, objective clinical analysis insights and the formulation of recommendations that achieve sustainable and measurable improvements.[3]

This objective can be achieved through both proactive and reactive processes that:

- identify and treat risks/hazards before they lead to patient harm (pro-active)
- identify when patients are harmed and promptly intervene to minimise the harm caused to a patient as a result of the incident (reactive)
- disclose a clinical incident resulting in patient harm (pro-active and reactive)
- ensure that lessons learned from clinical incidents are communicated and applied by taking preventive actions designed to minimise the risk of similar incidents occurring in the future (pro-active and reactive).

The aim of clinical incident management is to effectively incorporate improved and updated approaches to managing clinical incidents, with the view to proactively reducing preventable patient harm. The value of implementing clinical incident management processes in a safety-aware culture, is now, more than ever an essential component of achieving quality patient care outcomes.

The importance of culture in safety and quality improvement is articulated in a range of the Commission's work, including the National Safety and Quality Health Service (NSQHS) Standards, the National Model Clinical Governance Framework and the Communicating for Safety Program. Key aspects of a positive patient safety culture include a shared importance of safety, constructive communication, mutual trust, an engaged workforce, acknowledgement at all levels that things can go wrong and the ability to recognise, respond to, and give feedback about, and learn from, adverse events.[4]

Implementing systems to ensure that patient safety incidents are recognised, reported and analysed and information used to improve safety systems, is a mandatory requirement of the NSQHS Standards and are articulated under the Australian Health Service Safety and Quality Accreditation Scheme.[5] The Standards describe a level of care that consumers can expect from health service organisations.

The Clinical Governance Standard incorporates criteria relating to:

- Governance, leadership and culture
- Patient safety and quality systems
- Clinical performance and effectiveness
- Safe environment for the delivery of care.[6]

Purpose of this Guide

This Guide is a resource to help support individual and organisational learning and to drive quality improvement, in response to patient safety incidents. Quality improvement is an ongoing process. This means that activities aimed at minimising risk to patients, carers, healthcare staff and the organisation will be continually in various stages of review, improvement planning and implementation. Key aspects within the quality improvement review process include understanding:

- what happened
- how and why it happened
- what can be done to reduce the risk of recurrence and to make healthcare safer
- what was learned
- how the learning can be shared.

Organisations may choose to use the Guide to support quality assurance processes. A quality assurance mechanism assists to test whether relevant systems are in place and ensure that expected standards of quality and safety are in place including:

- how incidents are recognised and reported
- how patients and/or their carers express their concerns or incidents
- how staff and patients and/or carers are involved in incident review
- how feedback is provided from incident analysis review to improve safety and quality
- how risks are managed
- how incident management systems can be more effective.

Organisations may also choose to use this Guide to support a safety and quality culture by:

- enhancing the safety and quality of patient care
- promoting a culture of safety and learning within the organisation
- promoting patient and family-centred care
- encouraging learning and dissemination of learning within and beyond the organisation increasing the effectiveness of incident management
- improving the success of incident analysis as a tool in preventing and/or mitigating harm.

Scope of the Guide

This Guide is based on key Queensland Health Departmental Directives and Guidelines, and provides a framework of best practice approaches and practical tools that may be adopted or adapted to meet local hospital and health service circumstances and needs. This Guide should be read in conjunction with relevant legislation and guidelines, including but not limited to, the following Queensland Health and the Commission's governance documents:

- *Hospital and Health Boards Act 2011*
- *Hospital and Health Regulation 2012*
- Health Service Directive, Patient Safety QH-HSD-033:2014
- Health Service Directive, Guideline for Clinical Incident Management QH-HSDGDL-032-2
- Queensland Health Open Disclosure Guide 2020
- Australian Commission on Safety and Quality in Health Care- National Safety and Quality Health Service Standards second edition
- Australian Commission on Safety and Quality in Health Care - Australian Open Disclosure Framework.

Target audience

This Guide is designed to be used by those responsible for, or involved in analysing, managing and/or learning from patient safety incidents in any healthcare setting.

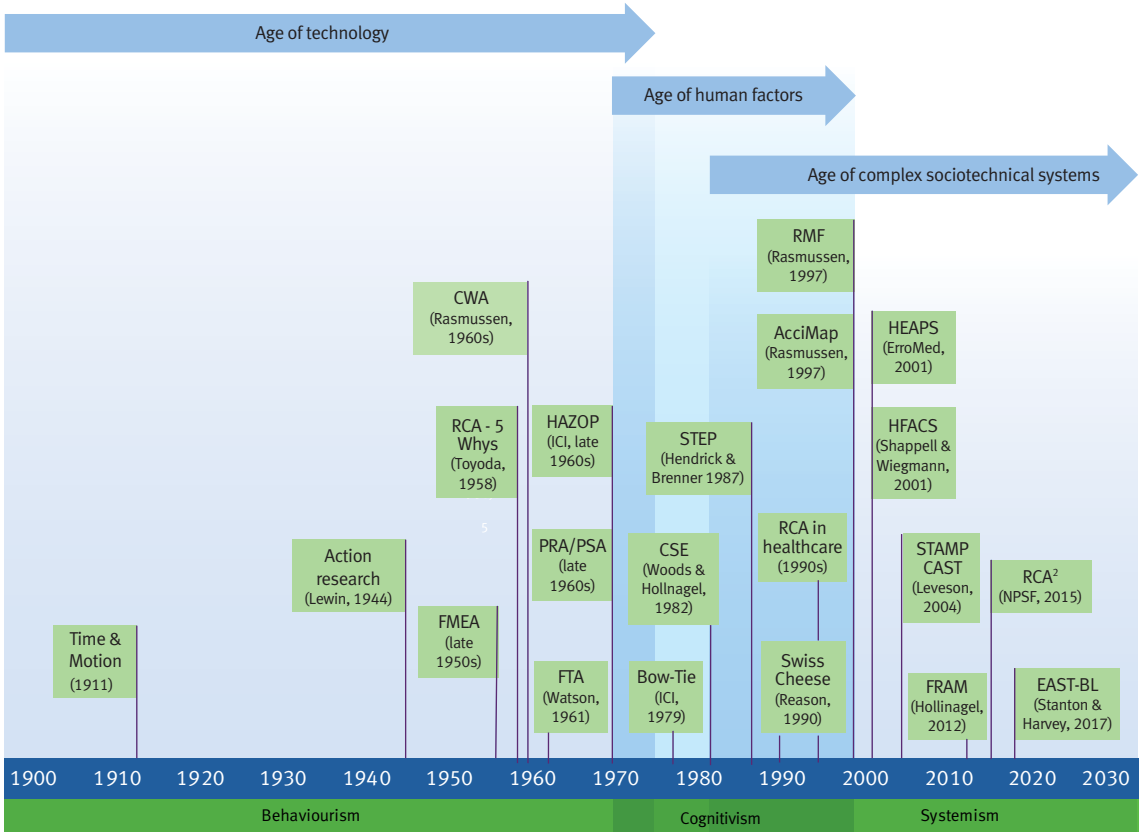
The sections including the introduction, the patient, family and carer and Step 1 of the clinical incident management process are recommended reading for executives, senior managers and safety and quality officers. The principles that underpin best practice for effective incident management, are described in the Step 1 of the clinical incident management process.

The clinical incident management process comprises six steps and these sections are recommended reading for safety and quality officers and their line managers focusing on practical suggestions and tools for incident analysis and learning.

Timeline of accident/incident analysis methods and models

The methods now used to analyse and manage incidents have evolved, from their early beginnings in industries such as aviation[7], to reflect the unique characteristics associated with complex healthcare systems. The value of applying different methods or models to investigate/analyse an incident is now well recognised. Figure 1 below shows the development of some methods from the early 1900s.[8,9,10]

Figure 1. Timeline of methods and models 1900–2030



Adapted from Hollnagel (2012), Waterson et al (2015) and Stanton et al (2019)

PRS/PSA	Probabilistic risk assessment / Probabilistic safety assessment
FTA	Fault tree analysis
RCA	Root cause analysis
RCA 2	Root cause analysis and action
HAZOP	Hazard and operability study
FMEA	Failure modes and effects analysis
STEP	Sequentially timed events plotting
CSE/CWA	Cognitive systems engineering / Cognitive work analysis
RMF	Risk management framework
STAMP	Systems theoretic accident modelling and processes
CAST	Causal analysis based on STAMP
HEAPS	Human error and patient safety
HFACS	Human factors and classification system
FRAM	Functional Resonance Analysis Method
EAST-BL	Event Analysis of Systemic Teamwork Broken Links

Patient, family, carer partnership

Involving the patient, family and/or carer

The NSQHS Partnering with Consumers Standard aims to create health organisations in which there are mutually beneficial outcomes by having:

- Consumers as partners in planning, design, delivery, measurement and evaluation of systems and services.
- Patients as partners in their own care, to the extent that they choose.[6]

Effective partnerships exist when people are treated with dignity and respect and provide the foundation for compassionate delivery of care and positive healthcare outcomes.

When patients need health care, they may feel vulnerable, frightened, upset and uncomfortable. Healthcare settings are generally unfamiliar to the patient and conversations that patients have with healthcare clinicians, before, during and after care or treatment, can help reassure the patient and allay some of their fears. The open sharing of information helps strengthen patients' trust in the care team and improves the safety and experience of patient care.

Person-centred care

Person-centred care is globally recognised as the gold standard approach to safe, high quality healthcare. It is a diverse and evolving practice, encompassing concepts such as patient engagement and patient empowerment. Partnering with patients in their care is an important pillar of person-centred care. It focuses on the relationship between a patient and a clinician, and recognises that trust, mutual respect and sharing of knowledge are needed for the best health outcomes.

When patients need to access the healthcare system, they expect the care provided will be safe and it will be sensitive to their needs and wishes; the principles of person-centred care are:

- treating patients with dignity and respect
- encouraging patient participation in decision-making
- communicating with patients about their clinical condition and treatment options.

Health services are required to incorporate information on the diversity of of its consumers and higher risk groups in to the planning and delivery of care. (NSQHS action 1.15). Partnering with Aboriginal and Torres Strait Islander communities to meet their needs is also referred to in (NSQHS action 2.13). Care should be provided in a way that is respectful of, and responsive to, cultural beliefs and practices, whilst recognising the disparities faced by Aboriginal and Torres Strait Islander peoples.

Immediate response or unexpected situations

When things don't go as expected, when conditions change or when harm occurs, the principles of safety and person-centred care are even more important. The immediate action is to ensure the patient is safe, and the necessary care is provided, including the provision of psychological support for the patient, staff and if required, their family and or carer.

Whether the cause of the issue may be a complication,error, an oversight, a safety incident or a case of 'we just don't know right now', patients, families and carers need the healthcare system to support them and commit to finding out what happened and to making improvements.

Handy tip

There are two information sheets available to to support hospital and health services in supporting the patient/family/carer when a serious incident occurs:

Clinical incident management for Health Service staff: Supporting the patient family carer when a serious incident occurs (Factsheet 2)

Patient/family/carer information sheet: What you can expect when a serious incident occurs

Clinician disclosure

Compassion and an acknowledgment that 'something unexpected has happened' is extremely important. Where the incident is temporary or minor, the clinician most directly involved in the incident or who first recognises the incident (medical officer, nurse, midwife or allied health professional) is usually the most appropriate person to speak with the patient and /or their support person.

The patient/ family/carer could be the first to see, feel or sense something isn't right. This can provide the healthcare team with valuable information from the patient/family/carer perspective; it is also an opportunity to understand what they require. Not responding or delaying disclosure creates more fear and erodes trust. When any type of incident occurs, patients need the healthcare clinician to meet with them to:

- acknowledge the incident
- explain clearly what has happened in an appropriate language style that all present can understand
- sincerely apologise for any harm and distress caused by the incident
- help the patient/family/carer understand how and why it happened
- explain what will happen next and follow through with commitments made.

Open disclosure

With incidents that result in unexpected death or permanent harm, it is highly likely that further discussion will be required, especially if there are a number of facts that are unknown or if additional treatment is required. The more formal process is known as Open Disclosure and should be offered to the patient or family or carer. Open disclosure follows on from the initial clinician disclosure. It should be delivered by a senior clinician (an Open Disclosure Consultant) who has had training in delivering information in a clear, mpathetic and structured way. For more detailed information, please refer to the Open Disclosure Guide.

Handy tip

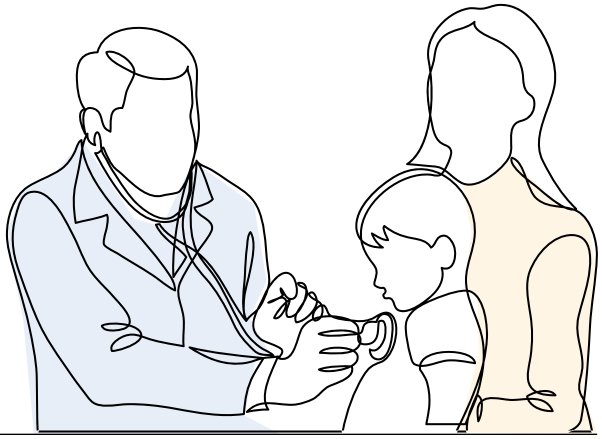
There are two types of disclosure used in Queensland Health:

Clinician Disclosure is where the treating clinician informs the patient of what has occurred and provides an apology. This disclosure should be the initial response to all adverse events (SAC 1, 2, 3 and 4) and occur as soon as practical after the clinical incident has been identified. For some SAC2 clinical incidents, along with SAC3 and SAC4 clinical incidents, clinician disclosure (the lower level of the two open disclosure components) may be sufficient.[11]

Formal Open Disclosure is a structured process ensuring clinical incidents are addressed and responded to openly between the patient, patient's family and/or carers, senior clinician and other representatives of the Hospital and Health Service. It is highly recommended that formal open disclosure is offered for all SAC1 clinical incidents and may be necessary for some SAC2 clinical incidents and occasionally SAC3 and SAC4 incidents.[11]

The analysis—what, how and why it happened

In assisting the patient/family/carer to understand what happened, it is highly likely the senior clinician will be required to speak to them as soon as possible, ideally within 24 hours and to also acknowledge that they may be feeling a significant level of grief or even anger. It is highly recommended to actively seek the patient/family/carer input and feedback in the analysis process, enabling the patient/family to contribute what they know from their perspective.[12]



Patients/families/carers will usually understand that the circumstances around how and why the event or incident happened may not be fully known at the time of initial disclosure, and that more information and time may be needed to gather all the facts. The process needs to be explained so that they can understand what will happen next. This includes talking to the patient/family/carer about the process, including how the event or incident will be analysed. It is important to allow plenty of opportunity for the patient and/ or their family / carer to ask questions. They will also need to be engaged in planning care following the incident. It is best practice to invite them to meet with a team member so that they can provide their perspective and information they know about the situation. In some cases, the analysis process can be very simple and straight forward. In other situations, it may be more complicated and involve many different people. Where possible, best practice would involve the patient/family/carer from the start of the process. An analysis of the facts, particularly when serious harm is involved, is not complete until all of the perspectives and information from everyone involved, including the patient/family/carer, have been gathered. The analysis team may, at this point, consider involving a consumer representative, who is familiar with the perspective of patients, families and carers, as part of the analysis team: it is an important consideration, so the family can be assured that their interests and perspectives will be included.[13]

Involving the patient/family/carer in the analysis stage also demonstrates respect for their point of view as the expert in their/their family member's experience. This emphasises that the patient, not the system, is at the centre of the concern. The goal is to make the system safer for patients through fostering understanding, learning and improvement.

While timely analysis is critical, there may be a range of circumstances which may prevent either the patient or a family member participating in the analysis process straight away. Try to be understanding and help find reasonable ways for them to participate. The respect, empathy and understanding of what they could be going through at the time, can help rebuild their trust in clinicians and the healthcare organisation.

Many patients/families/carers will want to keep in contact with the organisation during the analysis process. It is imperative that they are provided with contact information and it may help if a dedicated contact person is identified, preferably someone with whom they already feel comfortable.

In some situations where patients have been seriously harmed or where there may be significant system failures, it may be difficult for patients/families/carers (and sometimes even the general public) to re-establish trust with the healthcare organisation or system. Doubts may arise that analysis teams, when recruited from within the organisation, will not be as thorough or unbiased as outside experts. In these situations, consider the patient/family/carer request for an external analysis team; noting that 'external' may be a team from another facility in the hospital and health service or a clinical expert from outside the treating team.

Following the review of a serious incident, there may be occasions where the patient, or their family member is not satisfied with the process. It is ideal if resolutions can be achieved at the local level, however there may be times when a referral to to Office of the Health Ombudsman (OHO) may provide an additional review mechanism, as an independent body to assure fair and transparent oversight in health service complaint management. The OHO conducts investigations into individual practitioners where there may be evidence of professional misconduct or where the practitioner poses a serious risk to persons. OHO has the authority to refer to the Australian Health Practitioner Regulation Agency (AHPRA). The OHO can also open an investigation into a health facility or service to determine any systemic issues affecting the quality of health services.[14]

In more complicated situations, it may take additional time to complete all aspects of the analysis. Ensure that the patient and their family/carer are aware of the timelines and keep them informed of any delays or changes via the nominated contact person.

Following the analysis

Upon completion of the analysis, it is recommended to meet with the patient/family/carer in person if they wish, at a time and place that is agreeable to them. Cultural sensitivities should be taken into account when planning how and where disclosure occurs and consideration given to the inclusion of a local indigenous liaison officer/heath worker in the meeting. If a date for follow-up was previously agreed upon, keep to this commitment. If a delay is expected, inform the patient/family/carer, prior to the planned feedback date. Aim to send the patient/family/carer information or reports that will be discussed, in advance of these meetings, so they can also analyse them and come to the meetings prepared with their questions. It is easier to communicate, understand and re-establish trust when everyone has the same information.

These meetings can be very emotional for patients/family/carer members and for clinicians. Ensure everything possible is considered to make this time as easy as possible for patients/families/carers. Ask them about their perspective and include their suggestions for learning and improvements. The patient/family/carer view is a valuable resource for finding effective solutions. Who better to suggest improvement than those who have experienced failures in care and the system. Continue to talk with the patient/family/carer about the next steps and how they can continue to be informed or involved in developing or promoting these improvements. To the patient/family/carer this will show a continuing commitment to their safety and the safety of other patients. It also demonstrates transparency.

It is essential that all analysis reports are written, with the consideration that they can be provided to a patient/family/carer, should they wish to access the information. By providing a written copy of the report, this can help them come to terms with the consequences of the incident and to also provide assurance that everything is being considered to ensure this doesn't happen to anyone else.

A Root Cause Analysis (RCA) report with the statutory protections in accordance with Part 6, Division 2 of the HHB Act, can be provided with the permission of the commissioning authority, to any person they believe has sufficient personal or professional interest in the incident (s.115 *Hospital and Health Boards Act 2011*).

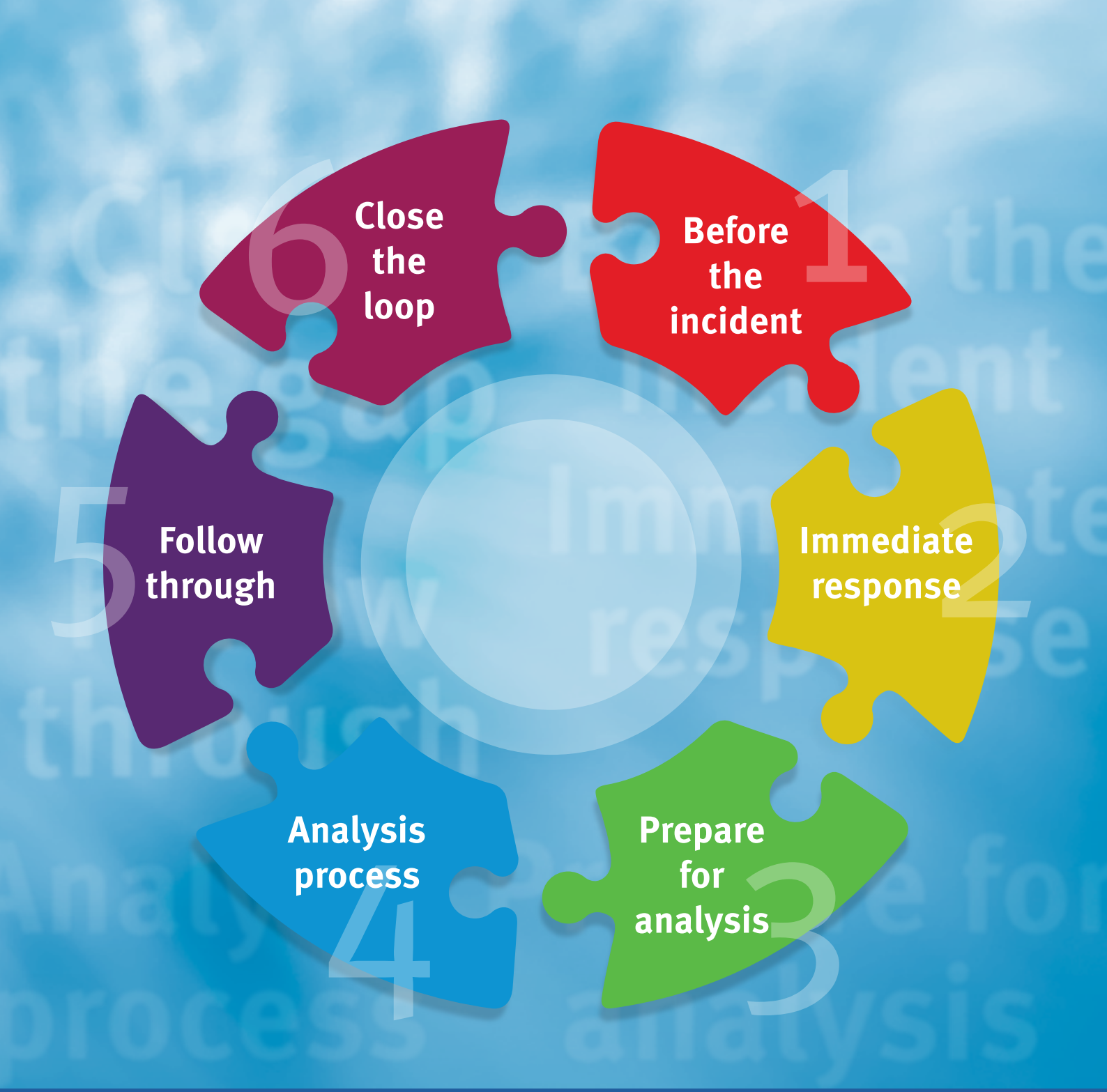
Partners in building trusting relationships

At a broader level, patients want to know that all current best practices related to national guidelines are being used in your Hospital and Health Services, and that patient safety incidents that do occur are analysed, actioned and implemented, and the learnings from these incidents are shared to prevent recurrence.

As new and improved ways are considered and used to incorporate safety and quality into healthcare, seek to involve patients, families and carers in the process. Partnering with consumer representatives, patients, families and carers assists to ensure that these advisory experiences are beneficial for all parties. [14,15]

Implementing systems to support partnering with patients, carers and other consumers to improve the safety and quality of care is a requirement of meeting NSQHS Standards. By enabling skilled and experienced consumer representatives to be involved in adverse event reviews, a strong patient-focused perspective can result with a number of benefits for the health organisation: including being involved in interviewing patients, ensuring the voice of patients/families/carers is heard and advocating for patient-centred recommendations.[13]

Partnering with Consumers Standard

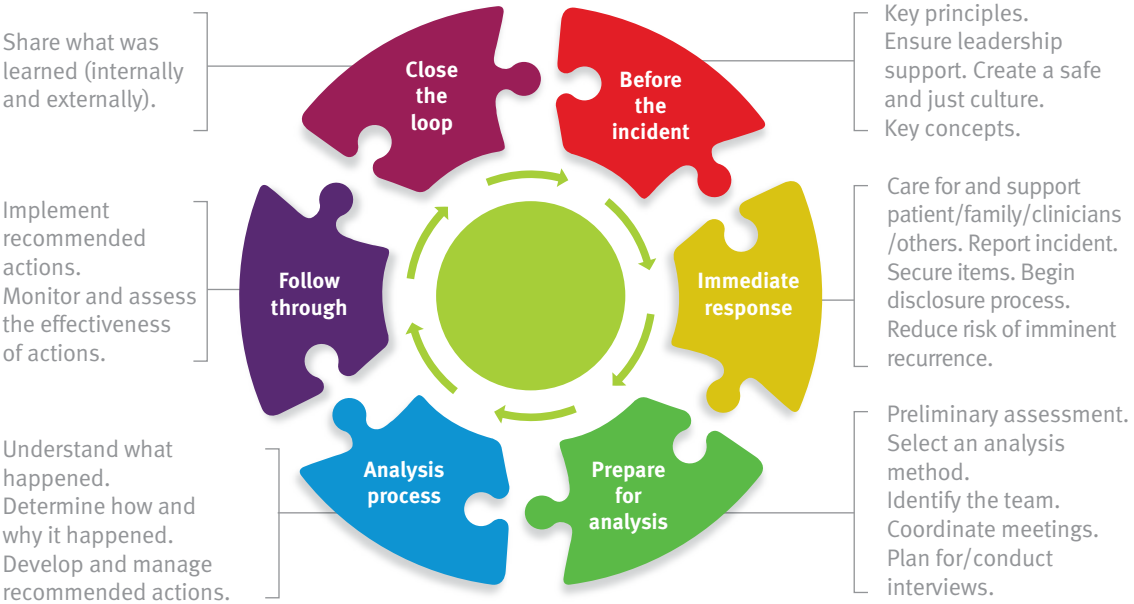


Clinical Incident Managment Process

Clinical incident management

Clinical incident analysis cannot be addressed in isolation from the multitude of activities that take place following a clinical incident. While there will be some variation in how healthcare organisations manage clinical incidents, the basic steps will be consistent. There is interconnectivity and interdependence between the identified activities, noting some may take place simultaneously. Figure 2 shows how incident analysis is an integral part of the incident management process and will be used throughout the Guide.

Figure 2. Clinical Incident Management Process Steps



Depending on the nature of the incident, these activities may be performed by a few individuals or a larger team. Refer to Appendix A (Analysis team membership and roles and responsibilities) for further information. In some cases, there may be different teams engaged at at each of the stages of the incident management cycle (e.g. there may be different teams/members who conduct disclosure processes to those who conduct analysis and review processes and those who manage implementation processes).

The Commission's Incident Management Guide outlines seven key principles of effective clinical incident management:

1. Transparency
2. Accountability
3. Partnering with consumers
4. Open, fair and just culture
5. Act in a timely way
6. Prioritisation of action
7. Shared learning.

The investigation and review methodology

There are a number of different methods available to investigate a clinical incident. It has been acknowledged that healthcare is more complex compared to aviation and other high-risk industries given the dynamic nature of the interactions between multiple clinicians, vulnerable patients, and complex care processes. Queensland Health does not stipulate to hospital and health services what type of method/analysis must be undertaken to investigate a clinical incident. This decision remains at the discretion of the of the hospital or health service in terms of what type of review methodology is best suited for the type of incident. This Guide focuses on three approaches - Comprehensive, Concise and Multi-incident analyses.

System based analysis review versus accountability review

In most organisations, there are two types of formal reviews that are generally available to manage unexpected clinical outcomes and clinical incidents:

- System-based analysis reviews - Comprehensive, Concise and Multi-analysis for system improvement
- Accountability review

This Guide is predominantly focused on system improvement, whereas accountability reviews are directed to individual performance or behaviour and are managed by the appropriate health practitioner stream i.e., Medical, Nursing and Midwifery, Allied Health or others (or through an administrative process e.g., a Health Service Investigation under the HHB Act). Further advice, including legal advice may be needed for an accountability review, depending on the particular circumstances. However, it is important that all parties understand that poor individual performance may occur due to ineffective systems e.g., inadequate training, ineffective policy and/or guidelines.

It is important to protect the integrity of the systems-based incident analysis process from a situation where there is potential for administrative, disciplinary, or criminal action. If reasonable concerns about individual performance or conduct arise during the course of a system-based analysis review, this should be escalated, and an appropriate accountability review set up as a separate process to address the identified issues. Likewise, issues concerning system issues or failures raised during an accountability review should be referred to a system improvement review.

In some circumstances it may be possible and appropriate to run parallel systems and accountability reviews. However, it is imperative that information not be shared from one process to the other and that all participants are aware of the distinction between the two. This is to ensure the integrity of each review and that any legal duty of confidentially is not breached. When the parallel investigations are complete, the learnings generated from each process can be valuable for improvement. In these situations, HHSs are advised to seek local human resource and legal advice.

Investigation legislation

Root cause analysis

A review team may determine that a root cause analysis (RCA) (refer to Part 6, Division 2 of the HHB Act), is the preferred methodology to review an incident. If during the RCA, the team becomes aware of '*a blameworthy act*' or the capacity of a person directly involved in providing the health service was impaired by alcohol consumed, or a drug taken by the person; or a member of the team reasonably believes the event involves behaviour of a registered health practitioner that constitutes public risk notifiable conduct, then the RCA must stop and the commissioning authority for the RCA must be notified. The Health Ombudsman must also be notified about the conduct (refer to section 102-103).

The HHB Act provides a number of mechanisms for consideration beyond an RCA, including clinical reviews and health service investigations. The following is a brief overview.

Clinical review

The function of a clinical review (refer to Part 6, Division 3 of the HHB Act) is to conduct a clinical review and to provide expert clinical advice.

The clinical reviewer may make recommendations on ways in which the safety and quality of public sector health services can be maintained and improved. A clinical reviewer can be appointed to provide clinical advice to:

- the Department Chief Executive or a HHS Chief Executive
- a person/entity whose role includes improving the safety and quality of public sector health services; or
- a health service investigation (HSI).

A clinical reviewer must prepare and provide a report to the appointer for each clinical review. Statutory protections limiting further disclosure apply to a clinical review report other than, as a result of a review undertaken to provide clinical advice to an HSI. The purpose of these clinical review reports is for improvement in clinical services and reports are not accessible under an order or admissible in any proceedings. A clinical review report prepared to provide clinical advice to a HSI however, may be admissible in civil, criminal and disciplinary proceedings.

If during a clinical review (except one undertaken to provide clinical advice to a HSI), a clinical reviewer reasonably believes that a matter under review involves a blameworthy act (refer to Part 6, Division 2, Section 94 of the HHB Act), the clinical reviewer must:

- stop the review
- give written notice to the appointer that states the review has been stopped and the reasons that the clinical reviewer formed the reasonable belief.

Health service investigations (HSI)

The function of an health service investigation (HSI) (refer to Part 9 of the HHB Act) is to investigate and report on any matters relating to the management, administration or delivery of public sector health services, including employment matters. A clinical reviewer may be appointed to provide clinical advice to an HSI. A health service investigator must prepare and provide a report to the appointer for the HSI. Where a clinical reviewer is advising, the HSI must:

- have regard to any report provided by the clinical reviewer; and
- attach the reviewer report to the investigation report.

An HSI report (and any attached clinical review report) may be admissible in civil, criminal and disciplinary proceedings or by other legal order. The appointer must be satisfied the clinical reviewer or health service investigator is, among other things, qualified for the appointment because they have the necessary skills, knowledge and experience or expertise. Any such appointment is then set out in writing (the instrument of appointment). In these situations, it is recommended that legal advice is sought.

Duty of Confidentiality

A statutory duty of confidentiality under the HHB Act applies in the performance of RCA, clinical reviews and HSI, with requirements for not disclosing information provided to them in that capacity, except in circumstances prescribed under the legislation. Refer to Appendix B Incident reporting and investigation legislation for further information.

Step 1: Before the incident

– Key principles
– Ensure leadership support
– Create a safe and just culture
– Key concepts

Key principles

The following principles in Table 1 form the foundation for effective clinical incident management. The employ of these principles will assist with reducing the risk of recurrence of similar patient safety incidents and aim to result in improved healthcare outcomes. Staff in Queensland Health's hospitals and health services are encouraged to support, enact and openly communicate these principles as part of a culture of patient safety, disclosure, quality and learning from incidents.

Table 1. Clinical Incident Management Principles [16]

Principle	Description
Transparency	Health services should provide the patient, family or carer, and staff with an honest, open and full explanation of what happened, why it happened and what actions have or will be taken, as per Queensland Health's Open Disclosure Guide, 2020.
Accountability	Health services have a duty to take reasonable care to avoid harm to patient, family or carer, and staff.
Partnering with consumers	The patient, family or carer who are associated with the incident are asked to contribute to the clinical incident management process as appropriate, during the investigation and review. Health services should seek to support the participation of a patient/consumer representative in reviewing serious clinical incidents.
Open, fair just culture	Health services should create a patient safety culture of trust, fairness, learning and accountability that encourages staff, patients, families or carers to feel safe to speak up when an incident occurs and to report incidents. The workforce is fairly supported when the system fails, and errors occur.
Act in a timely way	Health services take action to correct problems in a timely manner with clear allocation of responsibility.
Prioritisation of action	Health services prioritise actions that will have a high impact on harm prevention in areas of high risk and where there is high achievability of improvement.
Shared learning	Health services share the learnings from clinical incidents to prevent further similar patient harm occurring.

Ensure leadership support

Building high-reliability health organisations and systems for a strong patient safety culture that protect patients daily from harm, requires strong leadership at all levels.[17] Leaders must commit to creating and maintaining a culture of safety as inadequate leadership can contribute to adverse events. An engaged and skilled leadership team is paramount to improving patient safety. Having board members who are skilled in quality and safety has played a positive role in influencing safety.

The Australian Commission on Safety and Quality in Health Care (the Commission) Clinical Governance Standard aims to ensure organisations have systems in place to maintain and improve the reliability, safety and quality of health care. This Standard recognises the importance of governance, leadership, culture, patient safety systems, clinical performance and the patient care environment in delivering high quality care.[6]

Clinical incident management requires a whole of organisation approach that should foster a just culture and incorporate leadership responsibilities at each organisation level, including Board Directors and Executive. Hospital and health services board directors and executives have a key role in cultivating a culture that leads to improved patient care, by the establishment of specific committees overseeing all safety and quality activities across the organisation and the systems. Leadership prominence in clinical departments allows for frank discussions around safety concerns and can impact positively on safety culture when issues are raised, discussed and solutions identified and implemented. The reaction of leaders to an adverse event is crucial in determining if the heath service learns from the incident or not, and hence, if future harm to patients is reduced.

Pressure to act can mount quickly when a patient experiences an incident. Organisations can best handle the situation if they develop a plan ahead of an incident occurring that describes the steps and responsibilities for various actions (who is doing what, how and when) and indicates the resources available (policies, procedures, checklists, skills) to manage the incident.

The incident management plan requires visible leadership support at all levels of the organisation and is reinforced by a safe and just culture in place ahead of the incident.[18] Plans and procedures need to be tested, updated and revised periodically to ensure they are aligned with the evolving culture, structure and processes of the organisation.

Organisations that continuously build and maintain resilience in their structures, functions and way of thinking about clinical incidents are better prepared to manage the unexpected.

Five attributes characterise these organisations:

1. **Preoccupation with failure**—to avoid failure we must look for it and be sensitive to early signs of failure.
2. **Reluctance to simplify**—to understand the more complete and nuanced picture of an incident avoids over-simplification, labelling and clichés.
3. **Sensitivity to operations**—systems are not static and linear, but rather dynamic and nonlinear in nature. As a result, it becomes difficult to know how one area of the organisation's operations will act compared to another part.
4. **Commitment to resilience**—the organisation must maintain its functions during high demand events. Resilience has three components:
   - absorb strain and preserve function, despite adversity
   - maintain the ability to return to service from untoward events
   - learn and grow from previous episodes.
5. **Deference to expertise**—this may include deference downward to lower ranking members of the organisation, with greater emphasis on an assembly of knowledge, experience, learning and intuition rather than on one's position in the organisation. Credibility, a necessary component of expertise, is the mutual recognition of skill levels and legitimacy.[19,20]

To build and support both resilience and responsiveness in plans, organisations are encouraged to tap into the learning generated from previous incidents (near misses are of great value),[21] improvement efforts and learning from multi-incident analyses.

The importance of a strong patient safety culture

The patient safety culture of an organisation is a major component of supporting safety and quality improvement. Healthcare organisations are required to build and maintain a safety culture and this is well articulated through a range of the Commission's work. Safety culture is defined by the Commission as:

'the product of individual and group values, attitudes, competencies and patterns of behaviours that determine commitment to and the style and proficiency of an organisation's health and safety programs'.[4]

Positive safety cultures in health care are demonstrated by strong leadership, which aims to drive and prioritise the safety of all. Commitment from leadership and management personnel in this context is important because their actions and attitudes influence the perceptions, attitudes and behaviours of members of the workforce throughout the organisation.[4]

Organisations with positive safety cultures have:

- strong leadership to drive the safety culture
- strong management commitment, with safety culture a key organisational priority
- a workforce that is engaged and always aware that things can go wrong
- acknowledgement at all levels that mistakes occur
- non-blame, non-punitive response to error
- ability to recognise, respond to, give feedback about, and learn from, adverse events.[4]

A positive safety culture is comprised of many things, including openness, honesty, fairness and accountability. It requires strong leadership approaches that build and drive safety by encouraging the reporting of incidents and safety hazards. It supports opportunities for safety training and preparedness. It promotes understanding, learning and improvement. It requires flexibility and resilience, so that people, unexpected situations and priorities can be managed in a timely and effective manner.[22] It promotes person-centred care and partnering with consumers.

The World Health Organisation (WHO) states:

'all reporting and learning systems, whether large or small scale, must create first a positive culture in which reports are encouraged and valued, and staff are praised for participating.' [23]

All staff are responsible for identifying and reporting incidents. Most incidents are identified at the time; however, some may be identified later after the event. Sources of identification can be through complaints, media, audits, morbidity and mortality committee meetings, safety committees and through general discussion. **If incidents are NOT reported, learnings cannot be made and there is a high chance of a recurrence.**

Occasionally, clinicians will indicate that there is no need to analyse an incident because they believe that the harm resulted from a known complication. It is important to understand that with advances in care some complications will, over time, become preventable and, therefore, classified as patient safety incidents. Furthermore, clinical incidents that are coupled with complications and without conducting an incident analysis, opportunities for learning and improvement may be lost.

An organisation with a blame culture, is detrimental to patient safety and creates stressors on staff who may feel undervalued, unable to intervene to improve safety and most importantly likely to avoid reporting or involvement for fear of repercussions. A fear of blame is a principle reason for not reporting incidents.

The incident analysis process is most effective when it is conducted within a mature safety culture that has been established and underpinned by a restorative just culture. These types of cultures are largely based on an organisation *'possessing a collective understanding of where the line should be drawn between blameless and blameworthy actions.'* [2] Differences are drawn between actions of intent, recklessness and those of unforeseen circumstances or complications of care.

Culture cannot be implemented solely based on policy or procedure; rather, it needs to be consistently fostered over time and by example, at all levels in the organisation. Ultimately, everyone in the organisation has a role in helping to build and maintain a safety culture.

A just culture approach

A just culture is a culture of trust, fairness, learning, and accountability that asks the question "what went wrong?" **not** "who caused it?".[24] A Just culture has its origin in the aviation industry in 1980s, when the first fully developed theory of a just culture was published in James Reason's 1997 book, *Managing the Risks of Organizational Accidents*.[25] This concept was then applied by David Marx into the healthcare setting in 2001.[26]

In contrast to a blame culture, a just culture aims to create an atmosphere of trust and encourages the reporting of incidents and hazards by all, to help the organisation learn from the incident. Honest mistakes are seen as learning opportunities for the organisation and the employees.[27]

The just culture concept is related to systems thinking which purports that incidents/accidents are generally the result of system errors rather than an individual directly involved or responsible. It recognises that individual clinicians should not be held accountable for system failures, over which they have no control; however, it holds individuals accountable for willful misconduct or gross negligence.[24,25]

Whilst investigators principally attempt to understand why system failings occurred, many just culture models worked to firstly consider what went wrong in retributive terms, by asking questions of human behaviour (errors/slips, at risk behaviour or recklessness); a backward looking accountability.[24] Evidence of patient safety has shown that individual acts are responsible for only a very small minority of the incidents that occur. [28]

Handy tip

The United Kingdom, National Health Service (NHS) has incorporated the Clinical Incident Decision Tree into the Just Culture Guide. This guide moves away from asking 'Who was to blame?' to asking, 'Why did the individual act in this way?' when things went wrong.

It should help health service managers and senior clinicians decide what, if any, management actions are required for staff involved in a serious patient safety incident and promote fair and consistent treatment of staff within and between health services.

The NHS Guide has been adapted for use in Queensland Health as A just culture approach.

Refer to Appendix C (A just culture approach)

Applying a Restorative Just Culture (RJC)

Moving from a just culture to create a restorative just culture is an approach that replaces the backward-looking accountability, with an aim to repair trust and relationships damaged or hurt after an incident. A RJC creates a healing, learning and improving approach.[29] It has been defined as *"a process where all stakeholders affected by the injustice have an opportunity to discuss how they have been affected by the injustice and to decide what should be done to repair the harm"*. It asks three questions:

- Who has been hurt?
- What are their needs?
- Who should meet those needs? [30]

The process emphasises the importance of participation by those who have a direct stake in the event to tell their story; this is a powerful way to share their experience with others, to empower them and be involved in review process. Acknowledging who is hurt and what their needs are, is the first step towards becoming truly 'just'.

The following summary provides a comparison between a Just Culture and a Restorative Just Culture.

Just Culture	Restorative Just Culture
Which rule was broken?	Who is impacted?
How bad was that breach?	What do they need?
What should the consequences be?	Whose obligation is it to meet that need?
Accountability	**Accountability**
Account is settled, paid	Account is told, honest story
Backward-looking accountability	Forward-looking accountability
Who is responsible?	What is responsible?

What are the goals of a restorative just culture?

Meeting all the following goals is essential to supporting a just culture:

- moral engagement – all parties are engaged in considering the right thing to do now
- emotional healing – helps cope with feelings of guilt, humiliation; offers empathy
- reintegrating practitioner – does what is needed to get person back into their job
- organisational learning – explores and addresses systemic causes of harm.[30]

Access to: Sidney Dekker's Restorative Just Culture checklist

The restorative just culture framework (Appendix D) identifies as part of a restorative just culture framework, the various groups that can be hurt following an incident; the first and second victims, the organisation and the community.

Key concepts

This Guide directs our thinking beyond the linear representation of patient safety incident analysis of Safety I, by emphasising concepts related to Safety II, systems thinking, human factors and complexity, within the different system levels. It is important to understand the difference between simple, complicated and complex systems for a deeper awareness of how clinical incidents occur in healthcare to enable the development of improvement strategies.

Safety I and Safety II

The Safety I approach places clinical incidents as the focus point and aims to identify the causes of adverse events, while Safety II aims to understand how things usually go right and this forms the basis for explaining how things go wrong. Safety II approaches aim to complement, not replace Safety I. It assumes that the system's ability to respond and adapt to varying conditions, allows for things going right. Looking at the work environment and Work-As-Done rather than Work-As-Imagined, shows the flexibility and adaptiveness of people within the system; this variability is necessary for the system to function; human variability.[31]

Table 2 shows the difference between the Safety I and Safety II concepts.[8]

Table 2. Safety I and Safety II concepts

	Safety I	Safety II
Definition of safety	That as few things as possible go wrong.	That as many things as possible go right.
Safety management principle	Reactive, respond when something happens or is categorised as an unacceptable risk.	Proactive, continuously trying to anticipate developments and events.
View of the human factor in safety management	Humans are predominantly seen as a liability or hazard. They are a problem to be fixed	Humans are seen as a resource necessary for system flexibility and resilience. They provide flexible solutions to many potential problems.
Accident investigation	Accidents are caused by failures and malfunctions. The purpose of an investigation is to identify the causes.	Things basically happen in the same way, regardless of the outcome. The purpose of an investigation is to understand how things usually go right as a basis for explaining how things occasionally go wrong.
Risk assessment	Accidents are caused by failures and malfunctions. The purpose of an investigation is to identify causes and contributory factors.	To understand the conditions where performance variability can become difficult or impossible to monitor and control.

System

A system is an interconnected set of elements that is coherently organised in a way that achieves something; it consists of elements, interconnections and a function or purpose.[32] Systems can be generally classified in two categories: mechanical (e.g. cars, planes) or adaptive (e.g. organisms or organisations). Mechanical systems have a high degree of predictability and are easier to control because they respond consistently to the same stimulus. Adaptive systems have a low degree of predictability because all parts of the system do not respond in the same way to the same stimulus. When adaptive systems are also complex, there is an additional factor that decreases predictability—one individual's actions can change the context for other individuals working within the system.[33] This can be either helpful or harmful. It can be helpful because different responses and changes in context generate innovative approaches and better solutions. It can also be harmful because this unpredictability increases variation and thus the potential for harm. Health care is a complex adaptive system due to the large number of interacting services and is adaptive in that the system is able to self-organise and learn.[34]

System thinking and human factors (ergonomics)

At its core, the science of human factors examines how humans interact with the world around them. It can help determine how and why things go wrong. Human factors science draws upon applied research in many areas, such as biomechanics, kinesiology, physiology and cognitive science, to define the parameters and constraints that influence human performance. This specialised knowledge is used to design efficient, human-centred processes to improve reliability and safety. Because systems-thinking and human factors impacts all levels of patient safety incident management, these concepts have been integrated throughout the Guide in addition to a brief overview here.

Historically, when an incident occurred, the tendency was to look for the most obvious explanation of what and why it happened. In most cases, individual human error was identified as the cause, primarily because it was easy to identify and appeared to be easy to fix.[35] This approach ignored the underlying contributing factors that led to the incident and thus presented a shallow analysis of the circumstances. The outcome of such an analysis may have included the creation of new policies/procedures, additional training, disciplinary actions and/or an expectation of increased personal vigilance. The focus was almost exclusively directed at improving individual performance and as a result, this approach was likely unsuccessful in preventing the same or similar incident from occurring again.

Patient safety experts now strongly advocate for a way of thinking that views human error as a symptom of broader issues within a poorly designed system, such as an adverse physical or organisational environment. Dekker [36] refers to an old and new view of human error. In the old view, the objective is to find the individual's inaccurate assessments, wrong decisions and bad judgement. In the new view, the objective is not to find where the person went wrong, but instead assess the individual's actions within the context of the circumstances at the time. A deeper inquiry into the circumstances will yield system-based contributing factors.

Finding contributing factors that are embedded in flawed systems requires targeted strategies. Knowledge of the human factors involved is both useful and important when asking questions during the incident analysis process and can help the analysis team focus on issues related to systems and not on individual performance. An effective incident analysis always incorporates human factors.

Human factors or ergonomics are scientific disciplines concerned with: *"the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimize human well-being and overall system performance"*.[37]

Taking a human factors approach means that when safety incidents occur, it is important to have a non-punitive culture. Instead of blaming individuals for events, the systems approach focuses on:

- building systems to reduce potential risks and prevent future errors
- building system defences to reduce the likelihood of errors resulting in patient harm.

The overall human factors philosophy is that the system should be designed to support the work of people, rather than designing systems to which people must adapt.[38]

Because systems-thinking and human factors impacts all levels of patient safety incident management, these concepts have been integrated throughout this Guide and depict a non-linear approach that includes the consideration of 'categories of factors types' such as:

- patient factors
- task factors including technology
- team factors
- individual (staff) factors
- work environment factors (equipment, devices)
- organisational and management factors
- external factors (Government, National, International, economic and regulatory, other organisations).

Complexity

Complexity refers to the density of interactions between different components in a system and which produce roles and behaviours that emerge from those interactions. [39] Complexity science suggests that errors, threats to safety and accidents are not caused by any one thing, as in a conventional Root Cause Analysis, but emerge from the non-linear interactions of all components.[40]

Complex systems are characterised by features that may operate in patterned ways, but the interactions within them are continually changing. With complex systems, there is a low level of agreement on the outcomes or processes because situations involve multiple individuals or processes and there is a high degree of heterogeneity among them (e.g. different departments are involved). In addition, teams may self-organise around areas of competence, making relationships and resulting interactions even more fluid. The process for transferring a critically ill patient between facilities or an error with a blood transfusion involving labelling, in a pressurised environment with electronic systems, would be an example of a complex system.

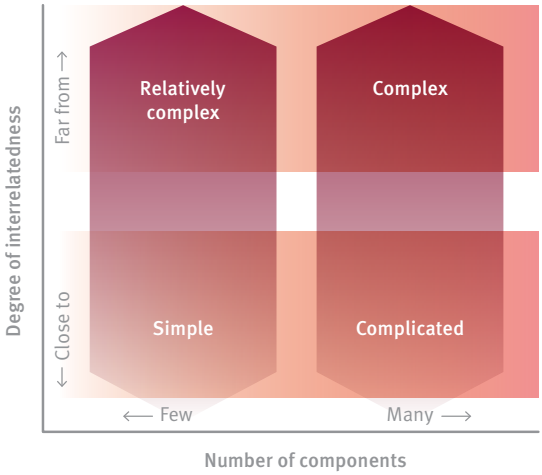
Complicated systems have many moving parts or tasks in a process, there are many possible interactions, but they operate in a patterned way. It is possible to make accurate predictions about how a complicated system will behave. They generally involve several individuals, often from different professions. The patient admission process would be an example of a complicated system.

Simple systems contain few interactions and are extremely predictable. The same action produces the same result every time. There is also a high degree of agreement on outcomes and processes. The process for obtaining a blood sample via venipuncture would be an example of a simple system.

Handy tip

In clinical incident analysis, complexity should be considered when selecting an incident analysis method, analysing contributing factors and building recommendations. The degree of interconnectedness and the relationships between the different parts of the system also help to differentiate complicated and complex scenarios. In a complicated scenario the relationships can be simulated and clarified (which increases the predictability), while in a complex system or situation this is not possible because the elements are not stable—they interact and influence each other continuously (making predictability impossible). See Figure 3 matrix for considering the distinctions.

Figure 3. Complex, complicated, simple systems matrix [39]



Sphere of influence

Sphere of influence refers to the number and strength of interconnections between the parts of the system.[41] A particular contributing factor could be influenced by any number of other factors. For instance, an incident may result from the failure to safely transfer a patient from a bed to a wheelchair. One contributing factor may be that the hoist used to facilitate the patient transfer is new to the service area. Another contributing factor may be that training did not occur before the hoist was put into operation. In this case, the lack of training and the new hoist influenced one another.

Additional contributing factors may be the unavailability of a trainer from the supplier and that the hoist was moved into service sooner than planned to replace another unserviceable hoist device. All of these factors (new hoist, no training, no training available from the supplier and the urgent replacement of an unserviceable hoist) when taken together, create a confluence of factors that acted upon one another and contributed to the incident.

In clinical incident analysis, the sphere of influence should be considered when analysing and prioritising contributing factors, especially when using the constellation diagram.

The concept of sphere of influence is demonstrated in the analysis of incidents with the use of a constellation diagram. The constellation diagram helps those responsible for analysis to visualise the incident and factors that contributed to the incident (explained in detail in Appendix E Creating a constellation diagram). The sphere of influence is visualised by connecting the contributing factors that influence one another. It is not intended to be linear in its representation. This step will support understanding of how a particular grouping of contributing factors, acting upon or in connection with one another, combined to produce a specific incident that may prove problematic for other patients in similar circumstances if not addressed.

In a complex incident, where elements constantly interact and influence each other, the constellation diagram and contributing factors identified should be considered a snapshot of the incident and the context. The role of the analysis team is to develop recommended actions to address the identified local factors. Based on this snapshot view, decision makers and leaders of the organisation need to identify and act on findings that affect the organisation as a whole.

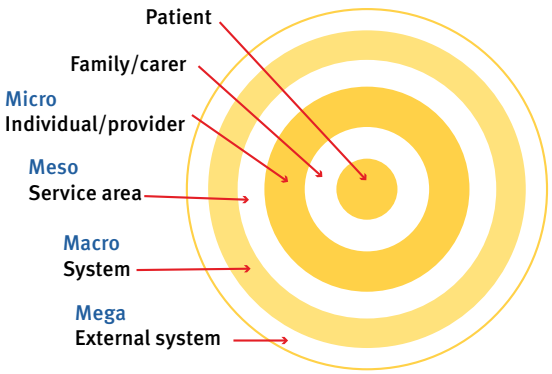
System levels

Systems are generally viewed from various levels (stratification) because there are differences in goals, structures and ways of working in different parts of the organisation. There is general agreement that the following four levels (three internal and one external to the organisation) are representative of most systems.[42] See Figure 4.

- **Micro**—the point where the care clinicians interact with the patient (e.g. clinical team or service area that provides care).
- **Meso**—the level responsible for service areas/clinical programs providing care for a similar group of patients, typically part of a larger organisation (e.g. a home care or a cardiac care program).
- **Macro**—the highest (strategic) level of the system, an umbrella including all intersecting areas, departments, clinicians and staff (e.g. boards, healthcare network, integrated health system or region that includes several organisations).
- **Mega (external)**—the level outside the organisational boundaries that influences

the behaviour or more than one system. The different sectors of healthcare such as regulatory bodies, licensing organisations, professional groups, liability protection providers, state and federal governments, national patient safety and quality organisations, the healthcare industry and the community all fall into this category.

Figure 4. System levels



Handy tip

In analysis, system levels should be considered when selecting the method of analysis, analysing contributing factors, or prioritising recommended actions. It is important to maintain focus on the level where activities will predominately take place and how that level is connected with (or influences) the neighbouring levels.

Context

Context is defined as the interrelated conditions in which something exists or occurs—environment setting.[43] Context can include a combination of relevant internal and external conditions [44] specific to the incident and system that influence the incident analysis process.

When conducting the analysis or managing the incident, teams need to consider internal factors, such as pressures and priorities generated from any of the following:

- incident data (historical reports or recommendations/actions) from the internal reporting system, patient complaints, accreditation reports, insurance claims, civil litigation, etc
- short and long-term strategic priorities and action plans
- resources available (human and financial), including leadership support and coordination.

External pressures such as the following also require consideration:

- regulations, requirements, preferred practices
- evidence from literature (e.g. the risk and frequency of the incident, its impact and cost, evidence-based interventions)
- information from public patient safety reports/databases including Queensland Health Patient Safety Notifications: https://qheps.health.qld.gov.au/psu/alerts/alerts
- anticipated demands from patients, public, media and other stakeholders.

In clinical incident analysis, context should be considered when selecting a method of analysis, analysing contributing factors and prioritising recommended actions.

Without a good understanding of the context, clinical incident analysis may not have the desired impact because the recommendations generated are not crafted to fit the reality of the organisation. To accurately understand the context, the involvement of organisational leadership is essential.

Step 2: Immediate response

- Care for and support patient, family, clinicians, & others
- Report incident
- Secure items
- Begin disclosure process
- Reduce risk of imminent recurrence

Care for and support of patient, family, carer, clinicians and others

A clinical incident can be a very traumatic experience for the patient, their families or carers and clinicians involved. Generally, the first action after recognising that an incident has occurred is to care for and support the patient and the family, as well as ensuring the safety of other patients who may be at risk.

Attending to the safety and wellbeing of the clinician/s involved and others (second victims) is also a necessity.[2] Incidents have the capacity to have lasting effects on all those involved including the organisation. It is essential that the hurts, needs and obligations are discussed with all parties.[30] In a restorative just culture, when a serious adverse incident occurs, it is expected the senior leaders would attend the scene immediately for support.

Report incident

While each situation will be different and guided by individual organisation policies and practices, the next activity after providing support to those involved generally includes reporting the incident so that further steps can be taken to manage the incident. All staff are responsible for identifying and reporting incidents in a non-punitive environment. In Queensland Health, this involves recording the details of the incident in the incident management system, RiskMan. Incidents with a high potential for harm to the patient, staff or reputation of the organisation should also reported verbally as part of the immediate response. See the Immediate response checklist and action plan. Timely reporting assists in understanding the next steps, such as whether further analysis is needed, and/or whether additional resources and other actions, such as further notifications are required. The appropriate manager or other recipient of the report will, at a minimum, analyse the facts of the incident and gather any additional information to ensure a preliminary understanding of what happened. Any contributing factors identifiable at this point will also be documented.

Reporting is the trigger for a chain of internal notifications that, depending on the nature of the incident, will target individuals and/or units at different levels of the organisation (e.g. attending chief executive officer, risk management committee, medical managers, health record staff, unit or program managers, public relations). External notifications may also be required to ensure alignment with regulations and to maintain the organisation's reputation as per legislation, policy, protocols (e.g. State Coroner, Department of Health) and current context (e.g. media). Effective, timely and respectful internal and external communication can result in increased trust of all stakeholders, including the public. It is recommended that organisations develop internal guidelines for this purpose. For serious adverse incidents likely to have an impact on safety, services, staff, reputation or resources, a Hot Issue Brief (HIB) to the Department of Health maybe required.

Secure items

Consider if any items/equipment related to the event need to be secured for testing and for analysis by the analysis team. Items include, but are not limited to, biomedical equipment, IV solutions, medications, packaging, garments, etc. The items should be carefully labelled (including lot numbers and serial numbers in the event of a product recall or if further testing is needed) and placed in a designated location (or given to a designated person) where they are protected, secured and access is restricted. Photographs of the items and workspace may also prove helpful. Health records in whatever format also need to be secured and access to them should be controlled. If the patient is receiving ongoing care, staff will need to have access, including to paper charts, that will need to remain with the ward or unit chart if the patient is receiving ongoing care.

Handy tip

During an analysis of an incident, it is helpful to gather materials such as equipment and any other materials used during or close to the time of the incident. Essentially, you need to review anything that may have influenced the human-system interaction during the incident and therefore may constitute a possible contributing factor. For instance, when reviewing a medication error, you would seek to make the following items available for further examination:

- medication administration record
- prescribers' order form
- medication vial or syringe labels
- IV pump
- other medical equipment used to deliver the medication.

You will need to consider the values that were written or entered into the medication record. You may also need to consider the design of the materials or equipment to see if they may have been a source of confusion. Also, it may be helpful to analyse the organisational chart, shift schedules, room or floor layout and measurements of the work environment, including room lighting or noise level.

Begin the disclosure process

Senior clinicians from the organisation should begin the disclosure process with the patient, family or carer as soon as possible after the incident (within 24 hours). Empathic and timely disclosure can help patients, family and staff deal with the consequences of a clinical incident. Throughout the disclosure process, due consideration must be given under Queensland's *Human Rights Act 2019* to undertake public functions in a principled way that places individuals at the centre of decision making and service delivery, ensuring that all have their human rights respected, protected and promoted.

Disclosure may be a one off events or is an ongoing process in which multiple disclosure conversations may occur over time, including an initial disclosure and a post analysis disclosure. Identifiable patient or staff information should only be used or disclosed with patient or staff consent, or if there is some other legislative means (for patient information refer to *Part 7, Division 2,s.145, 146 or 153 of the Hospital and Health Boards Act 2011)*. Disclosure to the community should not occur until appropriate expert advice (including legal) is sought to ensure there is no inadvertent release of private/confidential information.

There are a variety of guidelines to assist in clinician and formal open disclosure processes (roles, responsibilities, what to disclose and how):

- Patient Safety and Quality, Clinical Excellence Queensland
- Open Disclosure Guide
- Australian Commission on Safety and Quality in Healthcare

This structured open disclosure process supports the transparent discussion between the patient and the patient's family or carer, senior clinician and representatives of the health service about the clinical incident, that resulted in harm which was not reasonably expected as an outcome of the health care provided. The overarching aim of open disclosure is to ensure patients and their families or carer have a reliable, caring and effective means to receive honest and factual information about the clinical incident associated with their healthcare.[11] Importantly, empathetic and timely disclosure can help patients, families, carers and staff deal with the consequences of a clinical incident.

Handy tip

Open disclosure is comprised of two components: clinician disclosure (CD) and formal open disclosure (FOD).

Clinician disclosure is defined as an informal process where the treating clinician informs the patient/ family/carer of what has occurred, and apologises for the harm caused or adverse outcome. In general, it is used for the initial disclosure after the incident and may be all that is required for less serious events.[12]

Formal open disclosure (FOD) is the structured process to ensure communication between the patient/ family/carer, senior clinician and the organisation in response to the most serious clinical incidents. To enable this process, an open disclosure team involving members of the treating team and the organisation executive is activated prior to the meeting with the patient/family/carer. A senior clinician who is not part of the treating team and trained as an open disclosure consultant (ODC) leads this team through the FOD process. FOD involves multidisciplinary discussions that support clinical incident management processes and provides a format that facilitates and enables open communication between patients, families, carers, clinicians, senior clinical leaders and hospital executives.[12] http://qheps.health.qld.gov.au/psu/od

Health Service organisation are required to implement open disclosure as part of the Clinical Governance standard in the National Safety and Quality Health Service Standards (second edition), developed by the Australian Commission for Quality and Safety in Health Care. Open disclosure is described in Standard 1.12.

Often practical support is needed, and contacts should be provided to the patient, family, carer and clinicians so that those who may have suffered emotionally and physically can receive early assistance. Disclosure, expressions of compassion and offering an apology are important elements of communication, helping both patient, families, carers and clinicians in healing and in restoring trusting relationships.[12,13]

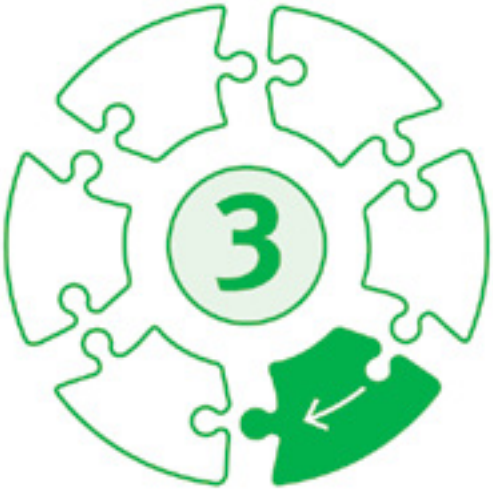
Reduce risk of imminent recurrence

Local actions to reduce the risk of imminent recurrence may need to be taken immediately; additional actions typically follow after a more thorough analysis has been undertaken. Patients, families, carers and staff should be informed of immediate actions.

Handy tip

A senior clinician should attend the scene of the incident to support the immediate response as soon as possible after the incident. They need to assess the patient and/or family, the staff involved, and any immediate issue, concerns or risks. They need to record the preliminary facts.

Step 3: Prepare for analysis



– Preliminary assessment
– Select an analysis method
– Identify the team
– Coordinate meetings
– Plan for/conduct interviews

Preliminary assessment

In order to determine appropriate follow-up to an incident, including the need for analysis, an initial assessment or preliminary fact-finding process is needed. The key outcome of this step will be a high-level sequence of events and documentation of known facts related to the incident. There will be organisational variation as to how the individuals responsible for the initial fact finding conduct this process and how the information is incorporated into the organisational response to an incident. It is recommended that individuals responsible for the preliminary assessment of clinical incidents be provided with education in incident analysis, including an introduction to systems thinking, human factors principles and other essential concepts. Staff undertaking reviews should also have access to organisational mechanisms/tools to assist with the identification of key trends in incident prevalence at the local level including any contributing factors.

Once the preliminary (or triage review) assessment phase is complete, a determination of next steps follows. In some cases, it will be clear that further system-based analysis is needed, while in others an accountability review or alternative quality improvement process may be more appropriate.

The Just Culture Approach has been adapted for Queensland Health and replaces the incident decision tree that was based on the work of Professor James Reason and the previous National Patient Safety Agency. (Appendix C) This Just Culture Approach should not be used routinely; only when there is evidence or a suspicion that an individual may require support or as part of an individual practitioner performance accountability investigation to enable constructive conversations.[45]

If based on the preliminary understanding of what happened (from incident report and initial analysis of facts) it is determined that an analysis is required, then it is usually at this point that a system-based method of analysis is determined. Three types of incident analysis are described in this guide—**comprehensive, concise and multi-incident**. Determination of the appropriate method is made using a range of criteria. This decision is usually made jointly by the manager involved, together with the quality and safety leads, the clinical leads, senior leaders and others as defined in the organisational policies and procedures. Each incident analysis method includes a systematic process to identify what, how and why the incident happened, what can be done to reduce the likelihood of recurrence and make care safer and share learnings.

Methods of incident analysis - overview

In numerous consultations with patient safety experts and those engaged in incident analysis, it became clear that one method of incident analysis is not necessarily appropriate for all types of incidents. A literature analysis and environmental scan of analysis methods confirmed the emergence of a variety of methods for clinical incidents analysis in healthcare. A range of methods is important for users, who can select the one most appropriate for their healthcare facility, context, skills, resources and type of incident. The methods included in this Guide have been designed to be flexible to accommodate use in different care settings.

This Guide offers three methods in total: there are two methods for analysing individual incidents (comprehensive and concise) and one method for multiple incidents (multi-incidents). All three methods aim to determine what happened, how and why it happened, what can be done to reduce the risk of recurrence and make care safer, and what was learned.

Regardless of the method used, the basic principles and steps in the analysis process are the same; however, the level of detail and the scope of the analysis will differ with each method. Below is a short description of each method, followed by guidance on how to select the appropriate method to analyse a particular incident or grouping of incidents.

Comprehensive analysis is usually used for complicated and complex incidents that resulted in catastrophic/major harm, or the significant risk thereof. Multiple sources of information are consulted, including interviews with those directly or indirectly involved in the incident as well as experts, supplemented by a literature analysis. A significant amount of time and resources (human and financial) can be invested to conduct the analysis. The final report produced will include a detailed sequence of events of the facts, contributing factors and their influences, findings from the literature search/ environmental scan, context analysis, recommended actions, and where applicable, implementation, evaluation and dissemination plans. Members of the senior leadership of the organisation need to be kept apprised of progress and may be directly involved in the process.

Concise analysis is a succinct, yet systematic way to analyse incidents with no, low or moderate severity of harm. Generally, the incident and analysis process is localised to the unit/program where care was delivered. The sources of information consulted are the available reports, supplemented with a small number of select interviews and a targeted analysis of other sources of information. The analysis is completed in a short interval of time by one or two individuals. At the end of the analysis, a report is produced that contains the facts (including a brief sequence of events), contributing factors, a brief context analysis and where applicable, recommended actions and plan for evaluation and dissemination.

Multi-incident analysis is a method for analysing several incidents at once instead of one by one, by grouping them in themes (in terms of composition or origin). Multi-incident analysis can be used for incidents that resulted in no, low or medium severity of harm as well as near misses that took place at any location in the organisation (possibly in a short interval of time). It can also be used to analyse a group of comprehensive and/or concise analyses. This method of analysis can generate valuable organisational and/or sector-wide learning that cannot be obtained through the other methods.

Detailed information on each of these incident analysis methods is set out in Step 4.

Selecting a method of incident analysis

The Severity Assessment Code (SAC) rating is the way patient safety events are classified in the Queensland Health public system. Refer to Appendix F (Severity assessment code (SAC) matrix).

The Patient Safety Health Service Directive requires that all SAC1 clinical incidents and analysis reports are submitted to the Patient Safety and Quality, Clinical Excellence Queensland within 90 days of being reported in RiskMan. Each analysis report must contain:

- a factual description of the event
- the factors identified as having contributed to the event
- recommendations to prevent or reduce the likelihood of a similar event happening again.

The method of analysis is a matter for local policy and need not be determined by the SAC rating alone. There are situations where an incident with a high level of harm SAC rating may be more appropriately analysed with a concise analysis and other situations where an incident with a low level of harm SAC rating requires a comprehensive analysis.

When selecting a method to analyse incidents, consider a number of criteria including:

- severity of the incident
- probability of recurrence
- complexity of the factors that appear to have influenced the incident on the organisation (unit, organisation or system)
- other contextual factors (preliminary assessment, frequency of occurrence, regulatory mandates, internal or external pressures).

In the case of near misses or incidents where the outcome is not known at the time of the analysis, the worst possible outcome should be considered. Additionally, factors such as incident analysis skills and limited resources available to analysis teams require consideration. These criteria are summarised in, Tables 3 & 4, and Appendices C (A just culture approach), F (Severity assessment code (SAC) matrix, G (Guide to level/type of analysis). See Step 1 for descriptions of complexity, area of impact and context.

Table 3. Criteria to consider in selecting an incident analysis method

Criteria	Comprehensive analysis	Concise analysis	Multi-incident analysis
Severity assessment code	SAC1 and some SAC2	SAC2 and some SAC3, SAC4	SAC1, SAC2, SAC3 and SAC4
Severity and probability *(see Table 4)*	A and some B	B and some C	A, B and C
Complexity level (degree of agreement, certainly, number of interactions)	Complicated, complex	Simple, complicated	Simple, complicated or complex
Area of impact	Team, unit / program, organisation, system	Team, unit / program, or possible organisation	Team, unit / program, or possible organisation, system, sector, industry
Context – internal and external pressures	High	Low	Low, medium or high
Resources required / available (time, financial, human)	Moderate to extensive	Limited	Moderate to extensive

Severity/probability matrix score

Table 4 below, is another type of stratification tool that links the severity of the clinical incident with its probability of recurrence. The tool applies to all incidents (harmful, no harm and near misses).

Table 4. Severity versus probability matrix[46]

Probability	Catastrophic	Major	Moderate	Minor
Frequent	A	A	B	C
Occasional	A	B	C	C
Uncommon	A	B	C	C
Remote	A	B	C	C

Key factors for the severity categories are extent of injury, length of stay, level of care required for remedy and actual or estimated physical plant costs. For harmful and no harm incidents, assign severity based on the patient's actual condition. If the event is a near miss, assign severity based on a reasonable 'worst case' system level scenario. For example, if you entered a patient's room before they were able to complete a lethal suicide attempt, the event is catastrophic, because the reasonable 'worst case' is death of the patient.

In order to assign a probability rating, it is ideal to know how often it occurs at your facility. Sometimes the data will be easily available because they are routinely tracked (e.g. falls with injury, adverse drug events, etc.). Sometimes, getting a feel for the probability of events that are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. At times it will have to be your best educated guess.[46]

It is important to note the analysis methods presented here are not mutually exclusive. For example, contributing factors derived during a concise incident analysis could also be the foundation for a comprehensive or multi-incident analysis. In the event that a comprehensive analysis was recently conducted, and a new similar incident occurs, a concise incident analysis may be sufficient to determine if any new contributing factors need to be addressed.

Level/type of analysis based on the degree of harm

There a number of triggers for review and an analysis should be conducted where appropriate to identify learning points from patient safety incidents, claims, complaints and concerns. In determining what type/level of analysis is appropriate, it is important to consider the degree of harm.

Hospital and Health Services may have their own policies on the type of review each SAC rating requires, and may stipulate the associated reporting requirements.

There may be situations where a clinical incident with a low level of harm SAC rating requires a comprehensive analysis based on the level of risk. When considering if an analysis is required there a number of criteria to consider including:

- severity of incident
- probability of recurrence
- complexity of the factors that influenced the incident
- other contextual factors (preliminary assessment, frequency of occurrence, regulatory mandates, internal or external pressures).

Appendix G (Guide to level/type of analysis) provides suggestions on what might be considered the appropriate the level/type of analysis required for a clinical incident based upon the degree of harm and assessed risk.

Identify the team and the team approach

Typically, an analysis team facilitator (with expertise in analysis such as the patient safety officer or equivalent) and an executive leader (with operational responsibility such as the Service Executive Director who understands and supports the analysis) share primary responsibility for conducting, coordinating and reporting on each analysis in accordance with applicable organisational policies. Decisions about the involvement and timing of involvement of various individuals are likely to vary from organisation to organisation and will be influenced by the incident context, as well as local culture and previous experience. In considering the involvement of various individuals, it is important to clearly define the roles and responsibilities of everyone who will participate in the analysis process.

Not all team members are required to be involved in all aspects of the analysis. For example, clinicians directly involved and patients/family/carers may participate in the information gathering stage and provide further input into solution development. Other direct care staff may participate in the actual analysis stage. Senior leadership representatives may actively participate in the analysis or support the process at arms length. Support and involvement of senior operational leaders in the analysis process helps to demonstrate a commitment to change at the highest levels of the organisation and also helps to ensure that recommended actions are developed within the context of the broader organisation. It is also useful to involve relevant external experts/consultants with specialised knowledge of the system undergoing analysis and/or the analytical process (especially for comprehensive analyses). For additional detail on team roles and management, see Appendix A (Analysis team membership, roles and responsibilities).

Handy tip

The analysis team is the group charged with incident analysis. Refer to Appendix H (Sample analysis team charter). Other individuals may be involved in the analysis process (e.g. through interviews, meetings, fact finding and/or consultations).

The team composition will vary depending on the incident and applicable legislative protection as well as on the organisation's approach to analysis (e.g. one individual may conduct interviews and fact finding then bring the group together to confirm and gain consensus on facts, contributing factors, recommended actions, or the entire process may be a team effort).

The success of the analysis depends on the involvement of those who provided care as well as the patient or family. There may be a number of staff and/or agencies who will have the responsibility for reviewing clinical incidents that occurred during a during a patient's journey across multiple health organisations and/or services. The process of engaging the key stakeholders is referred to in this Guide as a multi-agency review.

A multi-agency review may be indicated when a clinical incident occurs during a patient's journey across a number of health organisations, health providers and/or retrieval services. The complexity associated with different transitions in care may have contributed to an adverse outcome for the patient. An investigation into a clinical incident which involves more than one site, service or stakeholder is considered a multi-agency review.

Considerations relating to the patient/family/carer may also include ensuring they have the time needed to emotionally process what has happened or an immediate need to make care or funeral arrangements, the patient and/or family/carer may not be ready and/or able to be involved in the analysis.

Being respectful of the needs of the patient/ family/carer and keeping the lines of communication open may enable their participation at a later time. The same can be said of healthcare workers who were directly involved in the incident. However, it is essential that the patient/family/carers, involved healthcare workers and their relevant healthcare agency be part of the initial process of information gathering.

The key benefits are:

- An open and sincere partnership with all involved in the incident can result in healing relationships, regaining trust in each other and the system, and improving the wellbeing of all participants.
- When the team comes together, they may discover new information not previously known by all members of the care team.
- Analysis is an invaluable method that permits those involved in an incident an opportunity to help reveal information that may lead to solutions to make care safer. This allows all involved to impact the system they work in and to take ownership of changes, rather than feeling that changes are forced upon them.

Handy tip

There are several types of analysis teams:

- External—all team members are from outside the organisation.
- Internal—all members of the team are employed by the organisation.
- Internal with external support—most are internal staff, and few are external members..

The context and circumstances surrounding each incident are different and careful consideration should be given to all relevant factors before deciding on how to approach the analysis. It is important that organisations proactively develop a plan on how to approach the analysis that will help teams respond quickly and effectively when an incident occurs.

Analysis involving internal teams working collaboratively with internal and/or external experts (multi-agency review) are beneficial to the culture of the organisation as well as in rebuilding trust.

Coordinate meetings

It is common for an analysis facilitator to collaborate with the analysis executive team leader to conduct background work and collect the necessary information for the analysis (e.g. health record, sequence of events, relevant policies and procedures, evidence-based guidelines, etc.). The full analysis team is convened at a mutually agreeable date and time. It is recommended that all documentation provided to the team during meetings, include the sequence of events should be tracked and returned to the facilitator at the end of the analysis.

An experienced facilitator will be able to anticipate and manage issues that arise during the analysis process. Keys to success include providing a comfortable, private setting (ideally away from the care area where the incident occurred), setting ground rules for discussions and ensuring necessary information is readily accessible.

Some suggested ground rules include the following:

- respect for individuals
- respect for opinions expressed
- equal participation by all
- respect for confidentiality of the discussions
- ask questions to clarify rather than challenging others
- decisions by consensus.

A checklist can help the analysis facilitators to prepare for and manage meetings effectively. Refer to Appendix I (Team management checklist) for further information.

Plan for and conduct interviews

Interviews are key to collecting information for analysis and also help to support those directly involved in the incident. An interview is often the first opportunity that a patient/ family/carer or healthcare clinician has to share their detailed perspective about the incident. The interview process may cause anxiety and further distress—therefore it is important to be respectful and supportive of those involved and be clear about the purpose of the interview and what will be done with the information provided.

Interviews should be conducted as soon as reasonably possible after the incident for two reasons. Firstly, memories fade quickly and important details may be lost over time. Secondly, as individuals involved in the incident discuss their recollections with one another, versions may blur together and the opportunity to obtain unique perspectives and details may be missed.

It is recommended that individual interviews occur with all staff involved in the incident as well as individual or group interviews with the patient and family members as appropriate. A cooperative approach is encouraged, using open-ended questions. Individuals should be asked to 'tell their story' and possibly re-enact the incident or portions of the incident. If possible, do not interrupt while the interviewee is telling their story as this increases the likelihood that parts of the story may be missed. Instead hold the questions and further clarification until the story has been told. It is helpful to ask individuals being interviewed if there are any factors they think contributed to the incident (e.g. environmental factors such as lighting, noise levels, time of the day, workload etc.) as well as factors they feel mitigated the outcome of the incident (e.g. what went well).

It is important to record the interview in a comfortable way, noting that video or audio recording can increase anxiety for the interviewee and are not generally recommended. You will also need to ensure that you seek the interviewee's permission to record the interview.

It is preferred that interviews be conducted one person at a time so that individual perspectives about the incident are well understood for their nuances and unique points of view. Interviewers should provide information about the analysis process and encourage further follow-up if the interviewee recalls any other details, they feel are important to understanding the incident after the interview has been completed.

Finally, sincerely thank people for helping to provide an understanding of the incident and ensure their questions about the process are answered before drawing the interview to a close.

Some further guidelines that can be used or adapted by organisations are included in Appendix J Investigative interview guidance (cognitive type interview).

Handy tip

A common problem with any type of analysis is the failure to establish all the facts. Good witness interviews will help answer the questions:

- What should happen?
- What usually happens?
- What happened in this case?
- What is the variance?

Make sure

Before commencing interviews, the investigator must explain in precise detail the limits on confidentiality, what access mechanisms apply and what protections (if any) apply to staff who give a statement and whether they have the option to decline to participate if they consider they will be exposed to action.

Avoiding cognitive traps

Cognitive biases are implicit mechanisms that influence reasoning and decision making [47] and as a result, impact the analysis process. Bias can influence the team in a number of ways, resulting in the following:[48]

- oversimplification of what contributed to the outcome
- overestimation of the likelihood of the outcome
- overrating the significance of some factors and actions
- misjudging the prominence or relevance of facts/data
- premature completion of the analysis process
- overconfidence in interpretation of known information.

Awareness of bias needs to be cultivated in those leading and participating in the analysis and every effort should be made to recognise and reduce the influence of bias. One approach to reducing bias is to include people and/or consumer representatives on the analysis team who are not aware of the details of the incident under analysis, or who are naïve to the processes involved. Another is for all participants to be encouraged to listen actively to the contributions of each team member and avoid jumping to conclusions. Additional techniques include the use of guiding questions (Appendix J) and the constellation diagram (Appendix E) as decision aids— these tools will help the team to explore multiple categories of contributing factors and understand their interconnections. Using a combination of different approaches is encouraged.

Rarely are all of the important contributing factors immediately known and as a result, often the initial perceptions are found to be incorrect once a more thorough analysis that considers the whole system (work environment, organisation, context) has been undertaken.[49] Identifying and addressing potential biases in the analysis supports a just and safe culture and a learning environment.

Step 4: Analysis process

– Understand what happened
– Determine how and why it happened
– Develop and manage recommended actions

This Guide offers three methods total: two methods for analysing individual incidents (comprehensive and concise) are included along with another method suitable for review of multiple incidents (multi-incidents). All methods aim to determine what happened, how and why it happened, what can be done to reduce the risk of recurrence and make care safer and what was learned.

Regardless of the method used, the basic principles and steps in the analysis process are the same; however, the level of detail and the scope of the analysis will differ with each method. This section sets out each analysis method in detail. In summary, the following methods to be discussed are:

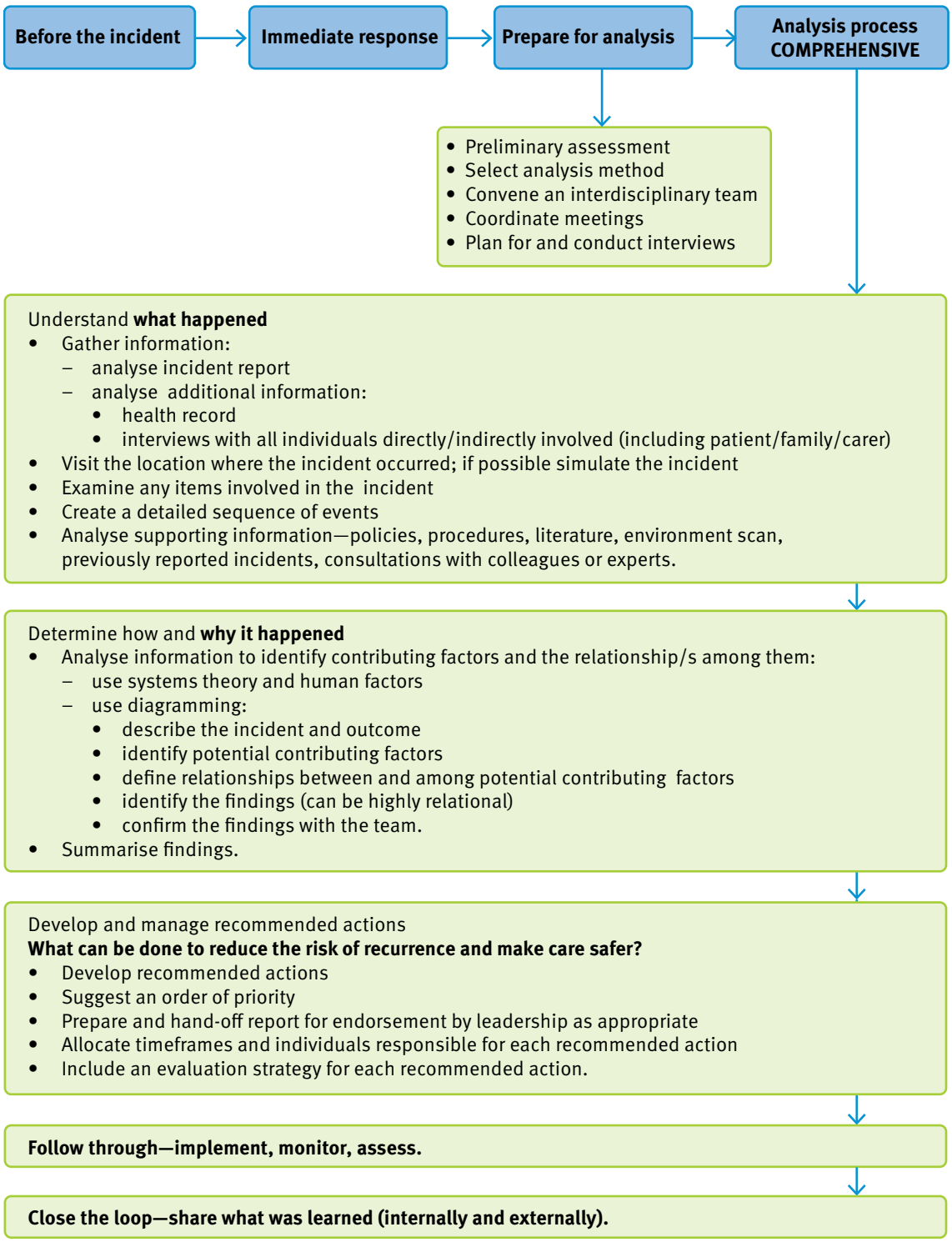
- comprehensive analysis
- concise analysis
- multi-incident analysis.

For each of the analysis methods, there are a range of different tools/templates available; a comprehensive analysis can be conducted with a RCA, London Protocol and the Human Error and Patient Safety (HEAPS). Of these, there are more than 40 RCA techniques described in the literature. The London Protocol and HEAPS have been modified by different agencies to suit their requirements. Individual facilities have designed their own concise analysis templates.

Comprehensive analysis

A comprehensive, or detailed analysis of a single incident is generally undertaken when permanent harm or death has occurred (or a significant risk thereof), the incident is complicated or complex, the area impacted is at micro, meso, or macro level, and/or the contextual pressures are high. See Appendix K (Case study-comprehensive analysis: resident absconds from a residential aged care facility) and Figure 5 below for the flow diagram.

Figure 5. Flow diagram for comprehensive analysis



Steps in conducting a comprehensive analysis

What happened?

Gathering information

The team's first priority is to gather information relevant to the incident. This stage of the process is intended to answer the 'what happened?' question and will begin to elucidate how the incident occurred. The importance of a thorough information gathering phase cannot be over-emphasised. The team cannot proceed to understand the contributing factors related to the incident if they do not have a clear understanding of the circumstances surrounding the incident. A systematic process for assessing information needs and gathering information will help to ensure that the analysis is both thorough and credible. It may be helpful for organisations to develop a template or checklist to help the facilitator prepare information for analysis by the team.

Handy tip

An analysis team should:

- analyse and interpret all sources of documented evidence
- if able, interview patient/family/carer
- identify and interview all relevant staff
- visit the physical area where the incident occurred
- inspect equipment/tools
- take photos
- analyse evidence of policies, procedures, standards and relevant literature
- have relevant evidence of trigger questions within the analysis
- if indicated, must identify and interview experts and seek external opinion/s.

Analyse incident report

The incident report is typically the first formal summary of information related to an incident and is based on an initial understanding of the facts. Analysis of information provided in the incident report will direct the preliminary analysis approach. Other sources of information that may trigger the initiation of a comprehensive analysis include patient concerns, information identified with the use of trigger tools, audits, attention from the media/ general public or coroner's reports.

Analyse additional information

In addition to gathering and analysing the health record in detail, it is important to interview all clinicians and others who were directly or indirectly involved in the incident, including the patient/ family/carer. Where possible, it is recommended that the team visit the location where the incident occurred. When a physical visit is not possible, photographs and videos are recommended. During the visit, important details or other contributing factors that people did not remember or did not recognise as important can be identified. Items that may have been involved in the incident (e.g. syringes, labels, devices, medications) need to be secured at the time the incident is identified. If the original items are not available the team should be given access to similar appropriate items to assist them to understand what, how and why it happened.

Create a detailed sequence of events

When all the information is gathered and analysed, the team should be able to fill in identified gaps in the initial understanding of the incident provided by the incident report or other triggering mechanism, and then create a detailed sequence of events. It is common to provide this information in the form of a narrative sequence of events description. (Refer to Appendix K case study). The detailed understanding will enable collation of the information from various sources, including the health record and interviews with key individuals. As the care of the patient after the incident may be relevant to mitigation of harm from the incident, it is appropriate to include details related to patient management once the incident was discovered.

Because the team will use the detailed sequence of events as a starting point for identifying system- based factors underlying the incident, it is crucial that the sequence of events include only the actual facts or processes as they occurred, and not what was supposed to happen. The detailed understanding of the incident is nearly always different from the initial information available, reinforcing the importance of fully investigating the circumstances of an incident designated for comprehensive analysis.

Handy tip

The detailed sequence of events should show the comprehensive sequence of events—presenting facts without speculation. Include key objective data including signs and symptoms, clinical assessments, analysis results, treatment provided and evaluation of progress.

Do not include entries which have information that is not relevant to the incident.

Analyse supporting information

An incident analysis should prompt the team to analyse existing policies and procedures. This is important for two reasons—firstly, it establishes the documented organisational expectations related to care; and secondly, it provides a baseline to evaluate current organisational practices in relation to current evidence and leading practice guidelines.

An environmental scan of current practices in similar organisations and a literature analysis (scope will vary depending on the incident) will help to provide context for the incident as well as determine if there are any leading practices or evidence-based guidelines relevant to the incident.

Previous similar incidents or near misses (reported internally or by other organisations) may also be identified. Incident descriptions and information about actions taken and challenges encountered by other organisations that have dealt with similar issues can assist the team in understanding contributing factors and developing recommended actions. It is suggested that as part of this process that you also review statewide Patient Safety Alerts and Advisories as well as national and international generated alerts to inform your information base.

Sometimes, unique incidents have no literature citations available. In these cases, consultation with the Patient Safety and Quality, Clinical Excellence Queensland may help determine if the issue in question has been previously observed in practice, but not published.

How and why it happened

As the team begins to understand the circumstances of the incident, contributing factors and relationships will begin to emerge. A series of investigative categories and guiding questions (refer to Appendix L Incident analysis guiding questions) have been adapted from work by international experts in incident analysis [49,50,51,52] to provide a starting point for analysis and assist teams to ensure all relevant aspects of the incident have been analysed in detail during the interviews and the analysis phase. This portion of the analysis is about answering the 'how and why it happened?' question.

The focus at this point is to recognise any related system issues that may have contributed to the incident. While it is human nature to identify factors at the intersection between the patient and clinician (e.g. the micro level), the goal of the analysis is to move the team towards the meso, macro and mega levels of the system (e.g. processes, policies, environment) to ensure all the contributing factors are identified.

During this phase of the analysis, the team will need to ask questions such as, 'what was this influenced by?' and 'what else affected the circumstances?' The team will use the detailed sequence of events of the incident, supported by the principles of systems and human factors theory, to answer these questions in order to identify the contributing factors.

Handy tip

The analysis team must define the real problem to be eliminated to prevent a similar incident occurring again. The problem statement is best constructed as a short verb, noun statement. Effective problem resolution begins with agreeing upon a definition of the problem. For example, Problem statement: Patient fractured his hip.

Use systems theory and human factors

There has been a major change in patient safety culture and thinking about incident causation in the health system in the last 20 years with the application of systems theory and human factors. Applying systems theory and the principles of human factors can assist in answering the above questions by focusing the analysis on the system-based contributing factors. In particular, human factors provide the tools, methods and theories to approach these questions. The goal when applying human factors is to focus not just on the human or the system alone, but rather the interaction between the human and the system, and to look for the factors that influence that interaction. These influencing factors may be related to the equipment, the task and the work environment, in addition to inherent human characteristics and limitations.

Various human factors methods can be employed at this stage of the analysis process to help answer the question, 'how and why it happened?'. They range in complexity, time and resources needed and expertise/ experience in human factors required. Three methods are described in Appendix M (Three human factors methods that can be used in incident analysis); cognitive walkthrough, heuristic evaluation and usability testing. All three methods assist in examining the human system interaction in detail.

- With cognitive walkthrough, the easiest and most cost effective method to employ is to ask participants to 'think out loud' while simulating the tasks that were involved in the incident.
- In a heuristic evaluation, an audit is carried out on the various parts of the system (such as equipment, paper forms, and computer systems) that were used in the tasks that were part of the incident. The audit is used to determine if human factors design principles were violated and as such, may be identified as possible contributing factors in the incident. Heuristic evaluation requires an understanding of human factor principles as they apply to different systems (e.g. computer systems).
- Usability testing provides an observation of the human system interaction with equipment, paperwork, or process (similar to a simulation). Participants are asked to carry out a set of tasks in a simulated environment and given the scenario as it occurred during the incident. Some level of human factors training is needed in order to plan and execute usability tests, and to interpret the results. If conducted correctly, the usability test provides important information about how the human system interaction occurs in the real-world setting.

Using diagramming

One tool that can assist the team to work through the questioning process is the use of diagramming. Diagrams can help teams to identify and understand the interrelationships between and among contributing factors. Diagramming shifts the focus away from individual performance, towards system performance and underlying factors, helping to clarify team understanding and ensuring a thorough analysis of the incident.

Ishikawa, also called Fishbone, (Figure 6) and Tree diagrams (Figure 7) are utilised to support analysis, however both these types of diagrams have limitations.[53,54] Ishikawa diagrams are helpful for brainstorming and clustering factors, but do not easily illustrate complex relationships between factors. Tree diagrams have been perceived as too linear and their top-down approach can be misleading in terms of relative importance of identified contributing factors.

Figure 6. Ishikawa diagram

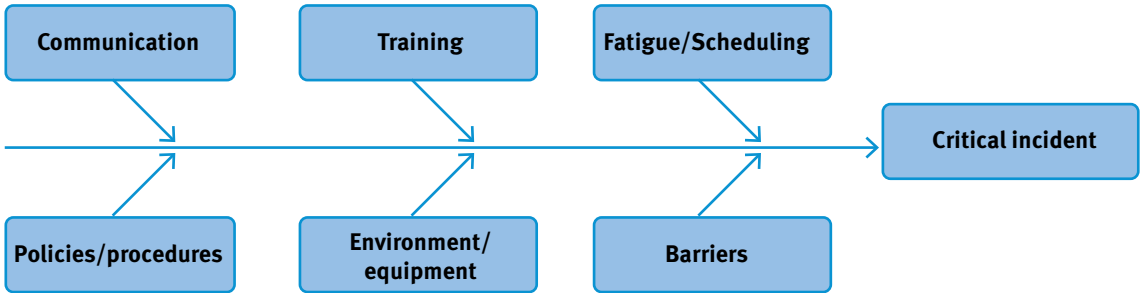
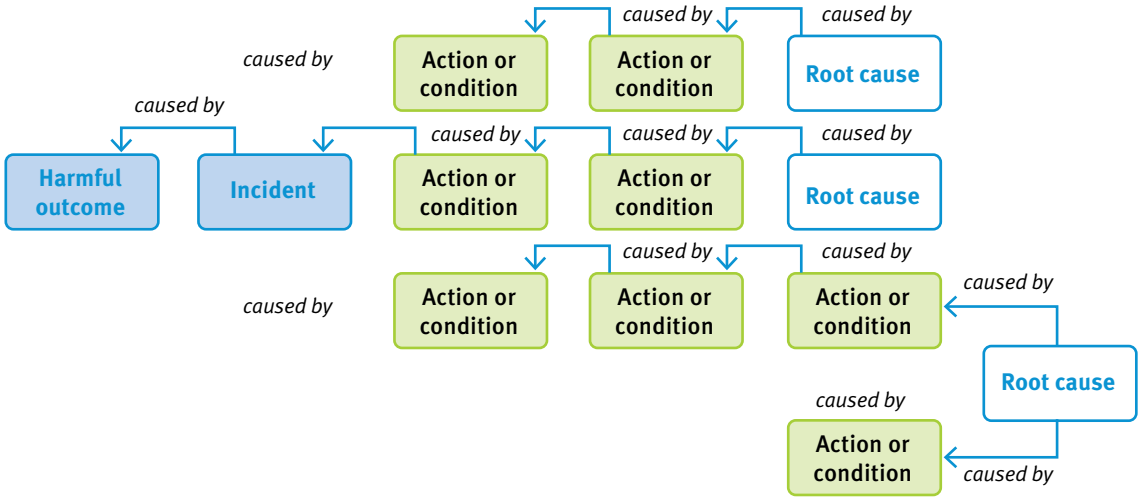
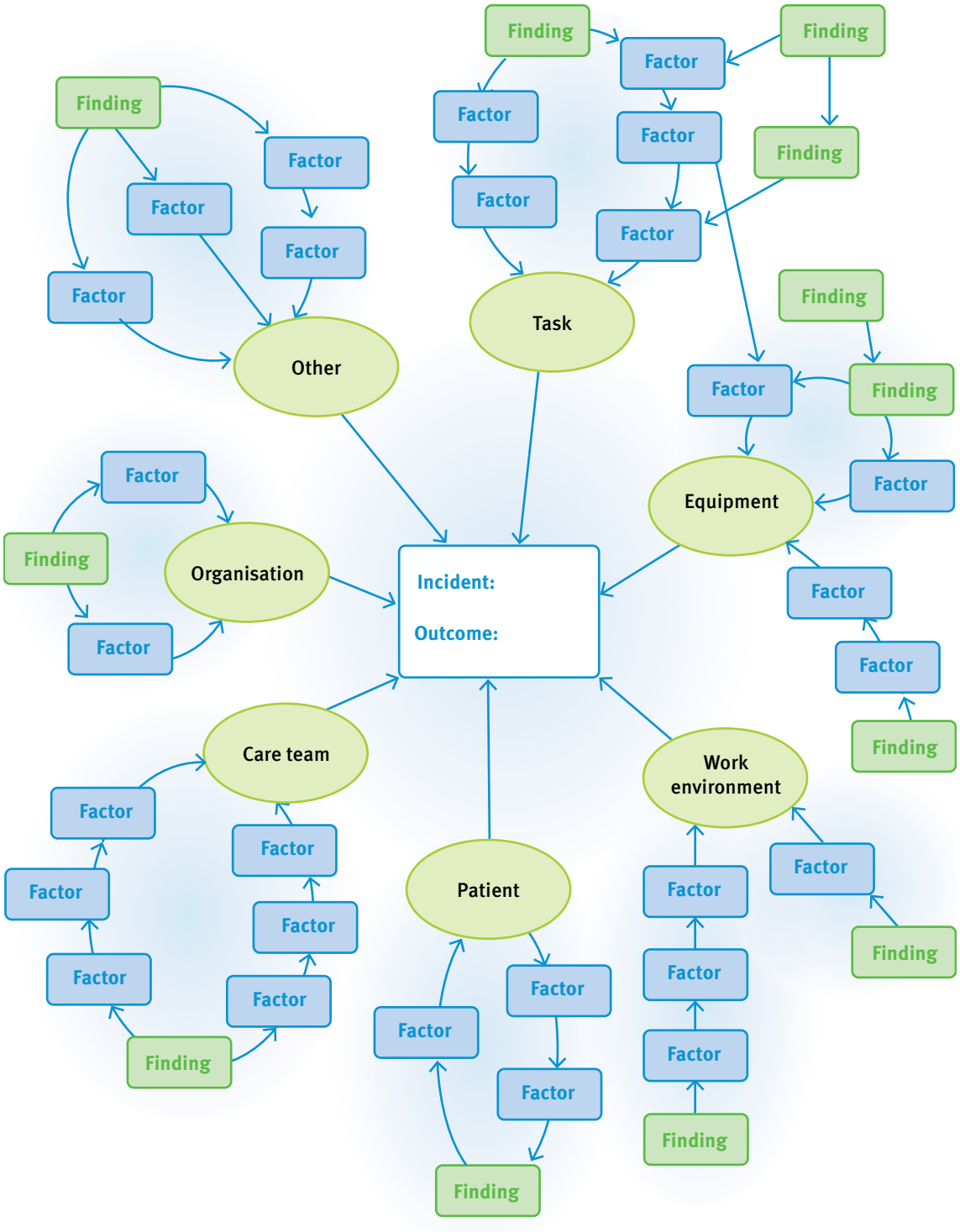


Figure 7: Tree diagram



To attempt to address the advantages and limitations of these two types of diagrams, the features of each were blended into an innovative diagram that evolved from the fishbone and tree diagrams into what is called a constellation diagram, illustrated in Figure 8 on the following page.

Figure 8. Example of a constellation diagram



Additional details and instructions for developing a constellation diagram are provided in Appendix E (Creating a constellation diagram).

Regardless of the type of diagram used to support incident analysis, the basic steps will be similar:

- describe the incident
- identify potential contributing factors
- define interrelationships between and among potential contributing factors
- identify the findings and confirm the findings with the team.

Summarise findings

Once the team has completed the analysis, a summary of what was found is prepared to clearly articulate the contributing factors related to the incident. The contributing factors are provided in the analysis report as a series of 'statements of findings'.

The statements of findings describe the relationships between the contributing factors and the incident and/or outcome. The statements focus on the contributing factors and should be as specific as possible (note that there could be a group of factors that together contributed to the incident or outcome).

For those familiar with RCAs, the statements of findings have been adapted from the previous 'causal statements'.

Formulation of the statements may be assigned to a sub-group of the analysis team and analysed with the full team at a subsequent meeting.

The statements of findings describe the relationships between the contributing factors and the incident and/or outcome. The statements focus on the contributing factors and should be as specific as possible (note that there could be a group of factors that together contributed to the incident or outcome).

The suggested statement format is:

'The contributing factor/s, within the context of the incident, increased/decreased the likelihood that this outcome would occur'.

Refer to Appendix N (Developing a statement of findings), for a template adapted from ACHS Improvement Academy. Two sample statements of findings are also provided with different scenerios used within the template.

A well constructed constellation diagram will assist in the development of statements of findings, working from the outside of the diagram, back towards the centre. Examples of statements of findings can be found in the case examples in Appendix K (Case study—comprehensive analysis: resident absconds from a residential aged care facility) and Appendix O (Case study-concise analysis: medication incident).

The Centre for Healthcare Engineering and Patient Safety, University of Michigan references the 5 Rules of Causation.

Handy tip

Hints for well constructed statements of findings using Five Rules of Causation

1. A statement of finding should clearly show the link between the contributing factor and the harm affected by the patient.
2. A statement of finding should use specific and accurate descriptors for what occurred, rather than negative and vague words.
3. A statement of finding should identify the preceding system contributing factors, not the human error.
4. A statement of finding should identify the preceding system causes of procedure violations.
5. Failure to act is only causal when there is a pre-existing duty to act.

What can be done to reduce the risk of recurrence and make care safer?

The ultimate goal of incident analysis is to take action to reduce the risk of recurrence and make care safer. Step-by-step guidance on developing and managing recommended actions is included under 'Recommended actions'.

What was learned

Additional attention is needed to identify learning from incidents within and outside individual practice settings and to share learning so others can take appropriate steps to provide safeguards in their own settings. Step 6 provides guidance on continuous organisational learning and sharing results.

Concise analysis

Given the complexity of the healthcare environment and the significant resources required for comprehensive incident analysis, healthcare leaders and patient safety experts have included a more concise method of incident analysis to help meet the need for timely and accurate action on a larger number of incidents. It is recognised that there are various types of analyses that may be appropriate in this respect; morbidity and mortality (M&M) reports or the use of specially designed report templates for recurring incidents.

Adopting a concise incident analysis, whilst conducted in a different format remains consistent with the principles and methodology of incident analysis, including the employ of a systems approach and consideration of human factors. (Appendix M details three human factors methods that can be used in in incident analysis).

Utilising a concise analysis requires a conscious and deliberate decision to focus primarily on four aspects:

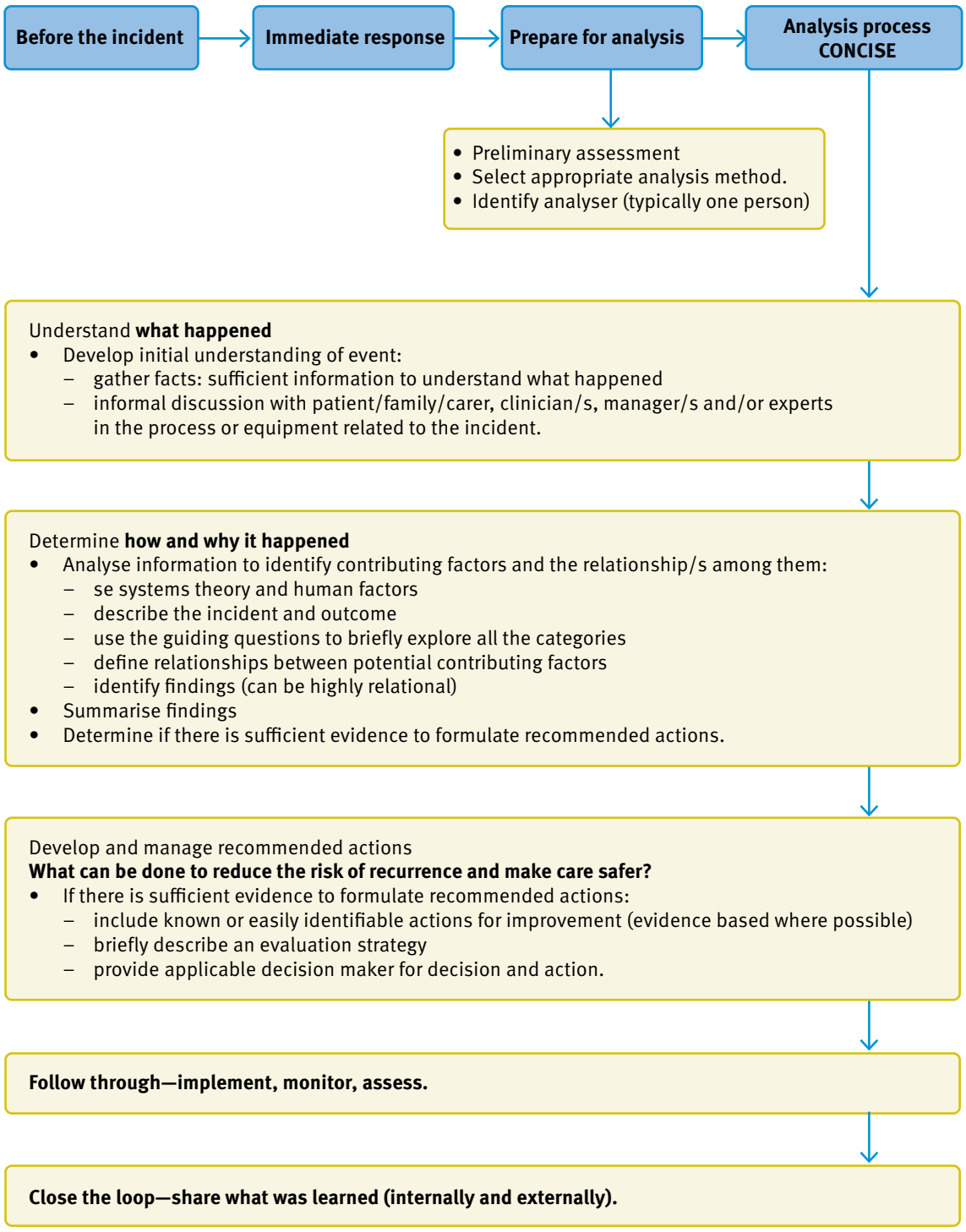
1. the agreed upon facts
2. key contributing factors and findings
3. actions for improvement (if any) and
4. evaluation.

Refer to Figure 9 (Flow Diagram for Concise analysis)

Refer **also** to Table 5 for comparing the characteristics of concise and comprehensive incident analysis[55] and see Appendix O for a case study using the concise method.

If at any point during the concise analysis the facilitator feels that the analysis should be escalated to comprehensive, they should discuss this with their line manager/delegate and seek further instructions. Note: All types of analysis benefit from a team approach.

Figure 9. Flow diagram for concise analysis



When to use a Concise approach

A concise approach is most commonly used for incidents or concerns that resulted in minimal or no harm to the patient. It may also focus on a new incident for which a comprehensive analysis was recently completed. Other incident analysis tools may not lend themselves to use in a concise approach, or be used in a limited way (e.g. sequence of events, constellation diagram, etc.).

Table 5. Characteristics of concise and comprehensive incident analysis [52]

Characteristic	Concise	Comprehensive
Should include person(s) with knowledge of incident analysis, human factors and effective solutions development.	✓	✓
Often conducted by an individual with input gathered from the patient, family, staff and physicians local to the incident as organisational or external experts.	✓	✘
Conducted by an inter-disciplinary medium to large ad hoc group (may include patients, family members, staff and clinician local to the incident as well as recognised independent internal or external experts/ consultants not involved in the incident).	✘	✓
Time taken for analysis	Short sequence of events (hours to days)	Longer sequence of events (up to 90 days)
Identifies contributing factors as well as remedial action(s) taken (if any)	✓ (focus on key factors)	✓
Recommendations for improvement	✓ (if applicable)	✓
Principles of incident analysis	Reflects the intent but may not address all	Incorporates all principles
Evaluation strategy	✓ (if applicable)	✓

Concise analysis is typically conducted by one person (analyser) with knowledge and skill in incident analysis, human factors and effective solutions development. The facilitator usually gains this expertise through a variety of formal education programs and mentored experience and practice. The individual may be a healthcare clinician and/or other process expert, and not necessarily a risk manager or patient safety/quality improvement officer.

Steps in conducting a concise analysis

What happened

It is vital to obtain sufficient information to understand what happened in order to understand how and why it happened. The analyser may conduct informal discussions with the patient/family/carer, healthcare clinician/s, manager and/or expert/s in the process/es and examine the equipment involved in the incident.

It is helpful to document key factual information in the form of a high-level sequence of events or narrative description.

How and why it happened

1. Analyse the guiding questions to briefly explore all categories, being mindful to move away from patient-clinician interface to systems level order to identify chains of contributing factors (Appendix L).
2. Select some of the guiding questions or develop unique incident specific questions to informally discuss the incident with a few individuals (this may include the patient, family member, carer, staff and/or clinicians local to the incident as well as organisational or external experts).
3. A constellation diagram may be used to facilitate a systematic approach. The process of developing a constellation diagram is intended to assist in the building of a visual representation of the incident and the system contributing factors. It is also possible to identify mitigating factors that prevented the incident from being more significant. See Appendix E for an explanation of the constellation diagram.
4. Once all of the contributing factors have been identified, it is appropriate to try to understand how these factors are clustered/linked with one another given that all incidents generally result from a cascade of events rather than an isolated contributing factor.
5. Once the cluster/linkage is completed, it is appropriate to transition to describing the findings and the development of recommendations (if appropriate) to make care safer for future patients in similar circumstances.
6. Identify the key contributing factors that contributed to the outcome by asking why and how they are related.

What can be done to reduce the risk of recurrence and make care safer?

Summarise the findings and determine if there is sufficient data to develop recommended actions. Are there known or easily identifiable evidence-based actions for improvement?

- If no, is there sufficient knowledge and expertise to develop local solutions for testing, evaluation and formalization of the response?
- If yes, proceed with formalising recommended actions and consult with relevant decision maker for decision and action. See the following section for additional information on developing and managing recommended actions.

The analyser (or other person/s designated by the organisation) formalises the action plan and ensures that an evaluation strategy is in place to determine if recommendations were implemented and sustained, as well as if there was any known impact to the safety of patients within the targeted care process/es.

Determine if a multi-incident analysis is required to effectively understand the applicable risks to patients (see the following section).

Track and document all key decisions and the action plan/evaluation strategy if applicable.

What was learned

Concise analysis can contribute important knowledge regarding a larger number of incidents and their contributing factors. The general lessons should be disseminated and findings and/or recommended actions should flow into the higher organisational level for prioritisation of risks and actions for improvement within the organisation.

Multi-incident analysis

The benefit of conducting a multi-incident analysis is the potential to reveal patterns and trends of contributing factors that are otherwise not previously perceptible. These analyses can also review previous recommendations and identify those that were or were not effective.

For example:

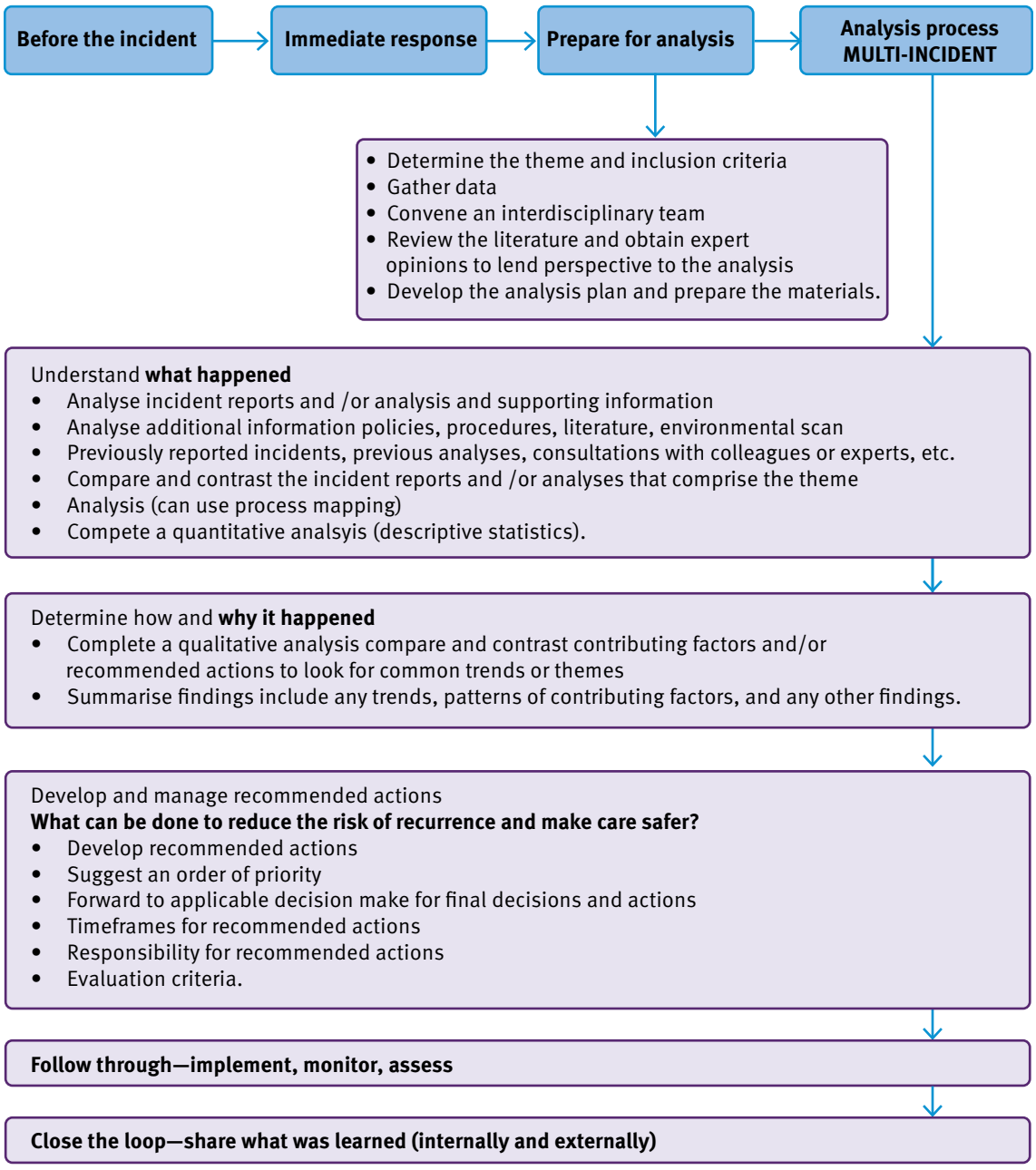
- A group of individual patient safety incidents, similar in composition and/or origin, that caused no harm or lesser degrees of harm.
- A group of individual patient safety incidents, similar in composition and/or origin, that may have caused varying degrees of harm (no harm to catastrophic/major harm).
- A group of patients who are impacted by a similar contributing factor/s, and who experience the same harmful incident (to greater or lesser degrees).
- A group of completed comprehensive and/or concise incident analyses.

For the purpose of this Guide, an analysis of multiple incidents (or more than one) is called multi-incident analysis. Alternate terms used in the literature for this type of analysis include cluster, aggregated and meta-analysis. Common features of any multi-incident analysis include:

- pre-defined theme or scope
- involvement of an interdisciplinary team including frontline clinicians and possibly a patient representative
- use of quantitative and qualitative methodologies.

Refer to Figure 10 for a multi-incident analysis flow and pages 57 and 58 detail four examples.

Figure 10. Flow diagram for multi analysis



Examples that describe various types of multi-incident analyses and the methodology for conducting such analyses are provided next.

Examples of multi-incident analysis

Example 1: A group of low and no harm incidents or near misses that have not been analysed.

All healthcare organisations have reporting systems in place to enable staff to report incidents that may have caused no harm or lesser degrees of harm. Although it is generally agreed that these incidents are valuable learning opportunities, in the absence of significant patient harm they are frequently filed away with little or no analysis. In particular, when multiple no or low harm incidents are analysed as a group, they have the potential to reveal trends or patterns of contributing factors that may not be identifiable by looking at a single incident. If actions are identified and taken as a result of this collated type of analysis, future incidents might be avoided.

This type of analysis would include three or more no harm, low harm and near miss incidents that have not previously been analysed as a part of a patient safety incident analysis. For example, an analysis of 15 falls or near falls that identified common patterns of contributing factors and safety deficiencies was conducted by Zecevic et al.[56]

Example 2: A group of incidents that are similar in composition and/or origin that may have caused varying degrees of harm (no harm to catastrophic/major harm).

Some healthcare organisations may decide to analyse multiple incidents involving a predefined theme or criteria. The patient outcome of these incidents may be varied—from no harm to catastrophic/major harm. For example, all falls occurring in an in-patient acute care unit during a six month period, including eight incidents that were low harm and not analysed, and one event where there was severe patient harm and a comprehensive analysis was previously conducted.

This type of analysis would include three or more near miss, no harm, low harm, or significant harm incidents occurring within a defined period of time or location. As noted above, one or more of these may have been previously analysed using a comprehensive or concise analysis methodology.

Example 3: A group of patients who are impacted by a similar contributing factor/s, who experience the same harmful incidents (to greater or lesser degrees).

The theme of this type of analysis is where a common outcome may impact multiple patients. Although the contributing factors may be complex and unique to each incident, learning can be achieved by analysing these multi-patient incident analyses, frailties in healthcare systems can be revealed and improvement strategies implemented.

Example 4: A group of completed comprehensive and/or concise incident analysis.

Organisations that conduct analysis of individual patient safety incidents will accumulate a rich source of information regarding identified risks, contributing factors and action plans to reduce these risks for patients. Organisations are encouraged to develop and utilise a management system to coordinate the learning and ensure what is learned about the health system is not lost or forgotten.

An analysis of multiple comprehensive and/or concise event analyses [46,55,57] is not unlike an aggregate or epidemiologic meta-analysis, although it does not have precise scientific and statistical methodology associated with it. This analysis consists of a group of completed analyses conducted on similar types of incidents.

Ideally an organisation will employ a management system to coordinate the identification of overarching themes related to multiple incidents that have been analysed. The overarching themes may include types of incidents analysed, contributing factors identified and action plans to reduce harm to patients. For instance, there may be a number of recommended actions made by analysers that identify the need for improved teamwork and/or communication. This may lead to the design of a strategic improvement priority for the organisation with designation of appropriate resources to support the effort. Queensland Department of Health and Patient Safety and Quality, Clinical Excellence Queensland, share their learnings through publishing learning updates.

Steps in conducting a multi-incident analysis

Prepare for analysis:

- Determine the theme and inclusion criteria e.g. identify the characteristics of incidents to be analysed (no harm to catastrophic harm) or multi-patient incidents, or identify a theme for multiple completed analyses to be analysed.
- Gather applicable data:
  - if applicable, conduct interviews with clinicians, patients/families/carers and others with knowledge of the incidents and/or care processes involved in the incidents.
- Analyse literature and obtain expert opinions to collect additional background and contextual information and lend perspective to the analysis:
  - analyse other reporting and learning systems.
- Develop the analysis plan, which will include both qualitative and quantitative analysis elements.

What happened

Analyse the patient safety incidents and/or previous comprehensive and concise analyses to look for common trends, patterns and issues. This will include comparing and contrasting sequence of events, contributing factors, and recommended actions from previous incident analysis. Process mapping, a tool frequently used to support Failure Mode and Effects Analysis (FMEA) [50,58] and Lean improvement methodology [51] can also be used to support the identification of system weaknesses when conducting an analysis of multiple incidents.

Note the frequency of system issues or failure points and if applicable, recommended actions. This represents the quantitative portion of the analysis and will include classifications such as severity of harm type of incident, patient diagnosis, etc.

Handy tip

For all methods of analysis:

- **Gather information:**
  - interviews
  - brainstorming
  - retrospective clinical records
  - multidisciplinary team analysis
  - photographs, diagrams or drawings.
- **Map the incident:**
  - narrative sequence of events
  - tabular sequence of events
  - cause and effect diagram.
- **Identify care and service delivery problems:**
  - multidisciplinary analysis meeting
  - brainstorming/brain writing
  - nominal group technique
  - change analysis.
- **Analyse problems to identify contributory factors and root causes:**
  - draw a diagram (e.g. constellation diagram)
  - contributory factors classification/ guide
  - five whys.
- **Generate solutions and recommendations:**
  - barrier analysis
  - risk benefit analysis.

How and why it happened

The qualitative analysis involves focusing on the identified contributing factors as well as similarities that may not have been apparent through an individual incident analysis. Narrative descriptions are particularly helpful for this portion of the analysis. As common patterns are identified, the team may need to further sub-categorise to clarify trends or issues.

When a group of comprehensive and/or concise analyses are analysed both the contributing factors and the recommended actions may be included in the qualitative analysis.

Summarise findings including contributing factors and previously recommended actions that may lead to system improvement. Include any trends, patterns or contributing factors and any other findings.

What can be done to reduce the risk of recurrence and make care safer?

Develop recommended actions that will lead to system improvement, giving consideration to available supporting information, including evidence-based guidelines and leading practices. Identify short-term and long-term strategies. See the next section for guidance in building effective recommended actions to reduce risk.

It is helpful for the team to consider a measurement and evaluation strategy before forwarding recommended actions to applicable decision makers for final decisions and delegation for implementation.

What was learned

The findings (contributing factors, trends and themes), recommended actions and their outcomes should flow into and be coordinated with the organisation's risk management and improvement processes, including processes for communicating and sharing learnings. See Appendix P (Lessons learned) for more information.

Recommended actions

Develop and manage recommended actions

Developing and managing recommended actions involves a series of activities at several levels of the organisation aimed to determine what can be done to reduce the risk of recurrence and make care safer. The success of the recommended actions is dependent on the quality of findings identified in the previous analysis step (how and why it happened).

It is important to consider that a few well thought out high-leverage recommendations will ultimately be more effective than a lengthy list of low impact actions. Figure 11 illustrates a hierarchy of effectiveness and leverage for recommendations.

The Patient Safety Health Service Directive Guideline for Clinical Incident Management (QH-HSDGDL-032-3) states that HHS "should have an established local documented process for the development of recommendations arising from SAC1 analysis, that should include engaging with relevant stakeholders and prioritising recommendations based on impact and achievability".

The analysis team has a fundamental role in the development of recommended actions. Findings identified in the previous analysis step (how and why it happened) are analysed by the team and actions proposed to address the contributing factors that allowed the incident to occur. Use of analysis diagrams (like the constellation diagram) assists to support teams in evaluating the best leverage points for recommended actions. The analysis team is generally responsible for proposing recommended actions, suggesting an order of priority, proposing timeframes, responsible positions and consulting with others such as treating clinicians before the analysis report is handed off to those responsible for validating and implementing the actions.

Handy tip

Recommendations made in conjunction with the treating clinicians and the relevant stakeholders, directly responsible for implementing, are far more powerful and likely to produce results than those that are delivered to them by 'people' who have not been consulted.

Note that in rare instances, analyses may not generate any new recommended actions (in particular, concise analysis).

Key features of effective recommended actions

Healthcare leaders and those involved in analysis in Queensland healthcare organisations have expressed the need for a tool to help build more robust and precise recommended actions. The list of key features presented below is a guide that can be adapted by teams and used locally to focus on developing effective recommendations/actions.

Effective recommended actions:

- Address the risk associated with the findings identified during the analysis.
- Utilise the most effective solutions that are reasonable/possible given the circumstances.[52]
- Offer a long-term solution to the problem.
- Ensure they are formulated using the SMARTER format [59] as in Table 6.
- Target the actions at the right level of the system and ensure the action is appropriate for that level (see Step 1 for a description of system levels). For example, if one of the recommendations from a medication error is to change the label design, the responsibility for implementation may lie outside the organisation where the incident occurred, requiring a national or international effort.
- Assign responsibility at the appropriate level in the organisation.

- Ensure there is a greater positive than negative impact on other processes, resources and schedules (balancing measures should be in place to ensure that unintended consequences are known and understood).
- Ensure recommendations are based on evidence that demonstrates the impact of this or similar action. Consider research literature, similar recommendations implemented in the organisation (e.g. from accreditation, patient complaints) or externally; and review patient safety alerts and advisories. Aim to use the highest level of evidence available (randomised controlled trials are the highest, followed by controlled observational studies, uncontrolled studies, opinion of experts and opinion of peers).[60,61]
- Provide enough context to ensure that if the action is implemented, those responsible will understand the rationale behind it.
- Consider whether there will be sufficient resources, engagement and willingness to change in order to fully implement and sustain the recommendations.
- Consider whether the recommendations will need to be tested in Plan-Do-Check-Act cycles, to learn what works and what doesn't, prior to full implementation.

Figure 11. Hierarchy of effectiveness [61]

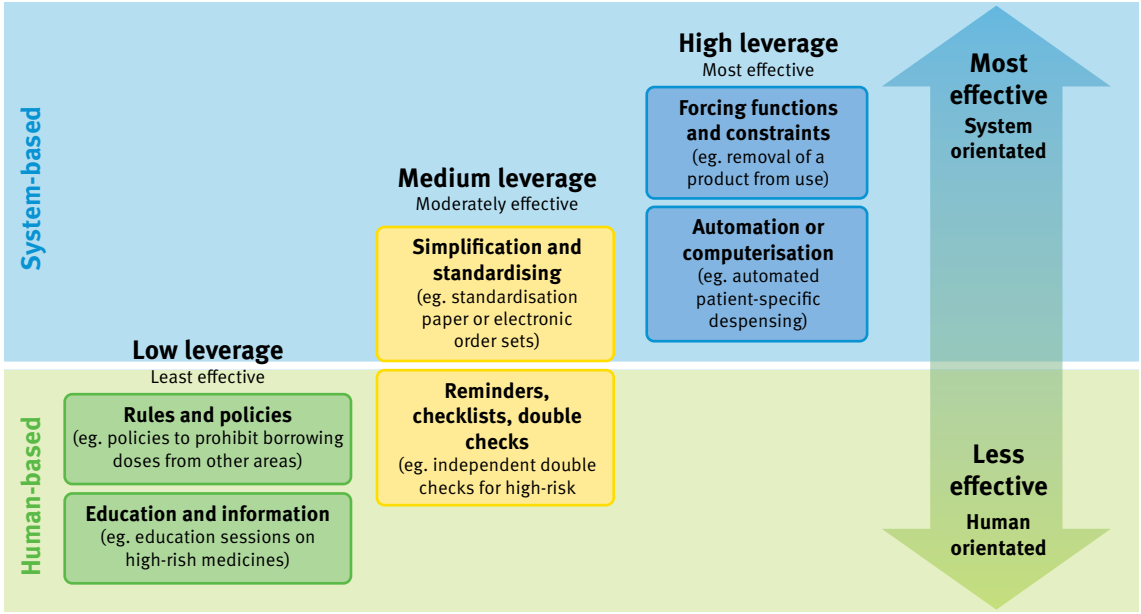


Table 6. SMARTER format [59]

Specific	Be clear about the issue you are targeting and write exactly what you recommend to address it.
Measurable	How will you know when the goal has been accomplished? Aim to incorporate quantifiable indicators into regular monitoring and reporting cycles where possible.
Accountable/ Achievable	Who is going to ensure these are followed through? Allocate single point of accountability for implementation of each recommendation. Can it be achieved with available resources?
Reasonable/ Realistic	Are the recommendations achievable given the current budget and available resources?
Timely	Prioritise your recommendations, streamline into manageable tasks for the implementing teams and allocate a target date.
Effective	Will this recommendation make a difference? Effective recommendations should reduce the frequency of a future incident recurring.
Reviewed	There is merit in having an external person/body/committee review all recommendations to assess whether they will achieve their intended outcome, and not negatively impact on other areas.

Handy tip

What to consider when developing recommendations:

- understand that re-training is not always the right solution
- intelligent use of checklists, policies and protocols
- minimal dependency on short-term memory and attention span
- simplification of tasks and processes
- standardisation of tasks and processes
- avoidance of fatigue (analysis of working hours/patterns)
- alignment with evidence-based practice
- alignment with organisational priorities and risk registers.

One of the benefits of using human factors principles to assist in identifying contributing factors is that the same approach can be used to identify and evaluate the effectiveness of recommended actions. In other words, identifying systems-based contributing factors correctly should lead to system-based solutions.

When recommending actions, many possible categories of options with varying degrees of effectiveness are available. The team should appraise this range (see Figure 11, listed in order from most effective to least effective) and be encouraged to recommend the most effective solution that is reasonable and/or possible given the circumstances. Note that items such as training and policy development are necessary components, but when used alone, do not change the underlying conditions that lead to the incident.

From a human factors standpoint, the strongest interventions are *'physical rather than procedural and permanent rather than temporary.'* [52] Organisations may find the assistance of human factors engineers or ergonomists helpful in determining if the proposed actions will be effective from a human factors perspective.

In many cases, a system-based recommended action involves a change or improvement to a process or protocol, work areas, software, order forms or equipment. A mistake-proofing step during the development of recommendations assists teams to determine whether the recommended action/s will have the desired effect/s. In this step, team members assess whether the recommended action, if implemented, would have prevented the incident or mitigated the harm. It is also an opportunity to consider the potential for introducing unintended consequences to processes (e.g. creating unnecessary steps or added workload, possibly leading to unsafe work arounds).

Consideration needs to be given to evaluating the likely impact of the actions before implementation. One way to do this is to conduct one or more of the methods described in Appendix M—cognitive walkthrough, heuristic evaluation or usability testing. The method selected will depend on the complexity of the sub- system being changed and the potential severity if the recommended action fails or introduces unintended consequences. If the potential failure or unintended consequence is potentially more severe, it should be elevated with usability testing or a combination of the methods, and the recommended action modified and improved before implementation. FMEA [50,58] is another prospective analysis technique that can be used to evaluate the impact of a proposed process change.

The initial focus is on the elimination of risk to patients. If there are no actions that can be applied to eliminate the risk, the team should seek the most appropriate controls to reduce the possibility of recurrence. It is important to note that applying a control means that although checks will be in place, there still is a chance of reproducing the same or related circumstances that led to the original incident. There are occasionally circumstances under which a team may choose to accept that one or more identified factors cannot be altered. For example, in analysing an incident related to lack of timely access to tertiary care, the team would have to accept the fact that this level of service will not be made available in remote locations and focus attention on rapid transfer of patients when such services are needed (in other words, implement a control measure).

Handy tip

A few well thought out high impact recommendations will ultimately be more effective than a lengthy list of low impact actions.

Suggest an order of priority for recommended actions

The need to prioritise the recommended actions is the result of several practical factors: [62,63]

- Related to the organisation:
  - abundance of recommendations from multiple sources generated from accreditation, patient complaints, insurance claims, coroner reports and other
  - limited resources (budget, staff time) to ensure good follow through of quality improvement and risk management initiatives
  - additional priorities and strategies described in strategic plans.
- Related to the external environment:
  - a variety of external pressure and requirements influence operations including required organisational practices, regulatory and policy requirements
  - public reporting and compliance with certain indicators
  - reports of similar incidents publicly available.
- Related to the characteristics of the recommended action itself (degree of change required).

The analysis team is generally responsible for suggesting an order of priority and desired sequence of events for completion of recommended actions. This is later confirmed by the executive team and delegated for implementation. The following criteria may assist in the prioritisation process:

- If the recommended action is not implemented, what are the risks (the worst possible outcome) for the patient, clinicians, organisation? If possible, rate the risk using the consequence and likelihood assessment as in Table 7.
- Which actions can be immediately implemented? Consider if there are quick, safe patient care wins that will empower the implementation team and others to continue (it is important to emphasise small wins are steps in the right direction, not the final destination).
- Consider if there are existing mechanisms (initiatives, programs or other improvement efforts) in place to implement the recommended action/s. Building an inventory (via a table, spreadsheet or other register) of current efforts to address this or similar issues (contributing factors) can prove valuable for improvement. The searchable inventory could be a living document maintained and used by all levels in the organisation.
- If possible:
  - recommend actions for different levels in the organisations and discuss what the most important action is at each level.
  - estimate the resources (human and financial) and sequence of events needed to implement each recommended action.

Table 7. Risk assessment matrix [64]

		Consequence				
		Negligible	**Minor**	**Moderate**	**Major**	**Extreme**
Likelihood	**Almost certain**	Medium (7)	Medium (11)	High (17)	Very High (23)	Very High (25)
	Likely	Medium (6)	Medium (10)	High (16)	High (20)	Very High (24)
	Possible	Low (3)	Medium (9)	High (15)	High (18)	High (22)
	Unlikely	Low (2)	Medium (8)	Medium (12)	Medium (14)	High (21)
	Rare	Low (1)	Low (4)	Low (5)	Medium (13)	High (19)

An example of a tool that can be used to summarise the draft prioritised recommended actions is provided in Table 8. For each column, enter a descriptor (high/medium/low or other as applicable), or a few short comments

Table 8. Example of table to summarise and prioritise recommended actions

Recommendation/s summary						
Risk (high, medium, low)	**Hierarchy of effectiveness** (high, medium, low leverage)	**Predictors of success**	**System level targeted** (micro, meso, macro, mega)	**Note if evidence is available and what type**	**Confirm validity, feasibility** (high, medium, low)	**Order of priority/ timeframe**

Handy tip

Recommendations should:

- be clearly linked to identified contributing factors or key learning point/s (to address the problems rather than the symptoms)
- be designed to significantly reduce the likelihood of recurrence and/or severity of outcome
- be clear and concise and kept to a minimum wherever possible
- be specific, measurable, achievable, realistic, timely, effective and reviewed (SMARTER) so that changes and improvements can be evaluated
- be prioritised wherever possible
- be categorised as those:
  - specific to the area where the incident happened
  - that are common only to the organisation involved
  - that are universal to all and, as such, have statewide or even national significance.

Recommendations might also include provision of ongoing support of patients and staff affected by the incident.

Strength of recommendation/s

To design strong recommendations, aim for high impact, low effort interventions such as forcing functions, architectural re-design, software changes, standardise and simplify processes. The stronger the action, the more likely that it will work. The weaker the action, such as writing policy or training staff, the less likely it will be sufficient to prevent a similar clinical incident occurring again. For training to hold its value it needs to be recurrent; nevertheless it remains a weak action.

Table 9 provides a comparison of strength of actions and the related effort required over time to implement.

Table 9. Strength of recommendations effect and effort actions

Strength of recommendation		
Strong actions	**Moderate actions**	**Weaker actions**
When implemented strong actions rely less on people's actions. Most likely to be effective and sustainable.	Systems fix. Remains reliant on individuals/ team vigilance.	Reliance on the individual. Rely on human behaviour. Less likely to be effective / sustainable.
• Architectural/physical plant changes • Tangible involvement & action by leadership in support of patient safety • Simplify the process and remove unnecessary steps • Standardise equipment or process or care maps • New device with usability testing before purchasing	• Checklist/cognitive aid • Increase in staffing/decrease in workload • Read back process • Audit • Enhanced documentation/ communication • Software enhancements? Modifications • Simulation based training • Eliminate look and sound-a-likes • Eliminate/reduce distractions (sterile medical environment)	• Redundancy/double checks Warnings and labels • New procedure/ memorandum/policy • Training • Additional study/analysis
Effort to implement recommendations		
High	**Moderate**	**Low**
>12 months	6-9 months	3-6 months

Consult on the draft recommended actions

Where possible, a consultation step may be beneficial in order to ensure that the recommendations are appropriate, the identified risks have been addressed, and there is a high probability to reduce the recurrence of this or similar incidents. Patients/families/ carers have a unique perspective on the incident and should be invited to provide their improvement ideas to the team. Clinicians from the area where the incident occurred, as well as experts should also be consulted. Those providing feedback on potential actions should be advised that their suggestions will be considered, but may for a number of reasons, not be implemented. These reasons should be explained to the contributor.

It may be appropriate again at this time to reprioritise the recommendations with the use of an Impact and Achievability Matrix (see Figure 12) to determine both the achievability of your recommendations (i.e. what is within the control and the means of the health service) and also the impact of the recommendations (i.e. on the prevention of the patient harm that has led to this analysis). Using this tool assists in reaching consensus among the team on which of the recommendations are best to prioritise your efforts and resources on.

Figure 12. Impact and Achievability Matrix

Prepare and hand-over report

A final task of the analysis team is to include the recommended actions and the findings of the analysis in a report that is provided to those responsible for:

- approving the actions
- delegating them for implementation
- allocating resources
- empowering and monitoring implementation (most frequently an executive manager or quality committee).

Having a clear record of the analysis and relevant supporting documentation will support confidence in decisions related to the analysis. If the steps, facts, evidence and supporting documentation are tracked throughout the analysis, the writing of the report should be relatively straightforward. It is suggested that the report have headings and sub-headings, as it will inform the basis for those responsible to make decisions regarding recommended actions.

Frequently, the analysis team will disband once the report is handed over for implementation. To ensure appropriate follow-up, a tracking mechanism should be put in place to trace the implementation of recommended actions and their accompanying outcomes (see Table 11 for an example).

Manage recommended actions

The individual or group of individuals (likely an executive manager or organisational quality committee) receiving the analysis report are responsible to ensure that the recommended actions are validated from a strategic and operational perspective, as well as delegated appropriately to implement the approved actions. This individual or group of individuals will generally be required to support decisions related to the implementation of actions to organisational leaders and other stakeholders, while demonstrating good stewardship of available resources and considering the long-term well-being of the organisation.

Validate actions from strategic and operational perspectives

The analysis report, including recommended actions, needs to be evaluated by the responsible individual/s in order to decide if and how actions should be implemented. The following three steps may be helpful in guiding their decisions:

1. **Confirm actions**
   To facilitate confirmation of the recommended actions, the responsible individual/s may choose to begin by merging actions from the analysis with recommendations from other sources. This builds on the inventory generated by the analysis team (Table 10) and aims to ensure that actions are considered in light of strategic and operational risks and priorities. Ideally, a centralised inventory is created to capture current recommendations in the organisation from all sources and their status (e.g. patient complaints, trigger tool findings, insurance claims, accreditation, coroner). The inventory can be housed in a simple spreadsheet or included in the organisation's patient safety or performance systems.

   It may be helpful to consider sorting the recommended actions by the main categories of contributing factors (e.g. task, equipment, work environment, patient, care team, organisation, other) and including high level key information about each recommended action (e.g. estimated risk for the organisation, implementation status). An inventory will assist with the prioritisation steps by ensuring the recommended actions for this incident are aligned with, and not competing with other ongoing efforts, in the organisation. Regular maintenance of such an inventory is required.

2. **Assess validity**
   Validating the recommended actions is important and will ensure that the actions are:
   - attainable (the resources, competence and tools needed are available—if not, there is a plan to put them in place before implementation starts)
   - feasible (the culture, readiness for change, technology, legislation and other contextual factors support the action and are not completing with it)
   - cost effective (potentially a cost benefit analysis may be needed)
   - aligned with the strategic and operational priorities of the organisation (implementation of the actions will not create a void in other areas or programs).
3. **Approve and set guidelines for implementation**
   A final validation step includes confirmation of the actions to be implemented and high-level guidelines for implementation. Guidelines for implementation should focus around the following criteria and include a brief rationale:
   - Set an order of priority for the actions—what should be implemented first?
   - Specify the system level targeted (micro, meso, macro or mega). Consider if the recommended actions should be generalised to other areas of the system. For example, if the incident is related to the use of a concentrated form of an injectable medication in one area of a hospital, it would be beneficial to address the management of the medication in all areas of the hospital and consider the management of similar concentrated injectable medications using the same intervention, at the same time.
   - Sequence of events—start time and estimated duration.
   - Accountability—include a senior leader and an implementation lead.
   - Propose success measures, milestones and determine reporting frequency.

Once approved and validated, recommended actions are prepared for hand-off to the team and individual/s responsible for implementation. There should be a process in place to share information about actions recommended and implemented with the patient and family as well as with the clinicians in the area where the incident occurred, organisational leaders, and others as needed. Step 6 provides for more information about learning and sharing.

Delegate recommended actions for implementation and empower implementation

The approved recommended actions are handed over to the team or individual/s responsible to implement the action. If possible, this should be done during an in-person meeting, so everyone has a common understanding and is clear on the purpose, objectives and direction of the actions. Clarity is important because the senior leader and the team responsible for implementation will base their work plans on the information received about the recommended actions during the hand-off process. It is important to ensure follow-through and follow-up of the status of the actions.

Translating incident analysis recommendations into action and sustainable change is not easy. See Table 10 as a tool to track implementation and status of recommendations.

Table 10. Example of a tool to track the implementation status of recommended actions

Implementation status								
Category	Recommended action	Expected completion date	Source and ID#	Date entered	Progress status	Priority / Timeframe	Risk level	Responsible person
Task factors								

Real improvement will only occur when a systematic, collaborative approach is used that has explicit leadership support and sufficient resources. These resources must include quality improvement and patient safety facilitators who have received ongoing education in the applicable methodologies and have developed and honed their skills over many years of experience.

Step 5: Follow through

– Implement recommended actions
– Monitor and assess the effectiveness of actions

Implement recommended actions

The implementation of recommended actions is an important step in the incident management process, with its effectiveness contributing to the overall success of the incident analysis process. Board directors and executive leaders have key roles to play in monitoring clinical incident management performance, in particular enacting the governance and ensuring legislation requirements are met, considering the effectiveness of potential recommendations and ensuring the sustainability of strategies. The Executive (senior leadership), therefore have the additional responsibility of providing direct guidance in the process of developing recommendations. This involvement can accelerate the implementation of supported recommendations and promote a culture of safety in the organisation. There are governance resources (eg Fact sheet: Key Information for Board Directors and Executives) available for Board members that offer valuable support for fostering a culture of safety.

Implementation can be very challenging if the actions are not focused on the contributing factors, do not have clear objectives, are not communicated clearly or are not visibly supported by the senior team. In addition to this, capacity to take on new initiatives in healthcare is challenging at times—frontline teams are always busy caring for patients and implementing current improvement efforts, and managers may feel time poor with additional change based projects that may be added to their usual day-to-day operations. To add to these existing pressures, it is expected that all approved recommended actions from clinical incident analyses will be implemented in a timely manner.

To successfully implement recommendations, especially the more challenging ones, an appreciation of the key elements for improving a system, helps with this understanding.[65] These elements are listed as follows:

1. **Appreciation of the system:** obtain a deep understanding of the what and the why of the underlying system. The problem can't be fixed unless the problem is properly understood.
2. **Theory of knowledge:** gain knowledge by testing improvement recommendations to see if they work. Apply small scale testing and analysis using quality improvement methodology if appropriate e.g. **Plan-Do-Study-Act (PDSA)** cycles are often needed before attempting a full-scale implementation.

3. **Psychology:** to implement change successfully, it is important to understand any underlying human factors. This is important when trying to implement change and to ensure staff are supported throughout the change. It is also integral in designing change initiatives and considering how to overcome identified obstacles, such as shortcomings in human memory and attention.
4. **Understanding data and data variation:** the use of data is required to evidence that the implementation has been successful. The data needs to be accessed from a valid source, and include metrics based on well understood numerators and denominators.

Any changes in the data need to be assessed to see if they are real changes (hopefully as a result of the implementation of your recommendations: this is called special cause variation) or whether the change is due to the natural small scale variation that happen in all processes (natural cause variation).

It is important to consider "work-as-done" versus "work-as-imagined". "Work-as-imagined" describes what should happen under normal working conditions. Unfortunately, it does not take account of staff constantly adjusting to the complexity of healthcare and the ever-changing conditions of their work environment.

In contrast, "Work-as-done" describes what actually happens and how people deliver care, in the complex reality of health services. Unless your recommendations are implemented in the "work-as-done" reality on the clinical floor, your improvement efforts are likely to be misdirected.[34,66]

Complexity science suggests trying multiple approaches and shifting time and attention to those strategies that appear to be effective. The PDSA process of small cycles of change to implement quality improvements is one example of an activity that enables experimentation within a scientific approach.[67] The organisation should also consider piloting or usability testing of interventions prior to broad implementation, especially in situations where substantial changes in process are planned.

Successful implementation requires that senior leaders have confirmed all the following:

- a "will" in the health service for the change/s
- sufficient executive support for the change/s
- sufficient resources being made available for the change/s
- an agreement/plan with executive sponsor what you will do if there are barriers
- the team involved in implementation have the necessary leadership skills, credibility, communications ability, authority, analytical skills and a sense of urgency.

Another easy to use and tested tool developed by the Boston Consulting Group—DICE— can assist with identifying and minimising the risk of implementation failure.[68] Their experts have determined that the outcome of change initiatives is driven by four elements (DICE).

- the **Duration** of the project
- the performance **Integrity** of the team
- the organisational **Commitment** to change and
- the additional **Effort** required of staff members.

Ideally, implementers will share the progress of their efforts with members of the analysis team and the unit/ program/organisation where the incident originally occurred. Once implementation is complete, the results of the evaluation and learning should be shared with others.

Monitor and assess the effectiveness of recommended actions

The purpose of implementing system changes is to make the system safer. However, some recommended actions—even well intentioned and well thought out changes—may not have the desired effect in practice. As a result, the effectiveness of the implemented recommended actions must be monitored to determine if the changes helped make the system safer, had no or limited impact on the safety of the system, or in the worst-case scenario, the changes actually made the system less safe. If surveillance indicates that, for whatever reason, the changes did not have the intended effect, the organisation needs to revisit the recommended actions to identify alternative solutions or to improve the impact of earlier solutions. Organisations invest considerable resources in investigating incidents in order to alter the conditions which led to these events. Monitoring the impact of recommended actions of an incident analysis promotes organisational learning and staff commitment to improve care.

Monitoring the effectiveness of recommended actions requires the diligent use of measurement approaches. One way to identify useful measures is to ask staff how they would know if an action was effective. Staff may be more familiar with existing data or have ideas about how to observe and record actions that the analysis team may not recognise. [52] Data that is available from existing data bases or reports can be useful, as well as data that can be recorded with simple audit tools used on a regular basis. The most useful measures of recommended actions are those that assess outcomes. Outcome measures provide direct evidence of the effectiveness of the actions taken and not just the completion of preventative measures.

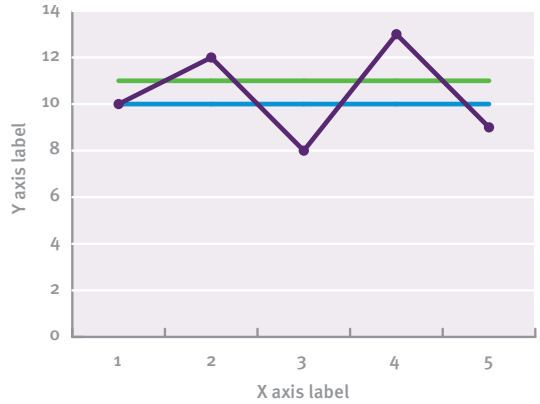
Outcome measures should be complemented with process measures that assess the extent to which recommended actions are implemented. A balance of outcome and process measures allows the individual or group charged with monitoring the recommended actions to interpret their impact and to revise or reinforce them if they fail to have the desired impact.

Evaluation or measurement? The methodology involved in evaluation is more complex than the one for measurement because its intent is larger: to make judgements, improve or further develop (program) effectiveness, inform decisions and/or increase understanding. [69] Measurement is one of many components in evaluation and quality improvement.

Many incidents are rare, so monitoring weekly or monthly incidence is not informative. In this case more advanced strategies such as control charts that monitor time between incidents [70] can be used. In settings where control charts are not available, teams can use measures of processes that identify important preventative measures as substitutes or proxies for outcomes.

Process measures should be displayed in run charts to permit quick assessment of performance over time. Run charts have several advantages—they are easy to create without specialised software, they are straightforward to interpret and they provide more information than bar charts or tables that do not show performance over time (and can hide undesirable patterns of performance including short term improvements that may not be sustained). [71] Annotated run charts include notes that help in understanding the factors that contributed to the change in performance (see example below in Figure 13). Run charts are even more useful if they are interpreted using a series of rules that signify non-random patterns. [72,73]

Figure 13. Run chart



The principal goal of measurement in monitoring recommended actions is to assess the improvement potential. [74] Measuring for improvement emphasises a practical approach with 'just enough' data in small sequential samples. [75] Small samples taken frequently can be more informative than large samples taken less often (and are also easier to incorporate into staff work). Measures need to be clearly defined and the strategies for collecting data need to be developed with the staff who will collect them. Collecting baseline data on a process before changes are introduced, is helpful in demonstrating whether the changes are improvements and are sustained over time. The sampling strategy and timeframe for measurement must be clearly stated. It is important to set realistic performance thresholds (e.g. a target for 100 per cent compliance should not be set unless it can be met).

Measurement may take the form of voluntary reporting, intervention tracking, direct observation of performance, chart review, computerised tracking and surveys. Regardless, it is important that measures be carefully defined, that data collection be designed to be practical and that staff are provided with information on why measurement is important and how it can be incorporated into their work. Table 11 provides key questions in designing a strategy to collect data.

Measurement sometimes looks like 'just more work' and measurement that is not well designed, incomplete or hastily done will not be informative. Good measurement helps to assure that improvements are made to ensure safer care environments and can translate into better outcomes for patients and more effective working environments.

Table 11. Key questions in designing data collection

1.	Have I defined the data so that I get exactly what I want?
2.	How accurate is it and does it matter?
3.	How can the data help me?
4.	Can I rely on it being consistent?
5.	What will I do with the data?
6.	Does my collection strategy work?
7.	How will I display the data

Step 6: Close the loop

– Share what was learned (internally and externally)

Close the loop

Sharing what was learned is the ultimate objective of clinical incident analysis and is represented as the last element of the continuum in the Guide and aims to close the loop. Sharing the learnings both within the organisation (with patients, families and carers, those involved in the incident, the analysis team, the executive leadership and Board, Quality Assurance Committees, Clinical Networks, Strategic Advisory Groups and others as needed) and outside the organisation (social media, conferences, webinars, podcasts) is key to preventing additional harm and making care safer. Without learning and sharing, the patients and organisation are still vulnerable, as the same or similar incidents could happen again. Additionally, there is an opportunity lost for other organisations benefiting from the learnings. Results of analyses should rollup into organisation-wide reporting and be shared with the senior leadership, Board and the public.

The incident management process needs to be continuously monitored to ensure that it is effective and reliable. Single-loop learning involves changing methods and improving efficiency to obtain established objectives. Consistent monitoring may also help to identify areas for further improvement, this is known as double-loop learning.

Double-loop learning is different from single loop learning which focuses on 'doing things right'. Double loop learning focuses on changing the objectives themselves (i.e. doing the right things). This learning approach may involve questioning the assumptions about the improvement objective and rethinking new alternatives, objectives, and ways to approach the problem. [76]

Continuous organisational learning and sharing results

Learning from an incident, understanding and articulating what can be done to prevent its recurrence and heal relationships are the ultimate goals of the patient safety incident management process. It is of utmost importance that the learning is fed backwards and forwards through multiple communication channels.

Organisations may wish to conduct a multi-incident analysis of several completed incident analyses where similar incidents can be re-examined to draw larger scale conclusions.

Feedback loops must be created for each incident analysis to share the learning with the various individuals and groups who assisted with analysis and implementation activities. The patient, family, carer and clinicians in the service area where the incident occurred should be informed and involved about what changes

have been implemented and with what results. The incident analysis team will want to know which of the contributing factors they identified were acted upon. Likewise, the implementation team will want to know which of the changes (actions) they implemented had the greatest impact.

This information may be shared in multiple ways, including memoranda, storytelling, huddles or any other modality the organisation is uses for communicating. The need for timely communication is an aspect that cannot be overlooked. Individuals should be specifically assigned this important task so that it is completed in a timely manner.

Feed-forward communication loops where the learning is shared externally are just as important because the same or similar incidents can occur in any organisation, system or country and the learning from one organisation should be transmitted to others to prevent harm. External communication should include what happened, why, what was the organisation's response, what actions (or changes) were implemented, and with what results.

Alerts, advisories or communiques are common tools for feed-forward communication. Sharing de-identified learning with others (in a manner that complies with privacy legislation) is highly recommended to prevent similar harm and also to help others with incident prevention management. For example, patient safety notifications are developed from reported incidents by the Patient Safety and Quality, Clinical Excellence Queensland, to share learnings across Queensland (see Table 12). Patient safety alerts and advisories may also be accessed from national and international data portals and may also be relevant to Queensland clinicians.

Table 12. Patient Safety Notifications (Alerts, Notices, Communiques)

	A Patient Safety Alert is issued for urgent dissemination of information to Hospital and Health Services about a patient safety matter needing immediate attention and action. It will specify mandatory action/s to be taken by health services, assign responsibility for action and the timeframes in which such actions should occur.
	A Patient Safety Notice is issued to inform Hospital and Health Services about potential quality and safety issues requiring a risk assessment at the local level to determine appropriate action/s regarding any identified issues. The Patient Safety Notice will specify that health services must undertake a risk assessment and recommends action to be taken.
	A Patient Safety Communiqué is issued to disseminate quality and safety information to Hospital and Health Services and Divisions to ensure lessons learnt from local, statewide, national and international sources are shared across the health system in a proactive manner.

Reflecting on and improving the quality of analysis and management processes

Organisations are encouraged to periodically dedicate time and resources to review and evaluate how well the incident analysis and incident management processes function within their health services. The purpose of this review effort is to ensure the processes are appropriate, reliable, there is appropriate resources, and staff strive to improve care. In addition, the review can assist in developing and/or improving protocols, checklists and other resources that help teams manage incidents.

Factors that influence the quality of analysis include: [77]

- timeliness of completing the analysis
- quality and strength of recommended actions
- implementation of recommended actions (completion status)
- effectiveness of the actions implemented in reducing the recurrence of harm (monitoring)
- sharing what was learned (internal and external)
- presence of one or more effective mitigating factors (barriers)
- clinician's perception of care safety.

Non-monetary incentives (e.g. awards) [78] that recognise those teams that demonstrate

improved performance can have a significant role in increasing engagement in the process and therefore also work to improve the quality of the analysis. The quality of the incident analysis is extremely important in restoring trust and rebuilding relationships amongst all those involved in an incident and in building a restorative just culture in the organisation.

Conclusion

Planning for, reviewing and improving the safety of patient care is a fundamental aspect of providing consistently delivered quality healthcare services. This Guide offers advice across the spectrum of clinical incident management, including a range of approaches to improve the safety of care practices in healthcare organisations. It can positively assist care providers to perform a system-based analysis of patient safety incidents, within the setting of a restorative just culture, that includes the identification of contributory factors, determination of recommended actions to reduce risk, development of action plans, and measurement strategies to evaluate the effectiveness of the plan.

Striving to identify and address the underlying reasons why incidents occur will lead to a greater understanding of hazards in the system and, ultimately, as we work to close the loop, to a safer healthcare system for all. It is integral that the culture of the entire healthcare organisation move from a backward-looking determination of blame to a focus on learning and support for all people affected by the clinical incident; a restorative just culture.

Appendices

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Appendix A
Analysis team membership, roles and responsibilities

Leader: someone knowledgeable about the general type of incident and has organisational authority to implement the process.

Attributes:

- has strong analytical and clinical skills in the subject area.

Responsibilities:

- keeps team focused on incident
- provides support for cultural change
- supports team members in their analysis
- removes barriers faced by team members.

Facilitator: quality specialist, patient safety officer or risk manager with knowledge and self-confidence.

Attributes:

- expertise in analytical methods and techniques
- skilled at group dynamics
- skilled at delegation
- skilled at group consensus building.

Responsibilities:

- coordinates team meetings
- keeps team focused on event
- facilitates constructive dialogue
- monitors sequence of events
- ensures that analysis process is followed per organisational protocol
- may be responsible for ensuring completion of final report.

Individuals knowledgeable about subject area: depending on the type of incident, this will vary. Clinical and non-clinical staff provide valuable insight. For instance, teams for suicide incidents may include physical plant or architecture staff, case managers, medical officers, nurses, security personnel, etc. Teams analysing medication events may include pharmacists, biomedical engineers, information technologists, medical officers, nurses, administration staff, pharmacy technicians, etc. Teams for patient falls may include physiotherapists, rehabilitation staff, medical officers and nurses, etc.

Attributes:

- extensive knowledge of the subject area
- credibility within organisation
- analytical, open minded
- interested.

Responsibilities:

- provide information relevant to the different steps involved in the incident
- provide information on the usual process
- help identify contributing factors and actions relevant to current practice.

Patient/family/carer or consumer representative

Attributes:

- understanding of the incident from a perspective different from others in the team
- ability to communicate their perspective and understanding of the incidents.

Responsibilities:

- provide their opinion, knowledge of the incident and other information to facilitate the identification of what happened, how and why it happened, and what can be done to prevent recurrence
- participation in constructive dialogue.

Senior leadership

Attributes:

- authority for decision making
- drives the safety culture by example.

Responsibilities:

- ensures that actions are implemented once approved
- ensures that staff are scheduled away from normal duty to participate in analysis
- ensure that results of analysis are communicated broadly
- ensure that healthcare clinicians and patient/family or representative involved are supported.

Other staff or consultants: include outside agencies as appropriate (home care, vendors, e tc.) as they can provide information that is not available to members inside the organisation.

Attributes:

- specific knowledge of equipment, technology, etc. that may have contributed to event or may be required for actions.

Responsibilities:

- provide expert opinion and knowledge to facilitate identification of contributing factors and/or development of recommended actions.

Appendix B
Incident reporting and investigation legislation

The information below is an overview only. Always refer to the relevant documents or legislation for further information and obtain legal advice if necessary.

The following requirements for reporting Severity Assessment Code (SAC) 1* clinical incidents is required by the Health Service Directive, Patient Safety which was issued by the Director-General under section 47 of the HHB Act:

- Hospital and Health Services will report all SAC1 incidents to the Patient Safety and Quality, Clinical Excellence Queensland by recording the incident in RiskMan within one business day of becoming aware of the SAC1 event.
- Hospital and Health Services will conduct an analysis of all SAC1 incidents.
- Hospital and Health Services will submit a SAC1 analysis report to the Patient Safety and Quality, Clinical Excellence Queensland within 90 calendar days of the incident being reported in RiskMan as a SAC1 event.
- Each SAC1 analysis report must contain:
  - a factual description of the event
  - the factors identified as having contributed to the event
  - recommendations to prevent or reduce the likelihood of a similar event happening again.

Please note, the following requirement of the HHB Act, (section 100(3)) if the SAC1 analysis report to be submitted to Patient Safety and Quality, Clinical Excellence Queensland is a RCA report in accordance with the Act, the report must not contain the name or address of the patient, the staff involved in providing the health service or members of the RCA team.

***SAC1 incidents are those incidents resulting in death or likely permanent harm which is not reasonably expected as an outcome of healthcare.**

There is no legislation or binding policy in Queensland that prescribes which form of analysis HHSs must undertake for SAC1 events. HHSs should be aware of the following enabling provisions of the HHB Act, for some forms of analysis (e.g. RCA or clinical review) in deciding which form of analysis to undertake for each SAC1 incident. Consideration should also be given to other forms of analysis other than the legislation.

Section 123 and a reportable event

Where an RCA team is appointed under section 98 of the HHB Act, and it transpires that the event is not a reportable event, the provisions in Part 6, Division 2 of that Act dealing with RCAs, will apply as if the event were a reportable event (refer to section 123). This includes the provisions dealing with disclosure of information and certain statutory protections. As an example, where an RCA team has been appointed under section 98 for an incident which has been registered as a SAC1, and the incident is then reassessed and rated as a SAC2, the statutory requirements, obligations and protections in Part 6, Division 2 of the HHB Act (*Root cause analysis*) will continue to apply, regardless of the SAC rating.

Root cause analysis

The HHB Act facilitates—but does not mandate—the use of RCA as a quality improvement technique by providing protections from RCA reports and documents being used in legal proceedings and providing certain protections for members of RCA teams (see sections 116 to 122).

For an RCA to attract the privileges and protections under the legislation it must (among other things) meet the following summarised criteria:

- the SAC1 event to be analysed is a *'reportable event'* as defined in the *Hospital and Health Boards Regulation 2012* (Figure B.1) or under section 123 noted above.

- a systematic process of analysis is applied which meets the requirements of section 100(1) of the HHB Act such as:
  - factors that contributed to the happening of the event may be identified
  - remedial measures that could be implemented to prevent a recurrence of a similar event may be identified.
- the analysis must not include:
  - investigating the professional competence of a person in relation to the event
  - finding out who is to blame for the happening of the event (refer to sections 102 and 103 HHB Act).
- the RCA team must comprise at least two persons and they must (refer to section 99(1)) HHB Act:
  - have the appropriate skills, knowledge and experience to conduct an RCA of the event, having regard to the nature of the event
  - have not been directly involved in providing the health service to be analysed.

Table B.1: Reportable events

For section 94 of the Act, definition reportable event, the following events are prescribed—

(a)	surgery or another invasive procedure being performed on the wrong site of a patient's body resulting in serious harm to the patient or the death of the patient;
(b)	surgery or another invasive procedure being performed on the wrong patient resulting in serious harm to the patient or the death of the patient;
(c)	the wrong surgical or other invasive procedure being performed on a patient resulting in serious harm to the patient or the death of the patient;
(d)	the unintended retention of a foreign object in a patient after surgery or another invasive procedure resulting in serious harm to the patient or the death of the patient;
(e)	a haemolytic blood transfusion reaction caused by ABO incompatibility resulting in serious harm to the patient receiving the blood transfusion or the death of the patient;
(f)	the suspected suicide of a patient within an acute psychiatric unit or ward;
(g)	an error relating to a patient's medication resulting in serious harm to the patient or the death of the patient;
(h)	the use of physical or mechanical restraint resulting in serious harm to a patient or the death of a patient;
(i)	the use of an incorrectly positioned orogastric or nasogastric tube resulting in serious harm to a patient or the death of a patient;
(j)	the discharge or release of a patient who is a child under the age of 15 years to an unauthorised person;
(k)	stillbirth;
(l)	any death of a patient, or serious harm or other harm to a patient that is likely to be permanent, that— i. is not mentioned in paragraphs (a) to (i); and ii. was not reasonably expected to be an outcome of the health service provided to the patient.

Other factors to consider in deciding whether to do an RCA under the HHB Act include:

Confidentiality (see section 105)	RCA team members and commissioning authorities are generally prevented from disclosing information acquired as part of an RCA. There are a number of exceptions to this general rule, including providing RCA reports to patient safety entities (such as the Patient Safety and Quality and statutory Quality Assurance Committees), the Health Ombudsman and the Coroner.
Protections for RCA reports (see section 119)	RCA reports, chain of events documents and other documents created by (or for) an RCA team cannot be accessed under administrative or court orders, and are not admissible in legal proceedings other than a coronial inquest (including civil, criminal and disciplinary proceedings).

Protections for RCA team members (see sections 104-115)	RCA team members are protected from civil liability for acts or omissions made honestly and without negligence for an RCA and must be indemnified by the appointing authority for the costs of defending any related proceedings.
Protections for RCA participants (see sections 116-119)	RCA team members cannot be required to give evidence or produce documents relating to an RCA in legal proceedings other than proceedings for an offence under the Act. Staff or other persons cannot be required to give evidence in legal proceedings about: • whether the person gave information to an RCA team • what information the person gave to an RCA team • a document the person gave to an RCA team that was created by the person for the purposes of the RCA • information the person was given, or questions the person was asked, by an RCA team.

Clinical review

The HHB Act also facilitates—but does not mandate—the use of a clinical review to identify recommendations on ways in which the safety and quality of public sector health services can be maintained and improved. When commissioned as a standalone review, the legislation provides protections from clinical review reports being used in legal proceedings and provides certain protections for those appointed to conduct the clinical review. These protections apply to clinicians appointed to provide expert advice to Health Service Chief Executives, the Director-General and a person or entity whose role includes maintaining and improving the safety and quality of public sector health services.

When a clinical review is undertaken to inform a HSI, this type of clinical review report is NOT privileged and may be accessed through administrative or legal proceedings.

Similar to RCA, some of the factors to consider in deciding whether to conduct a clinical review under the HHB Act are:

- Confidentiality
  Experts are generally prevented from disclosing information acquired as part of clinical review (see section 132).
- Protections for appointed clinical review reports
  Clinical review reports, except those to provide clinical advice to a health service investigator, cannot be accessed under administrative or court orders and are not admissible in legal proceedings, including civil, criminal and disciplinary protections (see section 138).
- Protections for appointed clinicians
  Clinicians who are appointed under the HHB Act are protected from civil liability for acts or omissions made honestly and without negligence for a clinical review (see section 280(1)(d)).

Clinicians appointed to conduct a clinical review under the HHB Act cannot be required to produce their report or give evidence relating to their report in legal proceedings (see section 138(3)).

Health service investigations

The HHB Act, Part 9 also facilitates—but does not mandate—the use of health service investigation to investigate and report on any matters relating to the management, administration or delivery of public sector health services.

Health service investigations are not primarily a safety and quality tool and do not attract the statutory privileges granted to RCAs and clinical reviews under the HHB Act.

If a RCA or clinical review is not appropriate, or is subsequently stopped, because the matter under analysis is believed to involve a Blameworthy Act* (see section 94), a HSI may be the most appropriate incident analysis tool, or if there is a mix of clinical and non-clinical issues issues, a HSI may be a flexible option.

* A *Blameworthy Act* is:

(a) an intentionally unsafe act;
(b) deliberate patient abuse; or
(c) conduct that constitutes a criminal offence

Appendix C
A just culture approach

A just culture approach

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate -most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this *just culture guide*, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:
- A **just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- A **just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- A **just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- The **guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here:	**Q1. Deliberate harm test** ↓			
1a.	Was there any intention to cause harm?	→	YES	**Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. **END HERE**
No go to this question:	**Q2. Health test** ↓			
2a.	Are there indications of substance abuse?	→	YES	**Recommendation:** Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. **END HERE**
2b. **2c.**	Are there indications of physical ill health? Are there indications of mental ill health?	→	YES	**Recommendation:** Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. **END HERE**
if **No to all** go to this question:	**Q3. Foresight test** ↓			
3a. **3b.** **3c.**	Are there agreed protocols/accepted practice in place that apply to the action/omission in question? Were the protocols/accepted practice workable and in routine use? Did the individual knowingly depart from these protocols?	→	If **NO** to any	**Recommendation**: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. **END HERE**
if **Yes to all** go to next question:	**Q4. Substitution test** ↓			
4a. **4b.** **4c.**	Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances? Was the individual missed out when relevant training was provided to their peer group? Did more senior members of the team fail to provide supervision that normally should be provided?	→	If **YES** to any	**Recommendation**: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. **END HERE**
if **No to all** go to this question:	**Q5. Mitigating circumstances** ↓			
5a.	Were there any significant mitigating circumstances?	→	YES	Recommendation: Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. **END HERE**
if **No**				
Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. **END HERE**				

Source: *NHS 'A just culture guide'*

Appendix D
Restorative just culture framework [29,30]

First victim/s	
Who is hurt?	**Patients/Client/Consumer, Family, Carer**
What do they need?	Information about the incident Access to the clinician/s involved Restitution Reassurance of prevention
Who should meet those needs?	Clinician/s
Obligation and action	Allow them to tell and retell their story and be willing to participate in the process Clinician Disclosure and Open Disclosure Engagement in the review process Evaluation – provide feedback
Second victim/s	
Who is hurt?	**Clinicians / Practitioners**
What do they need?	Psychological first aid, (support, compassion, healing) Tell their story and learning - forgiveness Reinstatement
Who should meet those needs?	Organisation to have support programs/policies/ procedures – Peer support
Obligation and action	Determine the most appropriate review process Recognise needs of first victim/s Express remorse Contribute to the review and the learning
Organisation/s	
Who is hurt?	**Directorates, Services within, Departments/Units or Whole of organisation**
What do they need?	Support and learning Information Leverage for change Reputational repair
Who should meet those needs?	Department to have programs, policies, plans
Obligation and action	Willing to participate Offered help Explored systemic processes – consider best practice – forward looking review
Community	
Who is hurt?	**Community members who witnessed or were affected by the incident – (small regional or rural centres including indigenous)**
What do they need?	Regular current Information about incident and aftermath via 13 HEALTH, hotlines and websites, Support and reassurance
Who should meet those needs?	Department and/or Organisation
Obligation and action	Development of plan to engage & communicate with community. A willing to participate in restorative process and forgiveness

Appendix E
Creating a constellation diagram

The diagramming step of the analysis process is focused on recognising all system issues that may have contributed to the incident rather than just the factors that are apparent and closer to the point of incident occurrence. Diagramming can assist teams to better understand systemic factors and the inter- relationships between them, better visualise these relationships, and help avoid the trap of hindsight bias. Diagramming is one of the elements that can increase the credibility, reliability and effectiveness of analysis in making care safer.

Many readers will be familiar with the use of Ishikawa (also called fishbone) [59] and tree [60] diagrams (Figures E.1 and E.2) to support analysis, however both these types of diagrams have limitations. Ishikawa diagrams are helpful for brainstorming and clustering factors, but do not easily illustrate complex relationships between factors. Tree diagrams have been perceived as too linear and their top-down approach can be misleading in terms of relative importance of identified contributing factors.

Figure E.1: Ishikawa (fishbone) diagram

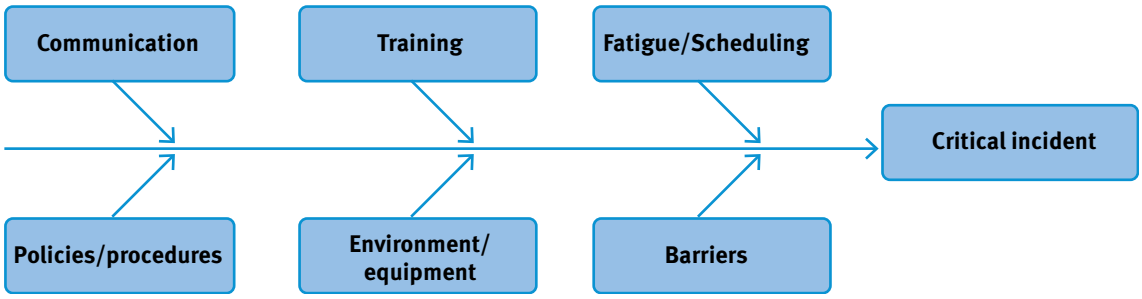
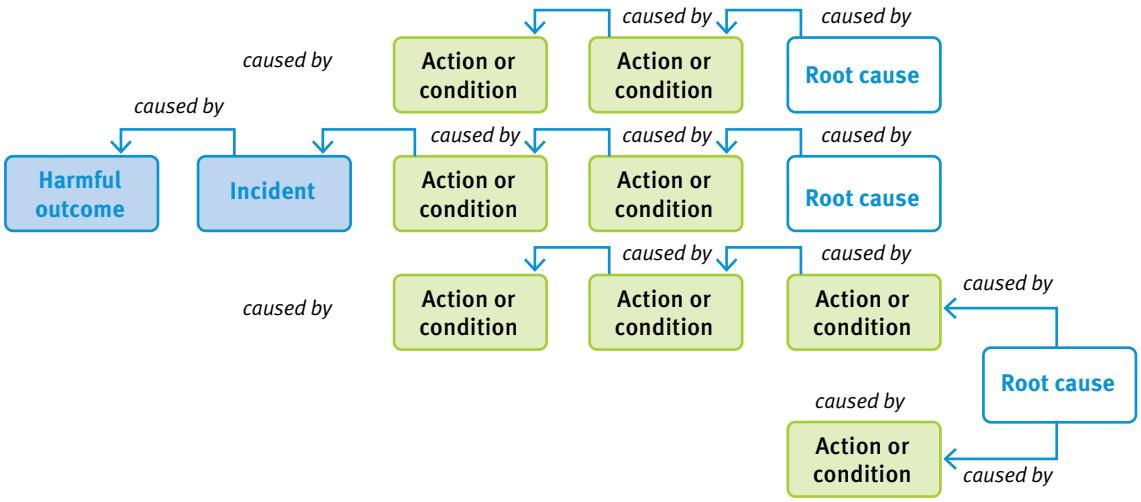


Figure E.2: Tree diagram



In an attempt to address the advantages and limitations of these two types of diagrams, the features of each were blended into a constellation diagram, and a new diagramming method was developed. A literature search did not identify any references to constellation diagrams in the context used here (diagramming and analysis methods (including statistical analysis) that emphasise the identification of groups of elements as well as their inter-relationships—for example, the functional resonance accident model, [79] concept and cognitive mapping [80,81] and social network analysis.[82]

Through its suggested categories of factors and use of guiding questions, the new diagram offers a systematic way to analyse contributing factors at the system level. In addition, the unique visual representation of the constellation diagram encourages and facilitates the identification of inter-connections and the sphere of influence among contributing factors, which will assist in identifying the contributing factors with the biggest impact on patient safety.

Improving safety and quality of care in complex adaptive healthcare systems is dependent on the ability to see how the parts of the system influence each other so the limited resources available can be focused with more precision to where the greatest risks are identified. The constellation diagram offers flexibility to accomplish this, more than the Ishikawa and tree diagrams.

There are five steps involved in developing a constellation diagram of a patient safety incident:

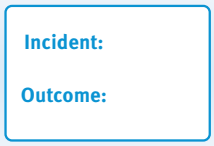
1. Describe the incident
2. Identify potential contributing factors
3. Define inter-relationships between and among potential contributing factors
4. Identify the findings
5. Confirm the findings with the team.

The development and recording of the diagram can be done using the local resources available, such as a hand-drawn diagram that can be scanned in an electronic format, a photograph of sticky notes, as well as using software like Word, Excel, Visio, Mindmap or others.

Step 1: Describe the incident

1. Briefly summarise the incident and harm/potential harm in the centre of the diagram (typically fewer than 10 words)(Figure E.3).

Figure E.3: Describe the incident



It is crucial for the team to clearly define the starting point for the analysis. This is usually a harmful outcome that the team wants to prevent. It is often, but not always, the actual outcome. For example, in the case of a near miss the potential incident may have been recognised prior to the patient being involved. Alternatively, an incident may have occurred but was recognised and action taken prior to harm resulting. In both of these circumstances, the analysis team would identify the starting point for analysis as the potential harm, as no harm actually occurred.

Step 2: Identify potential contributing factors

1. Add the contributing factor categories (task, equipment, work environment, patient, care team, organisation, etc.) to the diagram in a circle around the incident/outcome description. (Figure E.4).
2. Use the example guiding questions provided (appendix K), and other questions as appropriate, to identify potential contributing factors.
3. Place each potential contributing factor on a sticky note and group the factors near the category title (Figure E.5).

Figure E.4: Add contributing factors

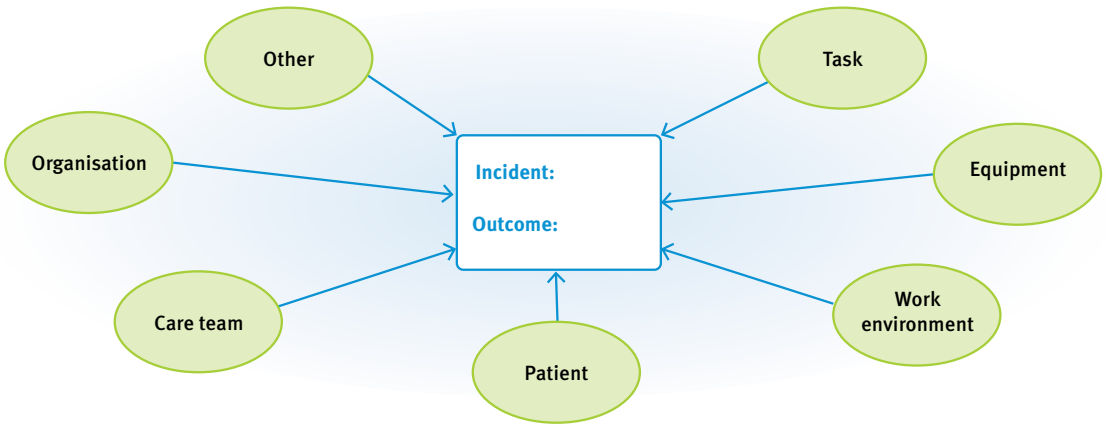
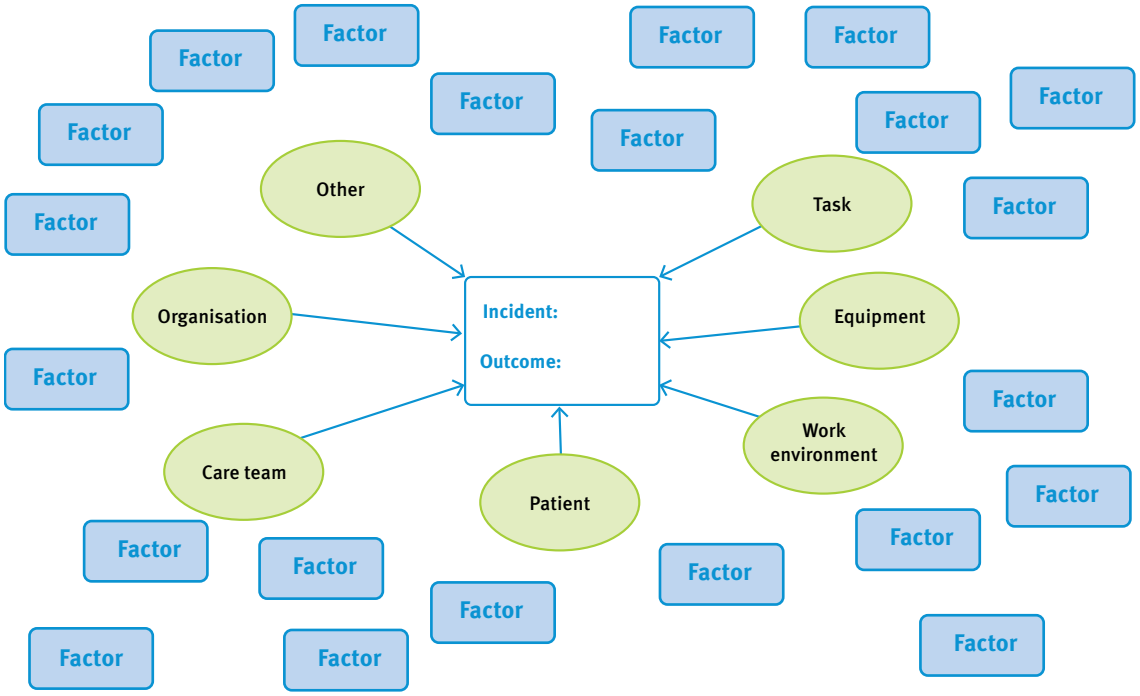


Figure E.5: Define relationships between potential contributing factors



When identifying potential contributing factors, focus on system-based factors to ensure that the recommended actions are not people-focused. Keeping in mind human factors principles and systems theory, analysis should focus on how and why certain human actions occurred, not just that they occurred.

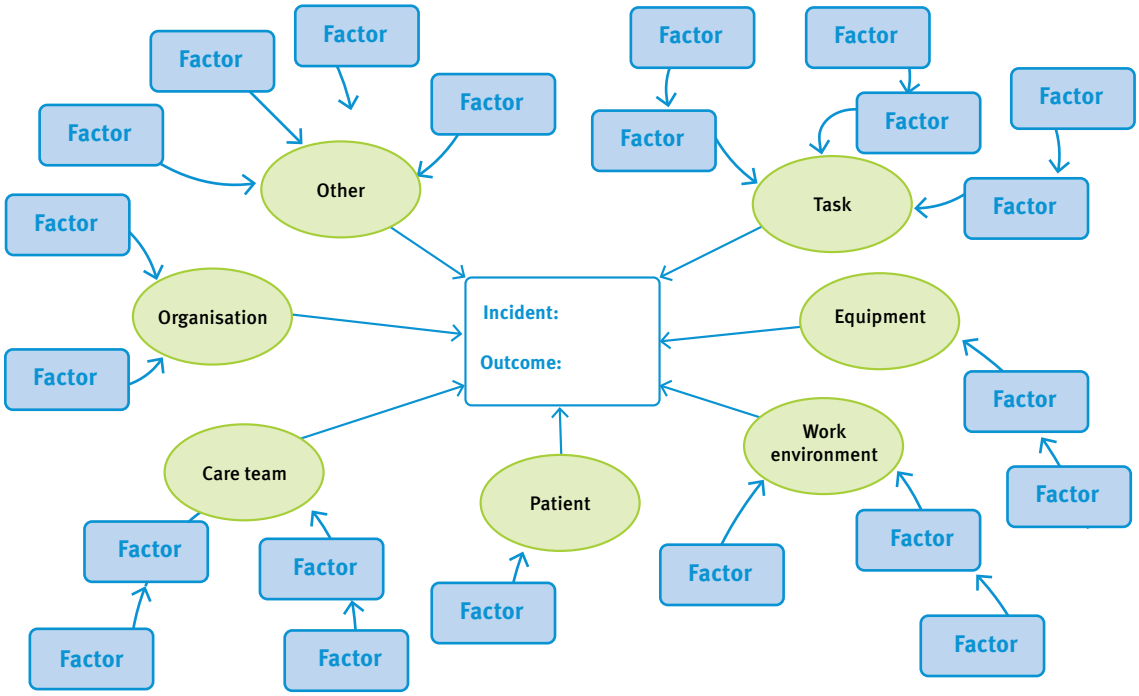
For instance, in the course of analysing an incident in which an incorrect medication was administered, it was determined that the nurse was in a hurry. The fact that the nurse was in a hurry is a factual detail of what happened, and not a contributing factor. The contributing factor/s are those that may have caused the nurse to be in a hurry. Examples could include: too many tasks were assigned (e.g. the nurse was assigned too many complex patients) or the patient's medication needs conflicted with shift change (e.g. the patient was admitted right before the shift ended and the nurse wanted to give the patient their pain medication so that they did not have to wait until after the shift change). By focusing on the systems-based contributing factors, the analysis team will be able to identify higher leverage solutions. Recommended actions should be consistent with one of the main tenets of human factors: fit the task or system to the human, not the other way around.

Step 3: Define inter-relationships between and among potential contributing factors

1. For each potential contributing factor ask, 'how and why did this happen?', 'what was this influenced by?' and 'what else influenced the circumstances?'
2. Add the answers to these questions to develop relational chains:
   a) some contributing factors may be directly linked with each other, within the same category, to create a chain
   b) some answers may come from different contributing factor categories. If so, show the linkage by drawing lines.
3. Continue to ask 'why' and 'what influenced it' questions until no further information can be generated.

Once the team has identified potential contributing factors using the categories of guiding questions, the second phase of analysis begins. Asking what this was influenced by? and what else influenced the circumstances? The team then expands the constellation diagram to include relational chains of contributing factors as shown in figure E.6. This questioning process continues until there are no more questions, knowledge becomes limited, or until the issues identified fall outside the scope of the analysis. Expect that factors from different chains will be inter-related and may influence each other.

Figure E.6: Define relationships between potential contributing factors



Step 4: Identify the findings

The next step in the analysis process is to identify the findings that are central to the incident. The team should expect to identify several findings. There is seldom only a single reason why an incident occurred.

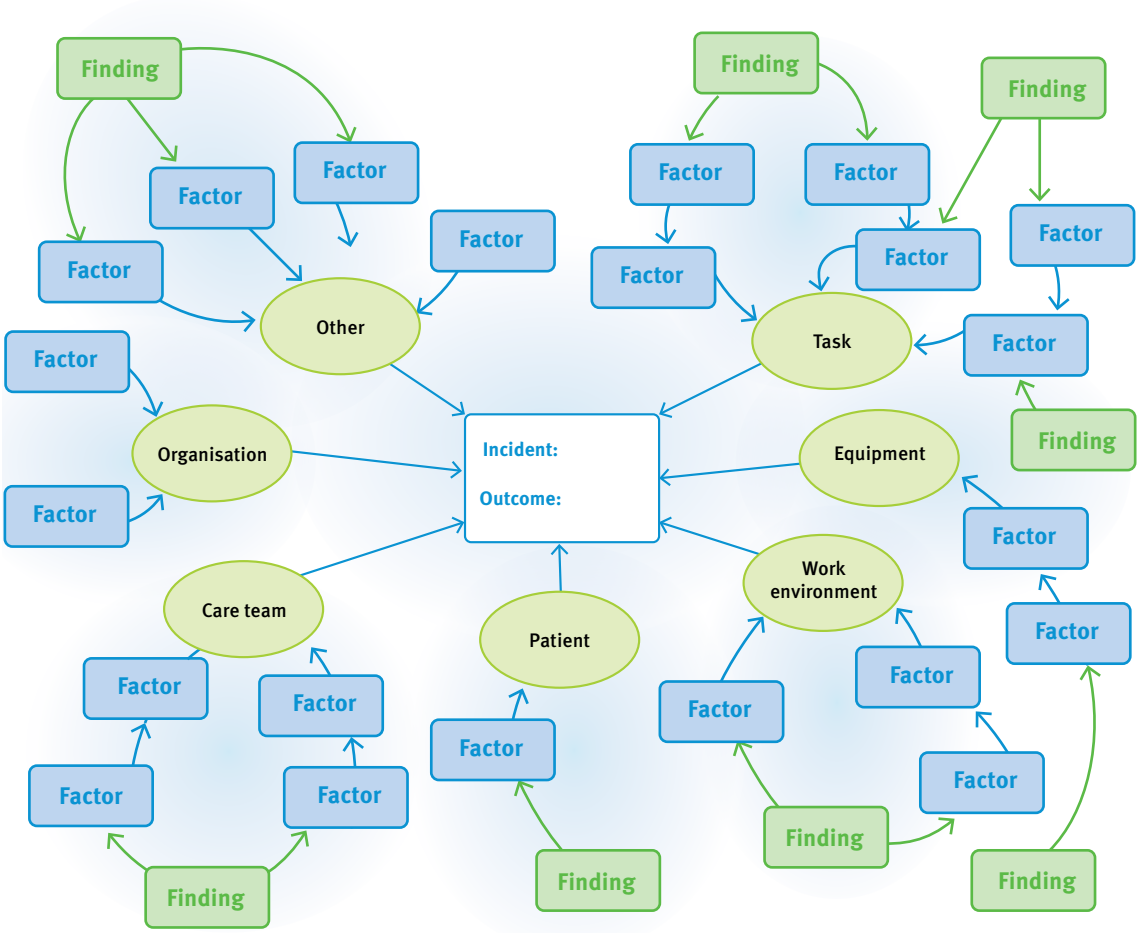
Findings will be identified in three categories:

1. Factors that, if corrected, would likely have prevented the incident or mitigated the harm—these will be the basis for developing recommended actions (note that these factors may require actions at different levels of the system).
   The question to be asked is 'if this factor was eliminated or corrected, would it have likely reduced the risk of incident recurrence and/or harm?' While it is possible that many contributing factors will be identified in the analysis, certain factors, if corrected, have the greatest probability to prevent the incident altogether, or mitigate harm from the incident. It is common for these factors to be highly relational—in other words, relationships or potential relationships between a number of the identified factors appear to have combined to enable an incident to occur; there is a sphere of influence amongst them. These findings will be the basis for developing recommended actions (note that actions may be required at different levels of the system).

   Two options:
   - would it have likely reduced the risk of the incident occurring?
   - would it likely reduce the risk of similar incident from recurrence?
2. Factors that if corrected, would not have prevented the incident or mitigated the harm, but are important for patient/staff safety or safe patient care in general. These issues should be included in the team's findings and brought to the attention of the appropriate individuals for follow-up and documented in the analysis report for future analysis and actions as appropriate.
3. Mitigating factors—factors that didn't allow the incident to have more serious consequences and represent solid safeguards that should be kept in place.

An example of a completed constellation diagram is illustrated in figure E.7 on the following page. See also Appendix K for a case study, including a complicated constellation diagram.

Figure E.7: Completed constellation diagram



Step 5: Confirm the findings with the team

1. Ensure consensus and support for the development of recommended actions.

   The team should agree on the findings before moving forward to develop recommended actions. If there is a lack of immediate agreement, it is important to discuss and work through any disagreements to strive to arrive at consensus before proceeding. If key individuals involved in the incident are not participants on the analysis team, it is helpful to ask for their feedback on the findings of the analysis team as part of the process for verifying the findings. This stage of the process should also include a back-checking step—in other words, consider the impact of correcting the identified vulnerabilities (e.g. if this factor had not been present or had been corrected, would the incident still have occurred?).

Appendix F
Severity assessment code (SAC) matrix

A clinical incident is defined by Australian Commission on Safety and Quality in Health Care (ACSQHC) as "an event or circumstance that resulted, or could have resulted, in unintended and/or unnecessary harm to a patient or consumer; and/or a complaint, loss or damage.

SEVERITY ASSESSMENT CODE (SAC)	SAC 1		SAC 2	SAC 3	SAC 4
ACTUAL CONSEQUENCE TO PATIENT	**Death or likely permanent harm** which is not reasonably expected as an outcome of healthcare.		**Temporary harm** which is not reasonably expected as an outcome of healthcare.	**Minimal or no harm** which is not reasonably expected as an outcome of healthcare.	**No harm or near miss**
SOURCE: 'Reportable event' in accordance with: *Section 29: Hospital and Health Boards Regulation 2012*	**Reportable events** For section 94 of the Act, definition reportable event, the following events are prescribed— (a) surgery or another invasive procedure being performed on the wrong site of a patient's body resulting in serious harm to the patient or the death of the patient; (b) surgery or another invasive procedure being performed on the wrong patient resulting in serious harm to the patient or the death of the patient; (c) the wrong surgical or other invasive procedure being performed on a patient resulting in serious harm to the patient or the death of the patient; (d) the unintended retention of a foreign object in a patient after surgery or another invasive procedure resulting in serious harm to the patient or the death of the patient; (e) a haemolytic blood transfusion reaction caused by ABO incompatibility resulting in serious harm to the patient receiving the blood transfusion or the death of the patient;	(f) the suspected suicide of a patient within an acute psychiatric unit or ward; (g) an error relating to a patient's medication resulting in serious harm to the patient or the death of the patient; (h) the use of physical or mechanical restraint resulting in serious harm to a patient or the death of a patient; (i) the use of an incorrectly positioned orogastric or nasogastric tube resulting in serious harm to a patient or the death of a patient; (j) the discharge or release of a patient who is a child under the age of 15 years to an unauthorised person; (k) stillbirth; (l) any death of a patient, or serious harm or other harm to a patient that is likely to be permanent, that— i. is not mentioned in paragraphs (a) to (i); and ii. was not reasonably expected to be an outcome of the health service provided to the patient. Additional information, including **specific definitions** relating to some of above is available here: *Section 29: Hospital and Health Boards Regulation 2012*	Includes the following as a result of a clinical incident: • Additional investigations performed. • Surgical intervention. • Procedures involving the wrong patient or body part resulting in temporary harm	Includes the following as a result of a clinical incident: • First aid treatment only required.	Includes the following as a result of a clinical incident: • No harm • Near miss

Appendix G
Guide to level/type of analysis

Level/type of analysis based on degree of harm

This table provides suggestions on what might be considered appropriate and proportionate when assessing the level of analysis required for a clinical incident. Health services may have local policies regarding the type of analysis for SAC2, SAC3 or SAC4 clinical incident and the reporting requirements. There may be situations where an incident with a low SAC rating requires a comprehensive analysis based on the level of risk. When considering if an analysis is required there a number of criteria to consider including:

- Severity of incident
- Probability of recurrence
- Complexity of the factors that influenced the incident
- Other contextual factors (preliminary assessment, frequency of occurrence, regulatory mandates, internal or external pressures)

PATIENT SAFETY INCIDENTS	Degree of harm	Assessment of risk	Level/type of analysis based on risk of harm
	NO HARM	Could have realistically resulted in severe or death outcome	Comprehensive analysis (there is often much to learn from how incidents were prevented)
		Incident occurring on subject where national guidance has been issued	Comprehensive analysis (there is often much to learn from how incidents were prevented)
		Frequently occurring	Consider multi-incident or concise analysis (combining multiple analyses may lead to more effective solutions)
		May represent significant concern or systemic service failure	Concise analysis or comprehensive analysis (combining multiple analyses may lead to more effective solutions)
		Attracting public concern or media interest and not included above	Concise analysis
	LOW HARM	Could have realistically resulted in severe or death outcome	Comprehensive analysis
		Incident occurring on subject where national guidance has been issued	Concise analysis or comprehensive analysis
		Frequently occurring	Consider multi-incident or concise analysis (combining multiple analyses may lead to more effective solutions)
		May represent significant concern or systemic service failure	Concise analysis or comprehensive analysis (dependent on potential for future harm)
		Attracting public concern or media interest and not include above	
	MODERATE	Could have realistically resulted in severe or death outcome	Comprehensive analysis
		Incident occurring on subject where national guidance has been issued	Concise analysis or comprehensive analysis
		Frequently occurring	Consider concise or multi-incident analysis (combining multiple analyses may lead to more effective solutions)
		May represent significant concern or systemic service failure	Concise analysis or comprehensive analysis (dependent on potential for future harm)
		Attracting public concern or media interest and not include above	
	SEVERE	Frequently occurring	Consider comprehensive or multiple-incident analysis (combining multiple analyses may lead to more effective solutions)
		All other patient safety incidents, claims or complaints with severe outcome	Comprehensive analysis
	DEATH	Homicide by or of patient in receipt of mental health care program approach in last 6 months	Comprehensive analysis and/or independent analysis (set timescales)
		Suicide of patient in receipt of mental health care program approach in last 6 months	Consider comprehensive or aggregated analysis (combining multiple analyses may lead to more effective solutions)
		Any other potentially avoidable deaths in healthcare or healthcare premises	Comprehensive analysis

Appendix H
Sample analysis team charter

Date:

From:

Subject: Incident analysis team charter

To:

1. This memorandum confirms that an analysis team will be convened to determine the contributing factors for the patient safety incident briefly described below:

   Date incident occurred ___ /___ /___ Date organisation was aware of incident ___ /___ /___

   The analysis method is (tick one): ◯ Comprehensive ◯ Concise ◯ Multi-Incident ◯ Other

2. As part of the process, the team will be responsible for developing a final report and recommendations based on their expert analysis. All analyses are quality assurance focused processes and the team's products (e.g. interviews, preliminary and final reports, etc.) are considered confidential.

   This analysis is a root cause analysis and will be privileged and protected under the *Hospital and Health Boards Act 2011* (tick one): ◯ Yes ◯ No

   Note: If in the course of conducting the analysis it appears that the patient safety incident/s under consideration may have been related to an intentional unsafe act or acts, the appropriate organisational representative should be contacted to determine if an administrative analysis, or other type of analysis process, should occur.

3. List of disciplines and/or services anticipated to be involved in the analysis:

_____

_____

_____

4. List of potential internal (e.g. facility) and external experts or consultants:

_____

_____

_____

5. Resources available to the team (e.g. room number, flip charts, laptop computer, etc.):

_____

_____

_____

6. The team's final report is due on: ___ /___ /___

(Adapted from the Veterans Affairs National Centre for Patient Safety, in the Canadian Root cause analysis Guide) [78]

Appendix I
Team management checklist

Team management checklist
Planning
◯ Team members identified and confirmed ◯ Room booked ◯ Refreshments ordered
Preparation
◯ Confidentiality agreement ◯ Project charter/terms of reference ◯ Health record ◯ Related policies and procedures ◯ Incident sequence of events ◯ Flip charts, sticky notes, markers ◯ Agenda and goals, pre-reading if required ◯ Ground rules
Follow-up
◯ Additional meeting/s scheduled: _____ ◯ Report preparation delegated to: _____ Target date: ___ /___ /___ ◯ Documents collected

Appendix J
Investigative interview guidance (cognitive type interview)

Cognitive type interview: taking a first-hand account of individuals' involvement in a patient safety incident.

An investigative interview is designed to help interviewees retrieve from memory the events associated with a patient safety incident.[83]

A cognitive interview is an interviewing technique based on psychological theory and research for examining the retrieval of information from memory.[84]

The interview style recommended for incident analysis is a modified approach of the formal cognitive interview. It involves actively listening to someone who recalls their first-hand account of an event they have either witnessed, or been involved in, as soon after it has happened as possible.

Preparation

Listening to the first-hand accounts from those involved in an incident as soon as possible after it has happened will help the investigation team start to build a picture of what happened and potentially highlight what other information will be required. The optimum time for holding an interview is between two and 72 hours after the incident. [84,85]

The interviewer needs to establish who they want to interview and make arrangements to do so as soon as possible. The identified staff should be invited to attend, told the purpose of the interview, what to expect and what preparation they need to do. It is essential that the interviewer and the room are prepared prior to the interview.

Inviting the member of staff to attend for an interview

Where appropriate, a written invitation to the interview can be provided and the details below included. Where this is not practical due to the need to see staff as soon as possible after the incident, staff should be advised in advance and be given the following information verbally:

- The purpose of the interview and details of the incident being investigated.
- The time, place and estimated length of the interview.
- Who will be conducting the interview and their role.
- How the interview will be conducted and the first-hand account record (e.g. the interview will be informal, notes will be taken to inform the investigation, but these will not act as a formal witness statement and do not need the interviewee's signature).
- What documentary evidence will be available to them during the interview.
- The fact that they can bring a friend or colleague for support (explanations need to be given regarding the role of this friend/colleague e.g. confidentiality, their involvement etc.).
- Advice on what will happen after the interview.

Interviewer preparation

- The interview should take place in a quiet, relaxed setting and, if possible, away from the interviewee's usual place of work and not at the scene of the incident.
- The room should be set out informally with refreshments available and steps taken to ensure, where possible, no interruptions occur (e.g. mobile phones).
- Where possible, the interviewee should have the opportunity to attend the interview in work time and arrangements may need to be made with their line manager to ensure this.
- Depending on the nature of the case or the interviewee's personal involvement, they may find the process of recounting the events either upsetting or disturbing. The interviewer will need to have information available on staff support/counselling.
- The interviewer should ensure they have all the relevant documentation available at the interview.

It is important to remember in the cognitive interview to only interview one staff member at once.

Conducting the interview

Introductions (where appropriate) should be made of those present in the room. Include details on roles and an explanation of the sequence of the interview and approximate length. The incident analysis process should be explained and an estimate given of how long it will take to complete.

It is important to reinforce that the incident analysis is not part of a disciplinary process. The interviewer should explain that notes will be taken throughout for the purpose of informing the investigation. It must be stressed that these notes will not act as a formal witness statement. Guidance and support should be given by a union representative or solicitor as applicable.

The interviewee should be asked to confirm they have understood all of the above and should be reminded that they should offer only factual information, but include everything regardless of whether they think it is relevant or not. The interviewee should be discouraged from making off the record comments. The interviewee should also be advised that the first-hand account and the final report will be written with due anonymity to staff and the patient.

Completion of the interview

On completion, the interviewer should ensure the interviewee feels appropriately supported and that any further support required is organised. The interviewer should reconfirm what will happen with the information gained from the interview and how this will be used in the incident analysis process.

Appendix K
Case study—comprehensive analysis: resident absconds from a residential aged care facility

Background

The scenario for analysis is based upon a resident who absconds from a secure dementia unit within a residential care facility. The care facility is located in a community in regional Queensland. In the summer months, temperatures regularly reach 35 degrees celsius and in the winter, it may be as cold as 8 degrees celsius.

In this scenerio, residents deemed to be at risk of wandering are provided with monitoring bracelets called wanderer alarms and there are monitoring alarms at the main entrance, at the front of the care unit (located adjacent to the front door of the building), as well as at a fire exit at the back of the care unit, which is at the rear of the building. The fire exit is equipped with an alarm that sounds when the door is opened. The monitoring bracelets are checked every couple of weeks to ensure they are functioning properly.

Incident

At supper time, a personal care assistant noticed that a 78-year-old female resident was not in the dining room. The personal care assistant was asked to look for her but could not find her in the nursing home. A code yellow was called. On notifying the police, it was learned that the resident had been found, cold and confused, walking on a highway two kilometres away and that police were trying to determine where she lived. The resident had been taken to a local emergency department for assessment and treatment.

Immediate response

The nursing director and administrator were notified and took the following actions:

1. Contacted the resident's family to advise them of the incident.
2. Instructed staff to:
   a. ensure the safety of other residents by testing all door alarms and monitoring bracelets
   b. secure the resident's health record
   c. quarantine the resident's monitoring bracelet upon her return to the home
   d. test the emergency exit alarms.
3. Met with the relevant staff the next morning to conduct a preliminary debrief to gather and establish known facts, and provide emotional support, including advising about the availability of the Employee Assistance Services (EAS).
4. Ensured completion of appropriate documentation in the health record and clinical incident report.

Prepare for analysis

In the days following the incident, the nursing director and the patient safety/quality coordinator made a preliminary assessment of the known facts related to the incident. In consultation with the home administrator, a decision was made that a comprehensive analysis would be required. This decision was communicated to the nursing director.

Once a decision was made to undertake a comprehensive analysis of the incident, a team was convened who included the following:

- analysis technical expert (patient safety/quality coordinator)
- content expert (nurse manager—East Wing)
- front line worker (carer—North Wing)
- person from another discipline (so what person) (receptionist).

Analysis process—what happened?

Prior to the first meeting with the analysis team, the patient safety/quality coordinator undertook some preliminary information gathering for the analysis team:

- Interviewed all staff directly involved (e.g. all staff working the day and evening shift that day, including carers, medical staff, nursing staff, etc.).
- Interviewed others who may have helpful information (e.g. the resident's family, other family visitors).
- Reviewed the resident's health record for relevant clinical information.
- Reviewed organisational policies and procedures related to monitoring of residents with cognitive deficits.
- Contacted other local residential care facilities for copies of policies and procedures related to monitoring of residents with cognitive deficits and reviewed the current state and national guidelines.

At the first meeting with the analysis team, the team:

1. Analysed information gathered by the patient safety/quality coordinator:
   a) Information from the incident report:
      i. 78-year-old female resident found two kilometres from the care facility by local police. Resident was distressed and confused.
      ii. Temperature 10 degrees celsius.
      iii. Resident dressed in light clothing and slippers.
      iv. Resident transported to local emergency department for assessment and treatment.
      v. Police received call from the care facility indicating that resident was missing - police advised that resident has been transported to hospital.
      vi. Resident assessed in emergency department, treated with warm blankets and IV fluids and observed overnight.
      vii. Resident returned to the care facility the following morning after breakfast.
   b) Policies and procedures related to monitoring of residents considered a risk for absconding.
   c) Results of a literature search and environmental scan for current best practices related to management of residents who are at risk for absconding.
2. Visited the secure unit in the care facility and walked around pertinent areas, including the resident's room, the dining room and the lounge, checking for the location of exits and alarms and conducted a safe simulation of the incident.
3. Examined monitoring devices available for use and reviewed manufacturer's instructions.
4. Created a detailed sequence of events of the incident (Table K.1).

Table K.1: Detailed sequence of events for abscond incident

Date/time	Information item	Comment/ source
Four months prior to incident	• 78-year-old female resident admitted to the secure dementia unit of the home. • Medical history: type 2 diabetes, dementia. • Admission medications: Metformin 500mg three times daily, Donepezil 5mg daily, multiple vitamins daily. • Initial nursing assessment: impaired cognition, poor decision-making skills, mild confusion, walks independently with a cane. • Assessed as a risk for absconding and a monitoring bracelet was placed on her right wrist.	Health record; staff interviews
Six weeks prior to incident	Resident has become increasingly confused and agitated. Assessed by physician who ordered Risperidone 0.25mg at bed time.	Nursing progress notes
Four weeks prior to incident	Resident found outside the home in the early evening. Resident was in the staff parking lot at the back of the building and was found by a staff member coming in for the evening shift. Staff on duty did not recall hearing any alarms sounds. The resident's bracelet was tested and found to be working.	Nursing progress notes, staff interview
Two weeks prior to incident	Resident very confused and attempting to leave unit, redirected numerous times by staff. Doctor contacted, order received to increase Risperidone to 0.25mg twice daily.	Nursing progress notes
Day of incident 1145hr	Resident told nurse who gave noon medications that she was going home. Staff planned for resident to eat lunch in the dining room and then nap in her room per her usual routine. She was last observed eating lunch.	Staff interview
1305hr	Back door alarm sounded, reset by staff without checking as one staff member had just left the desk on lunch break and usual practice was to exit through back door to gain easy access to the parking lot.	Staff interview
1600hr	Carer went to check on resident to get her ready for dinner but did not find her in her room, assumed she was already in the lounge watching TV.	Staff interview
1730hr	Carers noticed that resident was not in the dining room. Discussed with other staff who went to check her room.	Staff interview
1740hr	Carers unable to locate resident. Checked other care units and walked around perimeter of building but could not locate her.	Health record, staff interviews
1755hr	Carer reported to charge nurse that resident is missing. A code yellow alert was called, with a comprehensive search initiated of the entire facility.	Health record, staff interviews

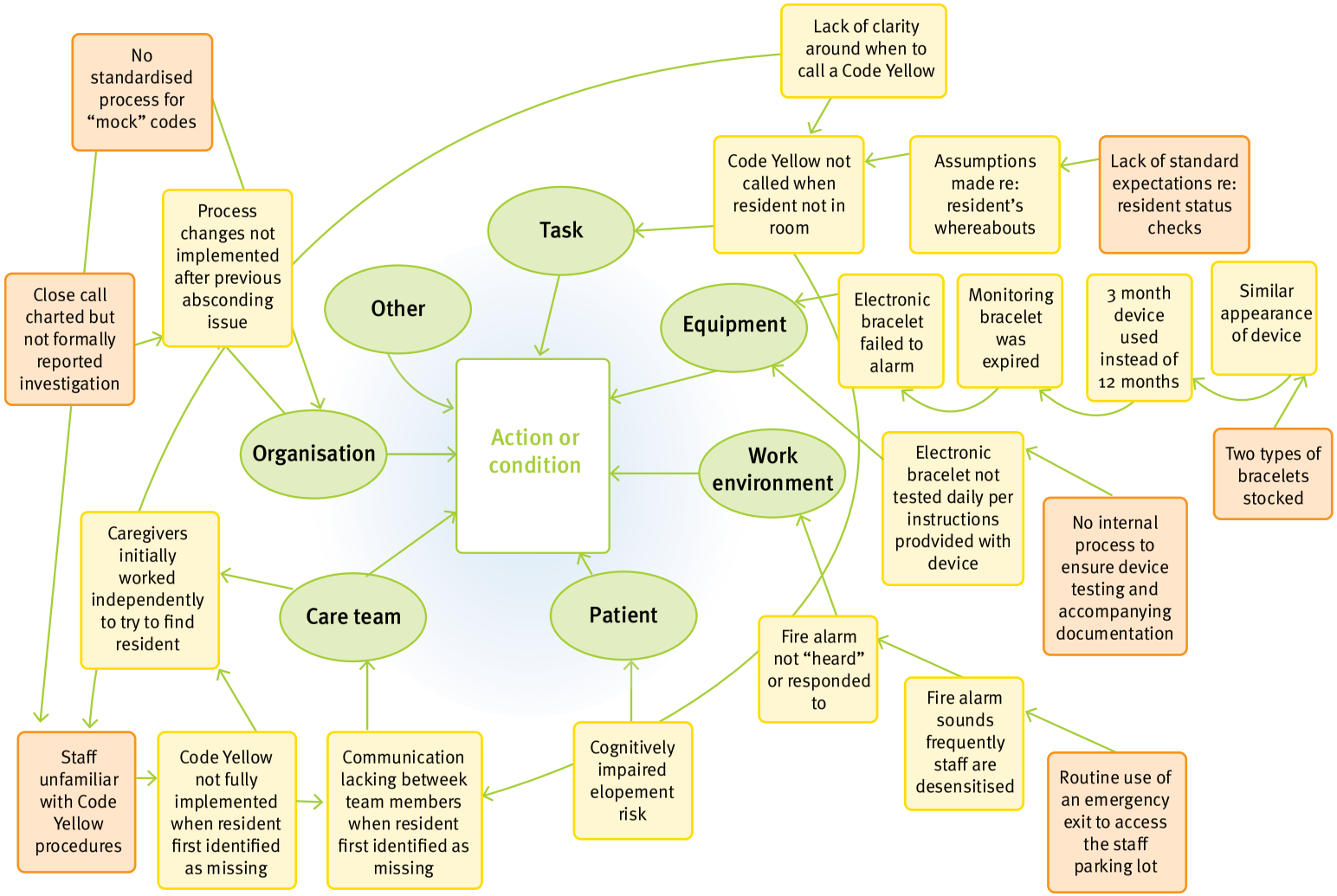
Date/time	Information item	Comment/ source
1840hr	Staff unable to locate resident on the grounds. Resident's family contacted. Evening staff are arriving so three of the day shift staff use their personal vehicles and begin searching the surrounding area. Call made to local police. Police advise that an elderly woman was found two kilometres from the home at approximately 1800hrs and that she has been transported to hospital for assessment as she was distressed (dressed only in light clothing and slippers, temperature 10 degree Celsius) and appeared confused.	Health record, staff interviews
1845hr	Resident's family contacted to advise that resident has been found and is being cared for at the local emergency department.	Health record, staff interviews
1850hr	CNC at the care facility contacts the local emergency department for report on resident condition. Resident has had IV fluids initiated and has been given warm blankets.	Health record, staff interviews
1900hr	CNC contacts nursing director to provide report of situations.	Health record, staff interviews
Day after incident 0930hr	Resident returned to residential aged care facility from hospital.	Health record
1030hr	The resident's monitoring bracelet is removed and tested. Found not to be working. It was later determined that the resident had been provided with a 90 day device, rather than a 12-month device as intended.	Health record

Analysis process: how and why it happened

At the second analysis team meeting, the team used information provided in the sequence of events and their understanding of the incident from the simulation to create a constellation diagram (Figure K.1). The following steps are required to create a constellation diagram:

1. Describe the incident:
   - outcome: resident found distressed and dehydrated two kilometres from the care facility
   - incident: resident absconded.
2. Identify potential contributing factors using contributing factor categories and guiding questions
3. Define relationships between contributing factors
4. Identify findings
5. Validate the findings with the team.

Figure K.1: Constellation diagram of abscond incident



[redacted]

Statements of findings

The analysis team identified the following findings:

- **Task:**
  - Lack of standard expectations regarding resident status checks decreased the likelihood that the resident absconding would be detected in a timely way.
- **Equipment:**
  - Two types of monitoring bracelets with similar appearance stocked in the care facility increased the likelihood that the incorrect device would be selected and applied.
  - No standardised internal process to ensure testing of monitoring bracelets with accompanying documentation decreased the likelihood that the bracelet would be identified as non-functioning prior to an absconding incident.
- **Work environment:**
  - Routine use of an emergency exit to access the staff parking lot decreased the likelihood that the alarm function would be effective as staff became desensitised to frequent alarms.
- **Patient:**
  - The resident's cognitive impairment decreased the likelihood that she would be aware of the risk of leaving the facility.
- **Care team:**
  - Communication lacking between team members when resident first identified as missing, combined with lack of familiarity with Code Yellow procedures, decreased the likelihood that a Code Yellow would be initiated immediately.
- **Organisation:**
  - Lack of a formal process to report and investigate close calls decreased the likelihood that a Code Yellow would be initiated immediately, would be followed-up to identify process changes to prevent future occurrences.
  - Lack of a standardised process for regular mock codes to provide ongoing training and assess staff understanding of processes decreased the likelihood that staff would be familiar with Code Yellow procedures.
- **Other**
  - No other factors identified.

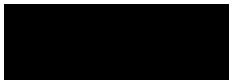
Analysis process: What can be done to reduce the risk of recurrence and make care safer?

The analysis team proposed the following recommended actions:

- **Task (T):**
  - T1: Establish routine procedures for confirming and documenting whereabouts of residents with wandering dementia.
- **Equipment (E):**
  - E1: Develop a standardised process for daily checks, with documentation, of monitoring bracelets.
  - E2: Standardise devices used to monitor residents at risk of absconding to either the 90 day or 12-month model.
- **Work environment (W):**
  - W1: Implement magnetic card access technology to enable staff use of the emergency exit door, elimination frequent nuisance alarms.
- **Organisation (O):**
  - O1: Work with frontline staff to develop and apply criteria for reportable incidents.
  - O2: Develop a protocol for analysing high risk near miss incidents to ensure that learning is applied to prevent recurrence (e.g. by using the concise incident method).
  - O3: Ensure staff members are familiar with the Code Yellow protocol through a scheduled in-service and ongoing inclusion in orientation sessions.
  - O4: Ensure staff members are proficient in the use of the Code Yellow and other emergency protocols through quarterly unscheduled mock code exercises.

Prioritise actions

Recommendation	Risk severity assessment)	Hierarchy of effectiveness (high, medium, low leverage)	Predictors of success (alignment, existing mechanisms, quick wins)	System level targeted (micro, meso, macro, mega)	Note if evidence is available and what type	Confirm validity, feasibility	Order of priority (or timeframe)
T1: Establish routine procedures for confirming and documenting whereabouts of residents with wandering dementia	High	Medium	Medium	Micro	No	Medium	Within 30 days
E1: Develop a standardised process for daily check, with documentation, of monitoring bracelets.	High	Medium	High	Micro	Yes, other unit is doing daily checks successfully	High	Within 30 days
E2: Standardise devices used to monitor residents at risk of absconding to either the 90 day or 12-month model.	Medium	High	Low	Meso	Yes, Global Patient Safety Alerts	Medium	Within 6 months
W1: Implement magnetic card access technology to enable staff use of the emergency exit door, eliminating frequent nuisance alarms.	Medium	High	Medium	Meso	No	Medium	Within 12 months
O1: Work with frontline staff to develop and apply criteria for reportable incidents.	High	Low	High	Meso	No	Medium	Within 6 months
O2: Develop a protocol for analysing high risk/ Near miss incidents to ensure that learning is applied to prevent reoccurrence (e.g. by using the concise incident analysis method).	High	Low	High	Macro	No	High	Within 6 months
O3: Ensure staff are familiar with the Code Yellow protocol through a scheduled in-service and ongoing inclusion in orientation sessions.	High	Low	High	Micro	No	High	Within 30 days
O4: Ensure staff are proficient in the use of the Code Yellow protocol through quarterly unscheduled mock Code Yellow exercises.	High	Low	High	Meso	Yes, simulation research paper XYZ	High	First mock code to be held within 3 months



Follow through

Evaluation implementation.

The Director of Care analysed the status of implementation of recommended actions one year after the incident analysis was completed.

Recommendation (category)	Sources and ID#	Date entered	Progress status	Timeframe (end date)	Target area	Risk level	Individual responsible
E1: Standardise daily device checks with documentation.	IA # ID	Sept. 13	Implemented as presented Oct. 1	Oct. 1	All residents	High	Director of Care
E2: Standardise devices to either the 90 day or 12- month model.	IA # ID	Sept. 13	Under consideration		All residents	High	Director of Purchasing
W1: Magnetic card access technology for emergency exists.	IA # ID	Sept. 13	Nothing done		All emergency	Medium	Director of Purchasing
O1: Development and application of criteria for incident reporting.	IA # ID	Sept. 13	Partially implemented	New reporting form implemented in June	All staff	High	Director of Care
O2: Protocol for analysis of high risk near miss incidents.	IA # ID	Sept. 13	Partially implemented	Two near miss events analysed (May and July)	All staff	High	Director of Care
O3.1: Code Yellow in service for all staff.	IA # ID	Sept. 13	Implemented as presented	Completed Oct. 15 and 20	All staff in home	High	Director of Care
O3.2: Code Yellow inclusion in orientation.	IA # ID	Sept. 13	Implemented as presented	January orientation session	All new staff	High	Director of Human Resources
O4: Quarterly unscheduled mock Code Yellow exercises.	IA # ID	Sept. 13	Steps towards implementation	One mock code held Feb. 20	All new staff in home Patient	High	Patient Safety Leader

Appendix L
Incident analysis guiding questions

A set of guiding questions is provided below to guide the identification of contributing factors, hazards and mitigating factors during the how and why did it happen stage of incident analysis. They are intended to assist with checking the availability and strength of safeguards at all levels in the organisation. The questions assist to guide the analysis towards the identification of system vulnerabilities that aligned in such a way that allowed for the incident to take place. Teams are encouraged to note, analyse and report the system barriers that worked well (mitigating factors) and which should be reinforced so they will continue to prevent future harm.

The questions are grouped around categories of factors designed to focus the analysis on the interaction between humans and the system, and in this way help identify system-level contributing factors at various levels in the organisation. The categories were developed by researching and adapting categories used in analysis throughout the world [49,50,51,52] and refined through pilot testing and consultation with a human factor specialist.

The way the list is used is a matter of personal preference. Some may choose to use the questions below to guide information gathering and interviews, while others may prefer to use them to cross-reference the information already collected. The goal of this exercise is to go through the questions to find if the safeguards were in place and functioning. For each category, consider what other factors may have contributed to the incident and include them in the analysis.

- The guiding questions are provided as examples—this is not an exhaustive list.
- The guiding questions are not intended to be used as the interview questions, but as prompts for analysis.
- For every guiding question, ask how it impacts the incident.
- If the answer to a guiding question suggests that the safeguard was not in place or did not work, probe further with additional questions (e.g. why is this the case? If so, how did this/these contribute to/impact the incident?).

Task (care/work process):

- Were there previous or predicted failures for this task or process?
- Were specialised skills required to perform the task?
- Was a fixed process or sequence of steps required (e.g. order sets, checklists)? Did it exist and was it followed?
- Was a protocol available, was it up-to-date and was it followed in this case?
- Were there constraints or pressures (e.g. time, resources) when performing the task?
- Was the information required to make care decisions available and up-to-date (e.g. test results, documentation, patient identification)?
- Was there a risk assessment/audit/quality control program in place for the task/process?
- Other?

Equipment (including information and communication systems):

- Were the displays and controls understandable?
- Did the equipment automatically detect and display problems?
- Was this display functional?
- Were the warning labels, reference guide and safety mechanisms functional and readily visible/accessible?
- Were the maintenance and upgrades up-to-date?
- Was the equipment standardised?
- Would the users describe this equipment as easy to use?
- Were the communication systems (phone, pager, software, hardware etc.) available and operational?
- Other?

Work environment:

- Did noise levels interfere with the alarms?
- Was the lighting adequate for the task?
- Was the work area adequate for the task/s being performed (e.g. space, layout, location and accessibility of resources)?
- Other?

Patient/s characteristics:

- Did the patient/s have information to assist in avoiding the incident? If not, what would have supported the patient in assisting their care team?
- Did factors like age, sex, medications, allergies, diagnosis or any other medical conditions contribute to the incident? How did they contribute?
- Did any social or cultural factors contribute to the incident? What factors? In which way?
- Was language a barrier?
- Other?

Care team:

Caregiver/s:

- Was the education, experience, training and skill level appropriate?
- Was fatigue, stressors, health or other factors an issue?
- Was the workload appropriate?
- Was appropriate and timely help or supervision available?
- Other?

Supporting team (all involved in care process):

- Was there a clear understanding of roles and responsibilities?
- Was the quality and quantity of communication (verbal and/or written) between team members appropriate (clear, accurate, free of jargon, relevant, complete and timely)?
- Were there regular team briefings/debriefings about important care issues?
- Was team morale good? Do team members support each other?
- Were the communication channels available and appropriate to support the needs of the team (e.g. email, pager and phone)?
- Other?

Organisation:

Policies and priorities:

- Were the relevant policies and procedures available, known, accessible and did they meet the needs of users?
- Were there workarounds to the documented policy/procedure?
- Was there a mechanism in place to identify and resolve gaps between policy and practice?
- Were the strategic priorities of the organisation clear to all?
- Other?

Culture:

- Was everyone (patients, clinicians, other staff) comfortable to speak up about safety concerns?
- Was there visible support from leadership and board for safe patient care?
- Was communication between staff and management supportive of day-to-day safe patient care?
- Were incidents considered system failures with people not blamed?
- Other?

Capacity (resources):

- Did scheduling influence the staffing level, or cause stress, fatigue?
- Was there sufficient capacity in the system to perform effectively (e.g. access to resources)?
- Were targets and/or incentives appropriate?
- Other?

Other—consider:

- Were there any local conditions or circumstances that may have influenced the incident and/or an outcome?
- Were there any sector specific conditions or circumstances that may have influenced the incident and/or outcome?
- Other?

Appendix M
Three human factors methods that can be used in incident analysis

Various human factors methods can be employed in the analysis process to help answer the question how did it happen? They range in complexity, time and resources, and expertise (in human factors) needed. All three methods (described below) assist in examining the human-system interaction in detail. With cognitive walkthrough—perhaps the easiest and most cost-effective method to employ —a participant is asked to think out loud as they simulate the tasks that were involved in the incident. In a heuristic evaluation, an audit is carried out of the various parts of the system (such as equipment, paper forms, computer systems etc.) that were used in the tasks that were part of the incident. The audit is used to determine if human factors design principles were violated, and as such, may be identified as possible contributing factors in the incident. Heuristic evaluation requires an understanding of human factors principles as they apply to different systems (e.g. computer systems). Finally, usability testing can be used, in which human-system interaction with equipment, paperwork, or processes are observed (similar to a simulation). Participants are asked to carry out a set of tasks in a simulated environment given the scenario in the incident. Some level of human factors training is needed in order to plan and execute usability tests, and to interpret the results. However, the information is extremely helpful and detailed because, if done correctly, the usability test examines how the human-system interaction occurs in the real world.

Cognitive walkthrough

As noted above, this is perhaps the quickest to conduct and takes the least amount of time, resources and human factors expertise to complete, as compared to the two other methods discussed here.

Cognitive walkthrough can be used to help identify contributing factors in the analysis phase, or it is used to help discover the details of the cognitive and physical activities that took place (or may take place, in the case of evaluating a recommended action).

To carry out a cognitive walkthrough, recruit participants who are either representative of the person/s involved in the incident (e.g. pharmacist or nurse) or the actual workers involved, to simulate the set of tasks surrounding the incident. Ask the participant to think out loud as they simulate, or walk through each step of that task. The key is that they verbalise what they are thinking as they are doing it. Throughout the simulation, it is helpful to ask prompting questions such as ‘what were you looking to do at this point?’, ‘what did you have to figure out?’, ‘where did you find the information you needed?’, ‘what did you have to think about next?’, ‘what made you think you needed to do that?’, ‘how obvious was it to you?’ or ‘how confident were you that you did it correctly?’.

The success of a cognitive walkthrough is heavily dependent on:

- The participant feeling comfortable to express their thoughts without fear.
- The proper identification of the task or activities that participants will simulate (if the task is too narrowly defined, it will limit the amount of information you can find).
- The facilitator of the cognitive walkthrough keeping their opinions to themself and not leading the participant (the facilitator should only tell the participant what task to perform, but not how they should perform the task, nor how they should have performed the task).

If possible, recruit between one and six people to participate in the walkthrough. It is best to have four to six participants because it will capture a wider cross-section of the human-system interaction. However, one participant is better than none and even one person will provide extremely rich information for the incident analysis.

At the end of the cognitive walkthrough, the person conducting the activity will have a more detailed understanding of the cognitive and physical activities that led to the incident and what aspects of the system may have failed to support these activities, and therefore may have been contributing factors.

Alternatively, if the cognitive walkthrough was conducted to evaluate proposed recommended action, the walkthrough will provide some insight into their effectiveness. It may also help determine if the recommended action has created some unintended and undesirable consequences, such as:

- Does it take additional unnecessary mental effort?
- Does it make the task overly complex or tedious?
- Does it create confusion or uncertainty?
- Does it create risk for other kinds of errors?

Depending on the response to these questions, it may be necessary to modify or select an alternate recommended action to pursue (and possibly evaluate again using any of the three human factors methods described in this appendix).

Heuristic evaluation

This method requires some knowledge of human factors design principles and how to apply them to specific systems (e.g. computer systems). It may take approximately the same amount of time to conduct as the cognitive walkthrough, though possibly longer depending on complexity, and does not require participants or other special arrangements. This method can be useful in the analysis phase to help identify contributing factors, or to help evaluate recommended actions before they are implemented.

In a heuristic evaluation, an audit of the system is performed to determine if human factors design principles are violated. The principles cover a wide range of issues related to whether the design of the system fits the task or human. The audit can identify where human-system interaction is negatively influenced.

The results of a heuristic evaluation can provide very detailed information about contributing factors and how they can be changed to improve the risk for errors. Also, the method can be used to help develop and design the recommended action.

Usability testing

Among the three methods described here, usability testing likely takes the most time and resources. It also requires some expertise in human factors to plan, execute and analyse the results. However simple usability tests can be performed that are not as time and resource consuming and can yield very helpful information about contributory factors, or about whether a recommended action is effective.

In a usability test, participants are recruited to carry out a specific task (or set of tasks). The test can be carried out in a simulated setting, or in some cases the actual work area. Then information related to how the task (or set of tasks) was executed is gathered, such as time on task, number (and nature) of steps, or errors. This allows for observation of how the human-system interaction plays out, and where difficulties are encountered (contributing factors). A formal usability test may require anywhere from 20 to several hundred participants and take weeks, if not months, of planning. However, for the purpose of gathering information for an incident analysis, a less formal approach can be taken, and fewer participants recruited, because the aim is to gain a qualitative understanding of possible contributing factors. Four to six participants would be desirable, but even involving only one or two participants may yield helpful qualitative information for the incident analysis.

Similar to other methods described, usability testing can be used for both identifying contributing factors as well as for evaluating the effectiveness of recommended actions.

Example of using human factors to guide an incident analysis.

When examining an incident in which a nurse incorrectly sets up a medical device, it is important to identify the contributing factors. An action, such as 'the nurse pushed the wrong button' is not a contributing factor; it is a factual description of what happened. The goal in the analysis is to determine how and why this happened. To approach this question using human factors, it is necessary to examine the equipment's user interface and look for design features that may have influenced this action. For instance, as part of a heuristic evaluation, questions you could ask include:

- Was the button close to the one they intended to push?
- Was it labelled in a manner that led them to believe that pushing that button was the correct action?
- Were the instructions that were displayed on the screen unclear as to what button they needed to push next?
- Was the button label inconsistent with the terminology used in the displayed instructions?
- Was the button grouped closely with other buttons that are typically used in the task the nurse was performing (leading them to believe that it was to be used in this task)?
- Was the button's appearance similar to (and possibly confusable with) other buttons?
- Were there other confusing features on the interface that may have caused a misunderstanding or confusion?

You could also look at materials that were involved in setting up the device. For instance, if an order form was used, you would examine its ease of use. Not only it's readability and legibility, but also how it related to the task of setting up the device. For instance:

- Does the nurse refer to the order form during device set up?
- What information does the nurse use to help with the set up?
- Is the information provided in a logical order that matches what they need to do with the device?
- Is the terminology used on the order form consistent with what's used on the device?
- Is there any information that may be confusing?
- Does the organisation of the information on the order form match the flow of the task?

Next, you would explore the nature of the task and how that may have influenced the human-system interaction. For instance, time pressure, performing multiple tasks at once, complexity of the steps, and so forth. Also, the environment, work area layout, organisation context, team and patient factors also may influence how work is carried out and therefore may be the source of contributing factors.

The guiding questions in Appendix L provide a starting point for examining the factors that may have played a role in the incident.

A cognitive walkthrough to observe nurses setting up the device will also provide information on aspects of the process that may be confusing, or where information is not readily available, leading to interruptions in the process that may also lead to errors.

Appendix N
Developing a statement of findings template and examples

Developing a statement of finding - TEMPLATE *'The contributing factor/s, within the context of the incident, increased/decreased the likelihood that this outcome would occur'.*		
Primary Outcome	↓	
Immediate *What happened?*	↓	
Intermediate *Why did it happen?*	↓	
Root cause *If we change, may prevent future harm*	**Statement of finding** →	
		led to,
Intermediate		
		contributed to,
Immediate		
		increased the likelihood of,
Problem statement		

Developing a statement of finding – EXAMPLE 1

'The contributing factor/s, within the context of the incident, increased/decreased the likelihood that this outcome would occur'.

Primary Outcome		a patient overdose of prescribed medication
Immediate *What happened?*		patient received twice the prescribed quantity of dopamine
Intermediate *Why did it happen?*		incorrect programming of the IV pump
Root cause *If we change, may prevent future harm*	**Statement of finding**	The lack of nursing induction training in IV pump operation
		led to,
Intermediate		the incorrect programming of the IV pump which
		contributed to,
Immediate		to the patient receiving twice the prescribed quantity of dopamine which
		increased the likelihood of,
Problem statement		a patient overdose of prescribed medication.

Developing a statement of finding - EXAMPLE 2

'The contributing factor/s, within the context of the incident, increased/decreased the likelihood that this outcome would occur'.

Primary Outcome		skin lesion being removed from the wrong limb
Immediate *What happened?*		a bypass of routine final checking
Intermediate *Why did it happen?*		a culture of non-compliance
Root cause *If we change, may prevent future harm*	**Statement of finding**	the absence of practise compliance monitoring
		led to,
Intermediate		a culture of non-compliance which
		contributed to,
Immediate		a bypass of routine final checking that
		increased the likelihood of,
Problem statement		a skin lesion being removed from the wrong limb.

Source: ACHS Improvement Academy - https://www.achs.org.au/improvement-academy

Appendix O
Case study—concise analysis: medication incident

Background

This scenario takes place within a community that is serviced by a hospital and busy home care service. The hospital emails new and updated home care referrals to a generic email address. The referral form provides demographic patient information, diagnosis, a list of discharge medications and doctor's orders for home care. During business hours Monday to Friday, a home care coordinator analyses the emailed document and accesses the Home Care Central Record for any existing patients. The coordinator then analyses the information in the documents and schedules the applicable home care visits. After business hours and on weekends, home care nursing staff periodically check the emails and sorts them by ongoing patients or new patients. Referrals updating the status of ongoing patients are given directly to one of the nurses responsible for the geographic area of the community.

Pharmacists and technicians dispense medications from the pharmacies in the community. Technicians are responsible for processing prescriptions in the computer and preparing and labelling medications as well as inventory management functions. Pharmacists are responsible for analysing the patient medication profile and completing the final check of the medications before they are dispensed for pick-up or home delivery.

Some attending doctors at the community hospital email prescriptions to patients' pharmacies so that patients and families can easily pick up any medications needed on the way home.

Incident

The incident involves a 78 year old male homecare patient requiring a leg ulcer dressing change every five to seven days. The patient is obese and has a history of angina, high blood pressure and deep vein thrombosis. He has limited mobility and was in hospital for eight days with a diagnosis of community acquired pneumonia. The patient was discharged on a Saturday with a referral sent through the home care email account to advise of his return home. His list of medications were noted on the form as: Nifedipine 10mg tds (calcium channel blocker), Atenolol 50mg bd (beta blocker), Coumadin 2 mg daily (anticoagulant), Aspirin 100mg daily (antiplatelet), doxcycline 100mg daily x 6 days (antibiotic), nitrospray prn and DuoDERM dressing to leg ulcer weekly. Additional background information: patient was weak and slightly short of breath at discharge.

Analysis process – what happened?

Based on the incident report, an analysis of the home care record, hospital chart and referral form, the facilitator responsible for conducting this concise analysis started to draft a sequence of events of the incident (Table O.1). The interviews conducted with the patient, pharmacist and registered nurses (RNs), together with an examination of the drugs involved in the incident, helped confirm and expand the sequence of events.

Table O.1: What happened: medication incident—final sequence of events

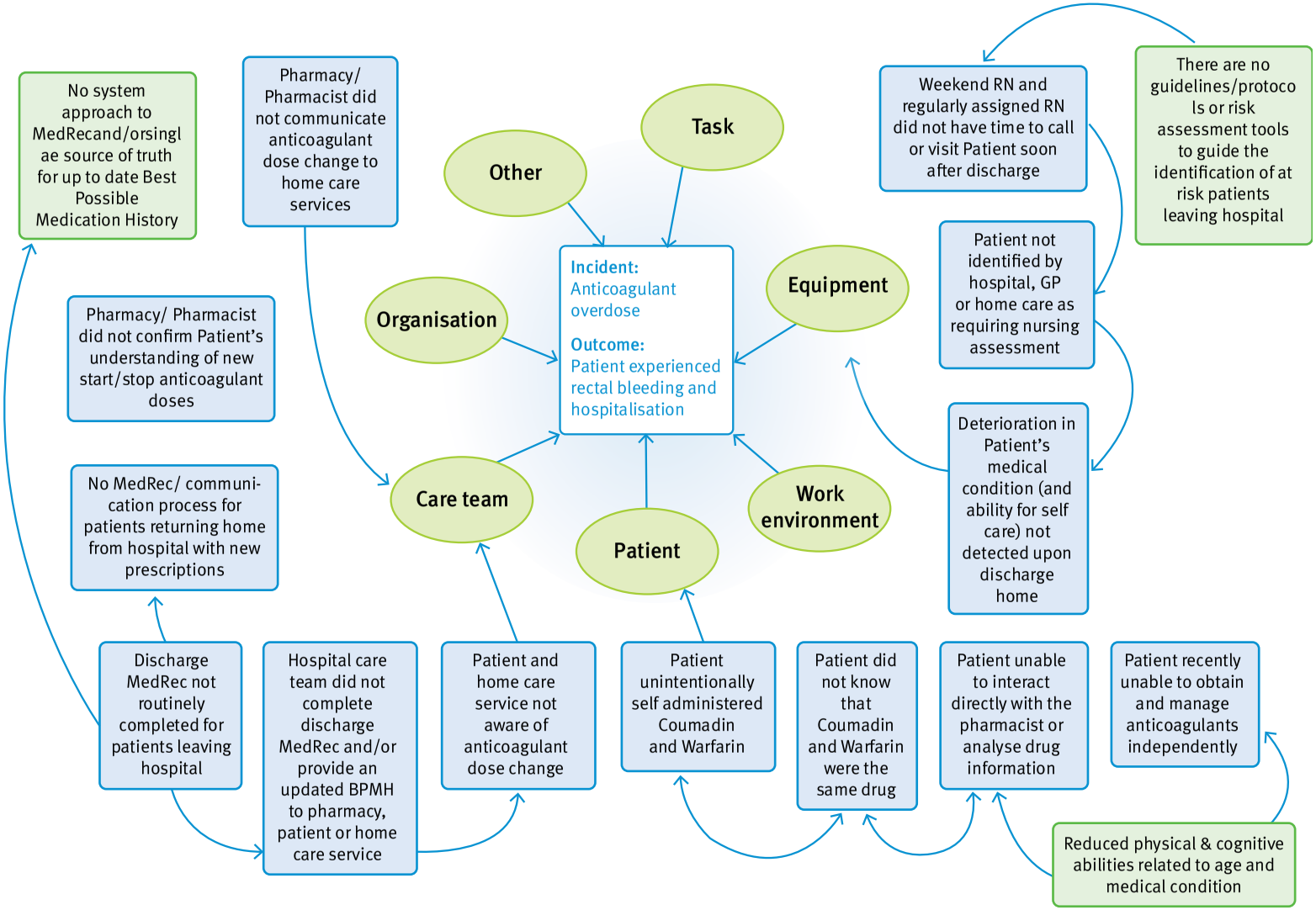
Date/time	Information item	Comment/source
History	Patient receiving weekly home care visit by RN for leg ulcer dressing change every five to seven days for approximately six weeks. Occasionally forgetful about caring for dressing and short-term memory mildly impaired, however able to manage own medications.	
Friday, 14 days prior to event. Five days prior to event	RN makes home visit to change patient's leg dressing. She notes that he is feverish and short of breath with congested cough. RN contacts patient's family general practitioner and transfer to hospital is arranged. Patient is admitted with community acquired pneumonia.	Home care record
Five days prior to event	Patient is discharged from hospital and returns to apartment. INR testing during hospital stay resulted in Warfarin dose being reduced to 2mg daily. Physician referral lists medications Nifedipine 10 mg tds (calcium channel blocker), Atenonol 50mg bd (beta blocker), Coumadin 2mg daily (anticoagulant), Aspirin 100mg daily (antiplatelet), Doxycycline 100mg daily x 6 days (antibiotic), Nitrospray prn and Duo DERM dressing to leg ulcer weekly and request to resume dressing change schedule as well as request for assistance with weekly bath. Referral received by fax on Saturday. RN responsible for that area of the community on the weekend does not know the patient however she analysed referral and home care record. Minimal changes noted so booked for RN visit for dressing change in five days (Thursday) and home care aide booked to make home visit for assistance with bath in six days (Friday). She leaves a voice mail for the regularly scheduled RN in the area to advise her of the patient's return home however, that RN is off work for several days before receiving the message. RN has significant backlog of messages and workload so does not take any action with this information.	Hospital chart and referral form RN interview (regularly scheduled in the area)
Five days prior to event	Neighbour picked up patient to bring him home. She agreed to pick up the new prescription when getting groceries later that day. The pharmacist at the pharmacy gave a patient information sheet with a new prescription. The neighbour provided this to the patient. Patient exhausted on the day he returned home from hospital. Grateful to neighbour for ride home and getting his prescription as well as groceries. He does recall the neighbour saying to read the information sheets but couldn't find his glasses and was too tired. He noted the two new pills and daily dose directions. He added them to his medication regimen until the one pill bottle was empty.	Patient interview

Date/time	Information item	Comment/source
Five days prior to event criteria for reportable event	At the drug store: • pharmacy technician processes filling the prescription in computer • pharmacist notes the change in Warfarin/Coumadin dose from 3mg daily to 2mg daily so ensures that new bottle of tablets provided for ease of self administration. All medications are filled for dispensing to ensure that patient has sufficient supply for upcoming month • pharmacist attempts to explain dosing information to neighbour. Highlights the dose change on the patient information sheets as well as the potential of increased anticoagulant effect with the combination of Doxycycline and Warfarin	Pharmacist analysis
Four days prior to event	Patient continues to feel tired and is not eating or drinking very much. Spends much of the day resting is in bed or watching TV.	Patient interview
Two days prior to event	Patient feels weaker and more concerned about colour of urine and more blood in stool. Doesn't want to bother neighbour so decides to wait for nurse visit in two days for dressing change.	Patient interview
One day prior to the event	Patient slept in bed most of day and doesn't recall many other details.	Patient interview
Day of event at 0900hrs	Patient was found in bathroom by RN on arrival at 0900hrs for dressing change. Moderate amount of bright red blood in toilet and floor. Ambulance called and transferred to ED.	RN interview
Day of event 1400hrs	RN called ED and spoke with charge nurse. Patient's INR 5.8. Upon analysis of medication bottles it was determined that patient was unintentionally taking 5mg of Warfarin daily as he did not know that Coumadin was the same medication as Warfarin so took previously ordered dose of 3mg and newly prescribed dose of 2mg as well.	RN interview
2 days after event	Patient remains in hospital but is recovering and should be ready to return home soon.	Hospital chart

Analysis process – how and why it happened

The facilitator created a constellation diagram (Figure O.1) to visualise and better understand the factors that contributed to the incident and their interconnections. The factors were confirmed by consultation with those engaged in the incident and operational and/or medical leaders. This step was very helpful in summarising the findings and developing recommended actions.

Figure O.1: Constellation diagram of medication incident



Statements of findings

- **Task:**
  - No key findings.
- **Equipment:**
  - No key findings.
- **Work Environment**:
  - The lack of a standardised home care risk assessment tool or protocol increased the likelihood that patients discharged from hospital back to the community would not be accurately triaged to ensure appropriate and timely home care services are provided.
- **Patient:**
  - The deterioration in the patient's physical and cognitive abilities increased the likelihood of a medication error in his self-medication management.
- **Care team and organisation**:
  - The lack of a formalised, system-wide and communicated Discharge Medication Reconciliation Process (including an updated best possible medication history) decreased the likelihood that the patient would receive the appropriate and timely support required for safe medication management.
  - No other factors identified.

Analysis process—what can be done to reduce the risk of recurrence and make care safer:

- **Work environment (W):**
  - W1: Establish a standardised home care risk assessment tool for screening patients that are transitioning back to the community from hospital. Consider the feasibility and effectiveness of the regularly assigned home care nurse beginning the screening process with a call from the acute care nurse planning for the patient discharge then completing the assessment with a telephone or in-person patient assessment.
- **Care team and organisation (CO):**
  - CO1: Develop, implement and evaluate a system-wide Discharge Medication Reconciliation Process. Consider using a pilot test approach initially to determine a successful strategy for spread.

Prioritise actions

Recommendation	Risk severity assessment)	Hierarchy of effectiveness (high, medium, low leverage)	Predictors of success (alignment, existing mechanisms, quick wins)	System level targeted (micro, meso, macro, mega)	Note if evidence is available and what type	Confirm validity, feasibility	Order of priority (or timeframe)
W1: Develop, implement and evaluate a standardised home care risk assessment tool for screening patients that are transitioning back to the community from hospital.	Medium	Medium	Medium	Micro, meso, macro	Expert opinion, related risk assessment tools validated in peer reviewed literature	Medium	Within 3 months
CO1: Develop, implement and evaluate a Discharge Medication Reconciliation Process Pilot.	Medium	Medium	High	Micro, meso, macro, mega	Yes, peer analysed research and expert opinion	Medium	Within 6 months

Follow through

An evaluation was completed by the Quality Improvement (QI) Director one year after the incident analysis was completed:

Recommendation (category)	Sources and ID#	Date entered	Progress status	Timeframe (end date)	Target area	Risk level	Individual responsible
W1.1: Develop standardised home care risk assessment tool.	1A # 1A	June 13	Implemented as presented	Developed and approved Aug. 13	Home Care	Medium	Home Care Executive Director
W1.2: Implement standardised home care risk assessment tool.	1A # 1B	June 13	Implemented as presented	Implemented Oct. 13	All current and new staff	Medium	Home Care Executive Director
W1.3: Evaluate standardise home care risk assessment tools.	d1A # 1C	June 13	Steps toward implementation	In progress	Chart audit — home care	Medium	QI Director
CO1.1: Develop MedRec Pilot.	1A # 1D	June 13	Implemented as presented	Developed and approved Oct. 13	Home care	Medium	QI Director
CO1.2: Implement MedRec Pilot.	1A # 1E	June 13	Implemented as presented	Implemented Nov. 13	Home care	Medium	Medical Director for Home Care
CO1.3: Evaluate MedRec Pilot.	1A # 1F	June 13	Steps toward implementation	In progress	Home care	Medium	Medical Director for Home Care
CO1.4: Share MedRec evaluation with organisational decision makers for decision regarding spread to system wide implementation.	1A # 1G	June 13	Not implemented		Home care	Medium	Medical Director for Home Care

Appendix P
Lessons learned

Lessons can be derived from any activity. They are a product of operations, exercises, training, experiments and day-to-day staff work. During the course of our activities most of us will recognise ways of doing things more easily or efficiently that can be passed on to our colleagues and successors to help them avoid problems and do even better than we did before. The challenge facing any organisation is to build a culture within which we all feel comfortable and motivated to share our knowledge in a productive way.[86]

In the course of learning lessons, we exploit both explicit and tacit knowledge.

Learning from explicit and tacit knowledge:

- Explicit knowledge is knowledge that has been or can be documented. This type of knowledge can lead to a lesson learned by the use of a lesson learned process, lesson learned information sharing tools, such as databases and training courses.
- Tacit knowledge is knowledge that has not or cannot be documented but is still extremely valuable. This type of knowledge is stored in our heads and can lead to a lesson learned when we interact with others by discussion and sharing experience within a community, perhaps facilitated by formal working groups, conferences or other events.

In any learning organisation, regardless of whether you are learning from explicit or tacit knowledge, you will follow the same three basic stages of learning.

Three basic steps to learning:

1. Identification: collect learning from experiences.
2. Action: take action to change existing ways of doing things based on the learning.
3. Institutionalisation: communicate the change so that relevant parts of the organisation can benefit from the learning.[86]

Activities used to promote learning from experience can vary across organisations.

Common ways to learn from experience:

- Lessons learned process: to gather, staff, action and communicate lessons to ensure learning from experience is converted into actual improvement via a formal process.
- Lessons learned information sharing: to make use of the databases, spreadsheets, websites, reports or other media to store and communicate lessons.
- Lessons learned community: to bring together subject matter experts at working groups, training courses, conferences and other events to share experience and learning.

Lessons learned summary:

- Lessons learned describes activities relating to learning from experience to achieve improvements. In context, this means reduced patient harm, operational risk, increased efficiency and improve operational effectiveness.
- Lessons can be derived from any activity—daily events, exercises, training, etc.
- Learning, in any organisation, involves three generic stages: identification, action and institutionalisation.

Role of the Patient Safety Unit/Clinical Governance Unit

- Support the lesson learned process—gather, analyse, staff, action and communicate lessons to ensure learning from the experience is converted into actual improvement.

- Support lessons learned information sharing—share lessons both within and outside of the organisation via (but not limited to) databases, websites, reports, newsletters, etc.
- Analyse and disseminate inside the organisation pertinent lessons learned information shared by others
- Support the lessons learned community—attend and organise relevant lessons learned sharing events (lessons learned conferences, forums, working groups, etc.).
- Support lessons learned capability—set up or improve the organisation's lessons learned capability.

Learning culture—actions you can take:

- In your local clinical governance/patient safety or board meeting, analyse the recommendations from incident investigations carried out in your facility over the previous twelve months.
- Discuss with your colleagues whether the recommendations were implemented and have been sustained over time. Check whether new colleagues and junior staff, who have joined your team after the investigation had been completed, are aware of the incident and understand why the recommendations made in the report are important.
- Repeat this self reflection task on a bi-monthly basis—it can help avoid organisational amnesia of previous lessons learned.
- Challenge and confirm what data is available to the board as evidence that recommendations have been implemented and sustained over time. Remember that you are looking for evidence that recommendations are being monitored and sustained—verbal assurances are insufficient.
- Consider how you integrate improvement actions and analysis in the daily work of the organisation to ensure that better results are sustained and spread throughout the organisation.

Glossary

Except where referenced, the following list of terms are taken are taken from the **Conceptual Framework for the International Classification for Patient Safety**.[87] This harmonised language allows clinicians, organisations and countries to classify like incidents similarly, enabling the patient safety community to share and compare information about incidents in order to learn and improve patient care.[87]

The Queensland Department of Health, Patient Safety and Quality, Clinical Excellence Queensland, encourages the use of these preferred terms for consistency and clarity, but also recognises that organisations may have reason to continue to use other terminology.

Term	Description
Adverse event	An unexpected and undesired incident directly associated with the care or services provided to the patient.
Best practices	Clinical, scientific or professional practices that are recognised by a majority of professionals in a particular field. These practices are typically evidence based and consensus-driven.
Clinician disclosure	The informal process where the treating clinician informs the patient /family/ carer of the occurrence of an adverse event and an apology for the occurrence of the event.[11]
Contributing factor	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.
Degree of harm	The severity and duration of harm, and the treatment implications, that results from an incident.
Findings	1. Factors that, if corrected, would likely have prevented the incident or mitigated the harm—these will be the basis for developing recommended actions (note: that these factors may require actions at different levels of the system). 2. Factors that if corrected, would not have prevented the incident or mitigated the harm, but are important for patient/staff safety or safe patient care in general. 3. Mitigating factors—factors that prevented the incident from resulting in more serious consequences and provide solid safeguards that should be kept in place.
Forcing functions	Something that prevents the behaviour from continuing until the problem has been corrected.
Formal open disclosure	Open disclosure is the discussion with a patient about a clinical incident resulting in harm which was not reasonably expected as an outcome of the health care provided.[11]
Harm	Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury.
Human Error	A term usually used to delineate one category of potential causes for unsatisfactory activities or outcomes... Studies in a variety of fields show that the label human error is prejudicial and unspecific.
Human factors	Study of the interrelationships between humans, the tools, equipment and methods they use, and the environments in which they live and work.

Term	Description
Incident (clinical)	An event or circumstance that resulted, or could have resulted in unintended and/or unnecessary harm to a patient or consumer; or a complaint, loss or damage. An incident may also be a near miss. [16]
Just culture	A just culture is a culture is an environment that seeks to balance the need to learn from mistakes and the need to take disciplinary action.
Near miss	An event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention.
Patient	A person who is a recipient of healthcare. Synonyms for patient include 'consumer' and 'client'.
Patient safety	Actions undertaken by individuals and organisations to protect health care recipients from being harmed by the effects of health care services.
Patient safety entity	An entity, specified within the *Hospital and Health Boards Act 2011*, whose responsibilities include the planning, implementation, management and evaluation of patient safety initiatives and programs for a health service.
Preventable event	An event that could have been anticipated and prepared for, but that occurs because of an error or other system failure.
Quality improvement	Quality improvement is the framework used to systematically improve care. Quality improvements seeks to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organisations. [67]
Restorative just culture	Restorative just culture aims to repair trust and relationships damaged after an incident. It allows all parties to discuss how they have been affected, and collaboratively decide what should be done to repair harm. [30]
Risk assessment	An assessment that examines a process in detail, including sequencing of events; assesses actual and potential risk, failure, or points of vulnerability; and, through a logical process, prioritizes areas for improvement based on the actual or potential patient care impact (criticality).
Root cause analysis (RCA)	A systematic process of investigating a critical incident or an adverse outcome to determine the multiple, underlying contributing factors. The analysis focuses on identifying the latent conditions that underlie variation in performance and, if applicable, developing recommendations for improvements to decrease the likelihood of a similar incident in the future.
Safety 1	Safety 1 takes accidents as the focus point and tries to prevent harm occurring.[8]
Safety 11	Safety 11 emphasis is on ensuring that as much as possible goes right, expanding beyond the area of incident prevention to promoting a real safety management approach over a simple risk assessment. [8]

Term	Description
Safety culture	Organizations with effective safety cultures share a constant commitment to safety as a top-level priority, which permeates the entire organization. Noted components include: (1) acknowledgment of the high-risk, error-prone nature of an organization's activities (2) a blame-free environment where individuals are able to report errors or close calls without punishment (3) an expectation of collaboration across ranks to seek solutions to vulnerabilities, and (4) a willingness on the part of the organization to direct resources to address safety concerns.
Severity Assessment Code (SAC)	Queensland Health SAC applies four SAC categories to capture the severity and duration of harm that results from an incident. • SAC1 death or likely permanent harm which is not reasonably expected as an outcome of healthcare • SAC2 temporary harm which is not reasonably expected as an outcome of healthcare • SAC3 minimal harm which is not reasonably expected as an outcome of healthcare • SAC4 no harm or near miss
Surveillance	Routine collection and review of data to examine the extent of a disease, to follow trends, and to detect changes in disease occurrence.
Systems analysis	An analysis of the resources (personnel, facilities, equipment, materials, funds, and other elements), organization, administration, procedures, and policies needed to carry out a given task. The analysis typically addresses alternatives in each category, and their relative efficiency and effectiveness.
System failure	The common categories [of systems failure] include failures of design (process design, task design, and equipment design) and failures of organization and environment (presence of psychological precursors such as conditions of the workplace, schedules, etc.; inadequate team building; and training failures).
System improvement	The result or outcome of the culture, processes, and structures that are directed toward the prevention of system failure and improvement of safety and quality.
Underlying cause	The systems or process cause that allow for the proximate cause of an event to occur. Underlying causes may involve special-cause variation, common-cause variation, or both.

References

1. Trew M, Nettleton S, Flemons W. Harm to Healing: Partnering with patients who have been harmed. Edmonton, AB: Canadian Patient Safety Institute. 2011.
2. Reason J. Human error: models and management. BMJ. 2000 Mar;320:768-770.
3. Institute for Healthcare Improvement. National Patient Safety Foundation. RCA2: Improving Root Cause Analyses and Actions to Prevent Harm. Boston, MA: 2015. [Accessed 5 Aug 2020]. Available from: http://www.ihi.org/resources/Pages/Tools/RCA2-Improving-Root-Cause-Analyses-and-Actions-to-Prevent-Harm.aspx
4. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. 2nd ed. – version 2. Patient safety definition [Internet]. Sydney (AU): ACSQHC 2021. [Accessed 5 Aug 2020]. Available from: https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/patient-safety-culture#defining-patient-safety-culture%C2%Ao
5. Australian Commission on Safety and Quality in Health Care. Australian Health Service Safety and Quality Accreditation scheme [Internet]. Sydney (AU): ACSHQHC 2021. [Accessed 5 Aug 2020]. Available from: https://www.safetyandquality.gov.au/standards/national-safety-and-quality-health-service-nsqhs-standards/assessment-nsqhs-standards/australian-health-service-safety-and-quality-accreditation-scheme
6. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. 2nd ed. – version 2. Sydney (AU): ACSQHC; 2021.
7. Vincent C. Patient Safety. 2nd ed. Hoboken (USA): Wiley-Blackwell; 2010.
8. Hollnagel E. Safety-I and Safety-II: the Past and Future of Safety Management. Farnham (UK): Ashgate Publishing Limited; 2014.
9. Waterson P, Jenkins DP, Salmon PM, Underwood P. 'Remixing Rasmussen': the evolution of AcciMaps within systemic accident analysis. Appl. Ergon. 2017;59(Pt B):483-503.
10. Stanton NA, Salmon PM, Walker GH, Stanton M. Models and methods for collision analysis: A comparison study based on Uber collision with a pedestrian. Safety Science. 2019;120:117-128.
11. Queensland Health. Open Disclosure Guide. Open and honest communication with patients, families and carers. [Internet] Brisbane (AU): Queensland Health Intranet; 2020 [cited 3 Jun 2020]. Available at: https://qheps.health.qld.gov.au/psu/od/open-disclosure-information
12. Queensland Health. What is Open Disclosure? [Internet]. Brisbane (AU): Queensland Health Intranet [Accessed 15 Feb 2022]. Available from: https://qheps.health.qld.gov.au/psu/od/open-disclosure
13. Safer Care Victoria. Consumer representative involvement in adverse event reviews: A guide for health services 2019. [cited 12 Dec 2021]. Available from: https://www.safercare.vic.gov.au/support-and-training/partnering-with-consumers/health-services/involve-consumers-in-incident-reviews
14. Office of the Health Ombudsman. For providers [Internet]. QLD (AU): Office of the Health Ombudsman. [Accessed 23 Nov 2021]. Available from: https://www.oho.qld.gov.au/for-providers
15. Zimmerman TM, Amori G. Including patients in root cause and system failure analysis: Legal and psychological implications. Journal of Healthcare Risk Management. 2007;27(2):27-34.
16. Australian Commission on Safety and Quality in Health Care. Incident Management Guide. Sydney: ACSQHC; 2021. [cited 22 Feb 2022]. Available from: https://www.safetyandquality.gov.au/publications-and-resources/resource-library/incident-management-guide
17. The Joint Commission. 2017. Sentinel Event Alert. Issue 57, March 1, 2017. Revised: June 18, 2021. [Accessed 13 Sep 2021]. Available from: https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf

18. Conway J, Federico F, Stewart K, Campbell MJ. Respectful Management of Serious Clinical Adverse Events. 2nd ed. IHI Innovation Series White Paper. Cambridge (USA): Institute for Healthcare Improvement; 2011.
19. Weick KE, Sutcliffe KM. Managing the Unexpected: Resilient performance in an age of uncertainty. San Francisco (USA): Jossey Bass; 2007.
20. Models of HRO. High Reliability Organising.
21. Wu AW, editor. The Value of Close Calls in Improving Patient Safety: Learning how to avoid and mitigate patient harm. Oak Brook (USA): Joint Commission Resources; 2010.
22. Vincent C. Patient Safety. 2nd ed. Hoboken NJ: Wiley-Blackwell; 2010. P.119-140.
23. World Health Organization. Patient safety incident reporting and learning systems: technical report and guidance. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.
24. Dekker S. Just Culture Restoring Trust and Accountability in Your Organization. 3rd ed. Boca Raton (USA): CRC Press; 2017.
25. Reason J. Managing the Risks of Organizational Accidents. Ashgate Publishing; 1997.
26. Marx D. Patient Safety and the "Just Culture". A primer for health care executives. Medical Event Reporting System – Transfusion Medicine (MERS-TM). New York, NY: Columbia University; 2001 Apr.
27. Boysen P. Just Culture: A Foundation for Balanced Accountability and Patient Safety. The Ochsner Journal. 2013 Fall;13(3):400-406.
28. Kirkup B. NHS Improvement's Just Culture Guide: good intentions failed by flawed design. Journal of the Royal Society of Medicine. 2019;112(12):495-497.
29. Turner K, Stapelberg N, Sveticic J, & Dekker S. (2020). Inconvenient truths in suicide prevention: Why a Restorative Just Culture should be implemented alongside a Zero Suicide Framework. Aust N Z J Psychiatry, 54(6), 571-581. Available from: https://doi.org/10.1177/0004867420918659
30. Dekker S. Restorative Just Culture Checklist. 2018. [Accessed 15 Jun 2021]. Available via: https://www.safetydifferently.com/wp-content/uploads/2018/12/RestorativeJustCultureChecklist-1.pdf
31. Hollnagel E, Wears RL, Braithwaite J. From Safety-I to Safety-II: A White Paper. The Resilient Health Care Net: Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia.
32. Institute of Medicine. Crossing the Quality Chasm: A new health system for the 21st century. Washington, DC: The National Academy Press; 2001. Appendix B.
33. Sargut G, McGrath RG. Learning to live with complexity. Harvard Business Review. 2011 Sep;89(9):66-76.
34. Hollnagel E, Braithwaite J, Wears R, editors. Resilient Health Care. Burlington (USA): Ashgate; 2015.
35. Edmondson AC. Strategies for learning from failure. Harvard Business Review. 2011 Apr;89(4):48-55.
36. Dekker S. The Field Guide to Human Error Investigations. Aldershot (UK): Ashgate Publishing; 2002.
37. International Ergonomics Association. What is ergonomics? [Internet]. Geneva (SW): International Ergonomics Association [Accessed 24 Jun 2021]. Available from: https://iea.cc/what-is-ergonomics/
38. Human Factors: Technical Series on Safer Primary Care. Geneva: World Health Organization; 2016. Licence: CC BY-NC-SA 3.0 IGO
39. Braithwaite J, Churruca K, Ellis L, Long J, Clay-Williams R, Damen N, Herkes J, Pomare C, Ludlow K. Complexity Science in Healthcare – Aspirations, Approaches, Applications and Accomplishments: A White Paper. Australian Institute of Health Innovation, Macquarie University (AU); 2017.
40. Sheps S, Cardiff K, Pelletier R, Robson R. (2015). Revealing resilience through critical incident narratives: a way to move from Safety-I to Safety-II. In Wears R, Hollnagel E, & Braithwaite J. (Eds.), Resilient Health Care, Volume 2 The Resilience of Everyday Clinical Work. Farnham (UK): Ashgate Publishing, Ltd. 2015: 189-206.
41. Java A. Sphere of Influence. Social Media Research Blog. Baltimore, MD: TypePad. 2008 Aug.

42. Nelson EC, Godfrey MM, Batalden PB, Berry SA, Bothe AE Jr, McKinley KE, et al. Clinical Microsystems, part 1. The building blocks of health systems. Joint Commission Journal on Quality and Patient Safety. 2008 Jul;34(7):367-378.
43. Merriam-Webster, Inc. Context. Dictionary and Thesaurus. Springfield (USA): Merriam-Webster; 2012.
44. Zecevic A, Salmoni AW, Lewko JH, Vandervoort AA. Seniors Falls Investigative Methodology (SFIM): A systems approach to the study of falls in seniors. Canadian Journal on Aging. 2007; 26(3):281-290.
45. National Health Service England. A Just Culture Guide [Internet]. UK: NHS Improvement 2018 [Accessed 8 Jun 2020]. Available from: https://www.england.nhs.uk/patient-safety/a-just-culture-guide/
46. Veterans Health Administration. VHA National Patient Safety Improvement Handbook. Washington, DC: Department of Veteran Affairs, Veterans Health Administration; 2011 Mar.
47. Lucchaiari C, Pravettoni G. Cognitive balanced model: a conceptual scheme of diagnostic decision making. Journal of Evaluation in Clinical Practice. 2012 Feb;18(1):82-88.
48. Dekker S. Just Culture: Balancing safety and accountability. Burlington (USA): Ashgate Publishing; 2007.
49. Canadian Medical Protective Association. Learning from Clinical incidents: Fostering a just culture of safety in Canadian hospitals and health care institutions. Ottawa (CA): Canadian Medical Protective Association; 2009.
50. Joint Commission Resources. Failure Mode and Effects Analysis in Health Care: Proactive risk reduction. 3rd ed. Oakbrook Terrace (USA): Joint Commission Resources; 2010.
51. Womack JP, Jones DT. Lean Thinking: Banish waste and create wealth in your corporation. 2nd ed. New York (USA): Free Press; 2003.
52. Lee C, Neily J, Mills PD, Hirschler KH. How to make the most of actions and outcome measures. NCPS TIPS. 2004 Jul/Aug;4(3).
53. Ishikawa K. Introduction to Quality Control. Productivity Press; 1990.
54. Leebov W, Ersoz CJ. The Health Care Manager's Guide to Continuous Quality Improvement. Lincoln (USA): Authors Choice Press; 2003.
55. World Health Organisation. High 5s project. World Health Organisation; 2011 Sept
56. Zecevic AA, Salmoni AW, Lewko JH, Vandervoort AA, Speechly M. Utilisation of the seniors falls investigation methodology to identify system-wide causes of falls in community-dwelling seniors. The Gerontologist. 2009 Oct;49(5):685-696.
57. Canadian Patient Safety Institute. Global Patient Safety Alerts. Edmonton (CA): Canadian Patient Safety Institute; 2011.
58. Institute for Safe Medication Practices (ISMP) Canada. Failure Mode and Effects Analysis (FMEA). Toronto (CA): Institute for Safe Medication Practices Canada; 2009.
59. Doran GT. There's a S.M.A.R.T. way to write management objectives. Management Review. 1981;71(11, AMA Forum);35-36.
60. Brighton B, Bhandari M, Tornetta P 3rd, Felson DT. Hierarchy of evidence: From case reports to randomised controlled trials. Clinical Orthopaedics and Related Research. 2003 Aug;(413):19-24.
61. Health Quality and Safety Commission New Zealand. Recognising human factors and strategies for preventing errors [Internet]. NZ. Health Quality and Safety Commission New Zealand; [2015]. [Accessed 7 May 2021]. Available from: Error-prevention-strategies-Mar-2015.pdf (hqsc.govt.nz)
62. Event Analysis Roundtable. Vancouver (CA): Canadian Patient Safety Institute; 2010.
63. White JL. Root Cause Analysis: A review of the relevant literature. Edmonton (CA): Canadian Patient Safety Institute; 2009.
64. Queensland Health, Risk Analysis Matrix. [Accessed 7 May 2021]. Available from: https://qheps.health.qld.gov.au/csd/business/risk-and-audit-services/risk-services/toolkit
65. Deming WE. 3rd Ed. The New Economics For Industry, Government, Education. MIT Press, Cambridge, MA. 2018.
66. Liker JK, Meier D. The Toyota Way Field Book. New York (USA): McGraw Hill; 2006.

67. Langley GJ, Moen R, Nolan KM, Nolan TW, Norman CL, Provost LP. The Improvement Guide: A practical approach to enhancing organisational performance. 2nd ed. San Francisco (USA): Jossey-Bass; 2009.
68. Boston Consulting Group. DICE: How to beat the odds in program execution. 2012.
69. Department of Evaluation and Research Services. Differentiation of Research, Quality Improvement and Program Evaluation. 2010.
70. Benneyan JC. Number between g-type statistical quality control charts for monitoring adverse events. Health Care Management Science. 2001;4:305-318.
71. Kotter JP, Schlesinger LA. Choosing strategies for change. Harvard Business Review; 1979;57(2):106-114.
72. Provost LP, Murray SK. The Health Care Data Guide: Learning from data for improvement. San Francisco (USA): Jossey-Bass; 2011.
73. Perla RJ, Provost LP, Murray SK. The run chart: a simple analytical tool for learning from variation in healthcare processes. BMJ Quality & Safety. 2011;20(1):46-51.
74. Solberg LI, Mosser G, McDonald S. The three faces of performance measurement: Improvement, accountability and research. Joint Commission Journal on Quality Improvement. 1997;23(3):135-147.
75. Safer Healthcare Now! Improvement Guides: Getting Started Kit. Edmonton (CA): Safer Healthcare Now!: 2011. Updated: [Accessed 30 Sep 2022]. Available from: https://www.patientsafetyinstitute.ca/en/toolsResources/ImprovementFramework/Documents/Improvement%20Frameworks%20GSK%20EN.PDF
76. Cartwright S. Double-loop Learning: a Concept and Process for Leadership Educators. Journal of Leadership Education. 2002;1(1).
77. Pham JC, Kim GR, Natterman JP, Cover RM, Goeschel CA, Wu AW, et al. ReCASTing the RCA: An improved model for performing root cause analysis. American Journal of Medical Quality. 2010;25(3):186-191.
78. Bagian JP, King BJ, Mills PD, McKnight SD. Improving RCA performance: the Cornerstone Award and the power of positive reinforcement. BMJ Quality & Safety. 2011 Nov;20(11):974-982.
79. Hollnagel E. Cognitive Reliability and Error Analysis Method (CREAM). Oxford (UK): Elsevier Science; 1998.
80. Trochim W, Kane M. Concept mapping: an introduction to structured conceptualisation in health care. International Journal for Quality in Health Care. 2005 Jun;17(3):187-191.
81. Snider C, Kirst M, Abubakar S, Ahmad F, Nathens AB. Community-based participatory research: development of an emergency department-based youth violence intervention using concept mapping. Academic Emergency Medicine. 2010;17(8):977-885.
82. Anderson C, Talsma A. Characterising the structure of operating room staffing using social network analysis. Nursing Research. 2011 Nov-Dev;60(6):378-385.
83. National Patient Safety Agency, National Reporting and Learning Service. Root Cause Analysis Investigation Tools: Investigative interview guidance (cognitive type interview). London (UK): NHS; 2008.
84. Geiselman E, Fisher R. Investigative Interviewing—Psychology and Practice. Chichester (UK): 1999.
85. Vincent C, Adams S, Chapman J, Hewett D, Prior S, Strange P, et al. A Protocol for the Investigation and Analysis of Clinical Incidents. RSM; 1999.
86. NATO, Joint Analysis & Lessons Learned Centre; 2011.
87. World Health Organization. World Alliance for Patient Safety. More than Words: Conceptual Framework for the International Classification for Patient Safety. Geneva: World Health Organisation; 2009 Jan. Report No: WHO/IER/PSP/2010.2. 2009

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