Government of **Western Australia**
Department of **Health**

Clinical Incident Management Guideline

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Clinical Incident Management Guideline

About this Guideline

The Guideline information is accurate at the time of publication. Please check the WA health resources and links for any updated processes or templates since the time of this publication.

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1. Introduction

Delivering a high standard of healthcare relies on a commitment to ongoing learning and quality improvement. Systems that support the identification, review, and analysis of clinical incidents are used to implement and evaluate system improvements and promote the provision of safer care to patients.

Learning from clinical incidents is a key factor in preventing future patient harm. Clinical incidents are complex and can have multiple contributing factors. Most errors are not due to individual failures but are a result of human factors[31] and flawed systems, which create environments of risk where failures can occur. The aim, then, is not to focus on the individual or the system alone but rather on the interaction between the two and how the system can be modified to prevent and protect from human error. Fostering a safety culture where investigations seek to identify systemic failures through systems thinking. The National Safety and Quality Health Service (NSQHS) Standards (second edition) have requirements for clinical incident management processes that underpin the MP 0122/19 Clinical Incident Management Policy.

1.1. Purpose of this guideline

The purpose of the Clinical Incident Management Guideline (the guideline) is to provide WA health entities, contracted health entities (CHEs) and licenced private health facilities with additional information to support the implementation of MP 0122/19 Clinical Incident Management Policy (the policy). This guideline should be used in conjunction with the policy. For ease of use, requirements within the policy may be repeated in the appropriate section. The only statements within this document that have the term 'must' or 'shall' are the same requirements within the policy.

The guidance provided in this document can be adopted by licenced private health facilities. For private or contracted entities, please refer to section 9 of the guidelines for further interpretation.

The guideline should be read and delivered in conjunction with the following documents:

- Clinical Risk Management Guideline
- Closing the Loop Program
- MP 0130/20 Complaints Management Policy
- CIMS Information Access and Disclosure Model
- CIMS User Guides and Business Rules
- Guidelines for the investigation of multi-site clinical incidents
- Policy for Mandatory Reporting of Notifiable Incidents to the Chief Psychiatrist
- Qualified Privilege information
- SAC 1 incident notification, investigation and evaluation forms and templates
- The Australian Open Disclosure Framework
- MP 0098/18 Review of Death Policy and Guideline
- SAC 1 clinical incident investigations – Roles and responsibilities
- Reporting of healthcare-associated Staphylococcus aureus bloodstream infections as a SAC 1 incident
- SAC 1 clinical incident investigations – Consumer-friendly document
- SAC 1 clinical incident investigations – Consumer friendly document (e-form)
- MP 0125/19 Notifiable and reportable conduct policy
- MP 0127/20 Discipline Policy
- DOH Discipline Policy

- MP 0083/18 Disputes About the Professional Conduct of a Contracted Medical Practitioner Engaged Under a Medical Services Agreement Policy
- MP 0041/16 Managing Unsatisfactory and Substandard Performance Policy

2. Clinical Incident Management Principles

The guideline aims to ensure WA health entities implement consistent and accountable processes and systems for the management of clinical incidents (or near misses) to prevent harm to patients and consumers, ensuring patients and staff are supported when a clinical incident (or near miss) occurs, and improve patient safety.

The guideline promotes best practices in Clinical Incident Management (CIM) to:

1. Identify hazards before they cause patient harm, treat the hazard, and review clinical risks.
2. Identify when patients are harmed and implement strategies to minimise harm.
3. Support the rights of patients and families to information and open disclosure.
4. Acknowledge that patients and families deserve respect and culturally appropriate care.
5. Support a partnership between healthcare teams and patients and families.
6. Ensure the rights of patients, families, and staff to privacy.
7. Ensure lessons are learned; provide opportunities to share lessons and take action to reduce the risk of similar events.
8. Recognise that clinical incidents can have a significant impact not only on the patient but also on the clinician(s) involved.

The principles below are based on the following best practice principles from the Australian Commission on Safety and Quality in Health Care Incident Management Guide.

Table 1: Clinical Incident Management Principles

Principle	Description
Transparency	Health service organisations will provide patients, carers, families, and staff who are involved in an incident with an honest and open explanation of what happened, why it happened and what actions have, and will be taken, as a result.
Accountability	Health service organisations have a duty to take reasonable care to avoid harm to patients, family or carer, and staff. When a patient is harmed, health service organisations will undertake an investigation and actions to remedy problems in a timely manner.
Partnering with consumers	Health service organisations facilitate and support patients, carers, and families as partners in incident investigations and reviews. Health services organisations should seek to support the participation of a patient/consumer representative in reviewing clinical incidents.
Open, fair, and just culture	Health service organisations create a patient safety culture of trust, fairness, learning and accountability that encourages staff, patients, carers, and families feel safe to speak up when a clinical incident occurs and to report incidents. The workforce is fairly supported when the system fails, and errors occur.
Act in a timely way	Health service organisations take action to remedy problems in a timely manner with clear allocation of responsibility.

Prioritisation	Health service organisations prioritise action to address problems and direct resources to the areas of highest clinical risk and where greatest improvements are possible.
Shared learning	The health system shares the lessons learnt from incidents across the healthcare sector to prevent further harm and to take collective remedial action.

2.1 Key concepts in safety and quality relevant to CIM:

Some of the key safety and quality concepts that are relevant to CIM are explained in Appendix 10. These include:

- Safe and Just Culture
  - Restorative Just Culture
  - Improving Patient Safety Culture
  - Role of leadership in improving safety culture
  - Cultivating a reporting culture
- System thinking and human factors
  - System Engineering Initiative for Patient Safety model
  - Systems analysis of clinical incidents: the London Protocol 2024
  - Swiss Cheese Model
- Relationship between Safety I and Safety II
- Partnering with consumers

3. Applicability

This guideline is applicable to all WA health entities and contracted health entities, excluding Health Support Services (HSS).

Licensed private healthcare facilities may be required to comply with this guideline pursuant to their licence requirements.

3.1. Clinical Incident Management System

The Clinical Incident Management System (CIMS) helps WA health entities support their workforce in recognising, investigating, and analysing clinical incidents to improve safety and quality within the service. WA health entities are recommended to ensure systems and processes that provide a consistent approach to the management of clinical incidents are maintained, including utilising the CIMS. The WA health system's electronic CIMS used for public clinical incidents is the Clinical Incident Management System (CIMS).

When a disruption to the CIMS occurs which results in the inability to access the system, WA health entities are to implement local procedures to continue to meet any policy requirement timeframes. This includes actions such as, but not limited to local procedures to make clinicians aware of how to access hard copy forms for clinical incident notification and contacting the Patient Safety Surveillance Unit (PSSU) to submit forms/reports via other accepted methods.

The key steps to effective CIM in the WA health system are shown in Figure 1 and are underpinned by CIM Principles. Step-by-step guidance is available in Appendix 2.

In order to maintain consistent approaches, WA health entities are to utilise CIMS for all clinical incidents.

For private facilities, this means managing this within their own local organisation wide CIMS to support their workforce in recognising, investigating, and analysing clinical incidents to improve

safety and quality within the service. For Severity Assessment Code (SAC) 1 clinical incidents, notifications, investigation reports and evaluations for private facilities are submitted to the PSSU to be entered into the WA health CIMS on their behalf.

3.2. WA Health Severity Assessment Codes

The SAC rating is the way clinical incidents are rated in the WA health system. Clinical incidents are categorised using the following SAC ratings to determine the appropriate level of analysis, action, and escalation. Key factors that are considered for the severity categories can be the extent of injury, length of stay or level of care required for remedy. If the event is a near miss and no harm was caused, the severity is based on a reasonable 'worst case' system-level scenario.

SAC 1	A clinical incident that has or could have resulted in serious harm or death (including near miss incidents); and which is attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness. When an event results in death, and the review determines that it was possibly preventable, WA health entities are to follow the policy requirements to notify the incident as a SAC 1 and investigate as such.
SAC 2	A clinical incident that has or could have resulted in moderate harm (including near miss incidents); and which is attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness.
SAC 3	A clinical incident that has or could have resulted in minor or no harm (including near miss incidents); and which is attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness.

4. Determination of SAC

4.1. SAC 1, 2, 3 Clinical incidents

When an event is confirmed as SAC 1, 2 or 3, the organisation is confirming that health care provision (or lack thereof) was a factor in the patient outcome. Healthcare provision encompasses the systems in place, including but not limited to decisions, actions, policies, and processes completed by healthcare professionals for patient care.

MP 0098/18 Review of Death Policy is complementary in relation to CIM processes as it assists in identifying potentially preventable deaths. The Review of Death flowchart (as available in Appendix 2 of the Review of Death Guideline) assists in determining the actions to undertake when a death occurs. It is a requirement to categorise all deaths within the scope of MP 0098/18 Review of Death Policy in terms of preventability using the Health Roundtable (HRT) tool and criteria.

For CIM, for any notified clinical incidents that result in death or serious harm, WA health entities should endeavour to use the HRT tool and criteria as best practice. For more information on the HRT tool and criteria, refer to MP 0098/18 Review of Death Policy.

4.2. For mental health patients

The SAC rating should reflect the level of risk for harm in the time leading up to the event. The assessment of a mental health patient as high risk is based on the patient's mental health condition and is determined using clinical judgment. High-risk mental health patients include those patients determined to be at high risk of causing significant harm to themselves or others or being harmed by others.

For example:

- If a mental health patient who is deemed at high risk of suicide goes missing from the health service, this should be notified as a SAC 1 clinical incident.
- If a mental health patient became increasingly agitated during a shift, which resulted in the patient physically, verbally, or sexually assaulting a staff member, it would be beneficial to investigate this clinical incident. This is to ensure all appropriate healthcare strategies were in place to prevent the patient from clinically deteriorating, becoming aggressive, and potentially harming themselves and others.

Some SAC 1 clinical incidents may also meet the definition of a Notifiable Incident reportable to the Office of the Chief Psychiatrist (OCP). The OCP accesses data for clinical incidents via CIMS that are also classified as Notifiable Incidents as per the Policy for Mandatory Reporting of Notifiable Incidents to the Chief Psychiatrist. It is the responsibility of relevant WA health entity staff to notify the OCP of any SAC 1 clinical incidents that also meet the criteria for a notifiable incident as soon as practicable, ideally within 48 hours. For further details, refer to the Reporting Notifiable Incidents - Public Mental Health Services on the OCP website.

5. Incidents out of scope

Not all adverse outcomes of healthcare delivery are regarded as clinical incidents to be managed under the policy. The policy's intent is to ensure there is a careful review of clinical incidents where potentially preventable harm has been experienced by a patient as a result of system or process failures, aiming to improve systems and processes to prevent future harm to other patients.

The policy is not intended to cover all adverse outcomes (for example, known surgical complications, reactions to medications, and so on) that might reasonably be expected to be part of the range of potential outcomes to result from healthcare delivery, despite the best intentions and efforts of the staff involved.

There are many other governance processes that are used routinely in healthcare services to review adverse outcomes, including but not limited to case reviews, audits, and Morbidity and Mortality reviews. It is important to know that these methods may look different in each health service and are outside the remit of the policy.

Additionally, incidents that are out of the scope of the policy include:

5.1. Notifiable and Reportable Conduct:

If, during an investigation, it appears that notifiable and reportable conduct or a suspected breach of discipline may have occurred, then the appropriate member of the investigation team must advise the relevant Integrity/Human Resources Officer for appropriate consideration and action. For further information, see MP 0125/19 Notifiable and Reportable Conduct Policy, MP 0127/20 Discipline Policy (applicable to Health Service Providers (HSPs) or the relevant Department of Health Discipline Policy (applicable to the Department of Health). Furthermore, the following policies are outside the scope of the policy.

- MP 0083/18 Disputes About the Professional Conduct of a Contracted Medical Practitioner Engaged Under a Medical Services Agreement Policy
- MP 0041/16 Managing Unsatisfactory and Substandard Performance Policy

5.2 Other:

Incidents that should **not** be managed through the CIM process include, but are not limited to:

- Work health and safety incidents that involve staff only. For further information on work health and safety incidents posing potential harm to staff, refer to MP 0180/23 Work Health and Safety Management Policy
- Incidents involving visitors unrelated to the provision of healthcare to a patient.
- Work health and safety incidents including:
    - workplace aggression between staff, e.g., rudeness, bullying.
    - physical or verbal aggression from non-mental health patients or visitors toward staff where the patient is not harmed.

For further information, refer to relevant mandatory policies housed in the Work Health and Safety Policy Framework.

6. Clinical Incident Management Policy Requirements

Clinical incident investigation 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 each WA health entity manages clinical incidents, the basic steps will be consistent. There is interconnectivity and interdependence between the identified activities, noting that some may take place simultaneously. Figure 1 shows the clinical incident management process.

Figure 1: Clinical Incident Management Process

6.1 Identification

All staff across the WA health system are responsible for identifying and reporting clinical incidents. Most incidents are identified at the time of the incident by a patient, carer, visitor, clinician, staff member or student; however, some may be identified later after the event.

Sources of identification can be complaints, media, audits, morbidity and mortality committee meetings, safety committees, and general discussions.

When a clinical incident is identified, WA health entities must take **immediate action** to reduce the risk to the patient. These actions include:

- ensure that any person affected by the incident is safe, and all necessary steps are taken to support and treat the person(s) and prevent further injury.
- ensure the surroundings are safe to prevent the immediate recurrence of the incident.
- remove malfunctioning equipment or supplies.
- gather essential information about the chain of events.
- notify a relevant staff member if a person suffers any harm or injury.

A clinical incident can be a very stressful experience for all involved. Care and support for the patient, immediate family members, carers, and the staff involved should be provided.

6.1.1 Care for and support of patient, family carer, clinicians and other

Culturally safe and appropriate care and support for the patient, immediate family members, consumers, and carers should be provided. This includes working with an Aboriginal Liaison officer when the incident involves an Aboriginal patient. For more information, refer to the NSQHS Standards User Guide for Aboriginal and Torres Strait Islander Health.

Attending to the safety and well-being of the clinician/s involved is also necessary. Incidents can have lasting effects on all those involved, including the organisation. It is essential that the hurts, needs, and obligations are discussed with all parties. WA health entities are recommended to implement a restorative just culture when a serious clinical incident occurs to support all parties involved in the clinical incident.

6.2 Notification of the clinical incident

While each situation will be different and guided by individual WA health entity's practices, the identification of the incident will usually trigger internal protocols on the management of a clinical incident and, in most cases, notification into CIMS.

Any staff member can identify and notify that a clinical incident has occurred. Notification can be done anonymously. Patients, carers, guardians/enduring guardians, or visitors can also notify clinical incidents. This may be done by an appropriate staff member (i.e., Nurse Unit Manager), patient/customer liaison unit, or other appropriate avenues for consumer feedback within the WA health entity.

Notification of a clinical incident is made using an online clinical incident form completed within the CIMS. Notifiers should provide as much factual/objective information as possible to assist with:

- further review and management of the clinical incident.
- accurate classification of the clinical incident.

Documentation of the clinical incident is to be recorded in the patient's healthcare record.

Notification of the clinical incident in CIMS is the trigger for a chain of internal notifications that, depending on the SAC rating of the clinical incident, will target individuals and/or units at different levels of the organisation. External notifications may also be required to ensure alignment with regulations and maintain the organisation's reputation as per legislation, policy, protocols (e.g. State Coroner, Office of the Chief Psychiatrist, Department of Health) and current context (e.g. media).

Where a private health care facility or contracted agency has a licence requirement or agreement to comply with the policy, SAC 1 clinical incidents are to be notified within 7 working days of the event's occurrence or 7 working days of the site becoming aware of the clinical incident. For private facilities, this is via the SAC 1 Clinical Incident notification form.

Staff who identify the clinical incident are to:

- inform relevant management within 24 hours and follow any other local notification processes.
- notify the incident in the clinical incident management system (CIMS) as soon as practicable (within 48 hours).
- notify the local work, health, and safety (WHS) team if a WHS hazard is suspected or identified as a causal or contributing factor to the clinical incident. The WHS team will determine if the incident is notifiable under the *Work, Health and Safety Act 2020* and will notify WorkSafe where required.
- assign a WA health Severity Assessment Code (SAC) rating.

Commencement of the Open Disclosure process

A structured open disclosure process supports the transparent discussion between the patient and the family or carer, senior clinician, and health service representatives about the clinical incident, which resulted or could result in harm that was not reasonably expected as an outcome of the health care provided. Open disclosure aims to ensure patients and their families or carers have a reliable, caring, and effective means to receive honest and factual information about the clinical incident associated with their healthcare.

WA health entities are to facilitate an appropriate level of open disclosure to the patient, their family, carers, and guardians/enduring guardians in accordance with the Australian Open Disclosure Framework. Senior clinicians or relevant staff from the organisation should begin the open disclosure process with the patient, family, or carer as soon as possible after the incident. Empathic and timely disclosure can help patients, families, and staff deal with the consequences of a clinical incident.

The decision to implement open disclosure for no-harm incidents and near misses should consider the following:

- potential to detect latent harm through discussion with the patient.
- whether open disclosure may reduce the risk of future incidents.
- whether the potential for distress or psychological harm will outweigh the benefit of disclosing, and
- whether disclosure will help maintain patient, family, carer, and guardian/enduring guardian trust in the service.

6.2.1. Initial assessment and Serious Clinical Incident Notification

After the notification of the clinical incident, a determination of what may have contributed to the event occurs next. This step will determine what sort of analysis the organisation may embark on. This includes undertaking a preliminary assessment of clinical incident and where required completing a Serious Clinical Incident Notification (SCIN) to relevant WA health entity's executive team as per local governance structure.

6.2.1.1. Preliminary assessment

In order to determine appropriate follow-up to a clinical 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 regarding how each WA health entity will 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 liaise with their relevant safety and quality team to understand key concepts of the preliminary assessment.

Once the preliminary assessment phase is complete, the next steps will be determined. 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.

6.2.1.2. Serious Clinical Incident Notification

During the notification of a clinical incident, if the clinical incident is allocated an initial SAC 1 rating (including near miss), a preliminary assessment by relevant WA health entity staff is to be undertaken. If the clinical incident meets the definition of a SAC 1 clinical incident after the preliminary assessment, a serious clinical incident notification (SCIN) should be provided to the relevant WA Health entity's executive team. This is to occur within 3 working days following the confirmation of a SAC 1 clinical incident.

The purpose of the SCIN is to:

- identify immediate actions for people to be safe and supported.
- understand the events around the clinical incident.
- identify remaining risks to other patients and staff.
- appoint a dedicated family contact to liaise with the family/carer/guardian.
- make any immediate notifications to external parties, such as the coroner.
- guide the next steps to be taken.

WA health entities can adapt the SCIN template[1] (refer to Appendix 3) to meet their local requirements.

6.2.2. Work Health and Safety incident

During the preliminary assessment, relevant staff are to determine if a WHS hazard is a suspected or actual, causal, or contributory factor to the clinical incident (or near miss). If a WHS issue is identified or suspected, the local WHS team should be contacted, who will determine if the incident is notifiable under the *Work Health and Safety Act 2020*. The clinical incident investigation team are to work collaboratively with the WHS team to assist with any reporting requirements and actions to be taken to address WHS risks. Examples of WHS hazards include, but are not limited to, injuries to patients caused by faulty equipment, slips, trips, and falls arising from unsafe flooring, inadequate lighting, staff fatigue, and burnout.

6.3. Confirmation

All clinical incidents require review by the relevant staff involved in the management of clinical incidents in the service to determine and confirm the SAC rating and, thus, the level of investigation and escalation required. Relevant staff involved in CIM are to undertake the following actions:

- Review, confirm and allocate a WA Health SAC rating within 3 working days of the incident being notified into the CIMS.

In addition to the notification to the relevant WA health entity's executive team, all SAC 1 clinical incidents must also be notified to the Department of Health PSSU within 7 working days of a

[1] Adapted with permission and thanks from South Metropolitan Health Service.

confirmed SAC 1 clinical incident (or near miss) or 7 working days of the site becoming aware of the clinical incident.

The SAC rating will then determine the choice of investigation methodology, and an initial assessment of the contributing factors can be commenced.

6.3.1. Prioritisation of Investigation

In the WA health system, the SAC, once confirmed, helps to determine the prioritisation of investigation, including the level of analysis required for the clinical incident. Key factors that are considered for the severity categories can be the extent of injury, length of stay, and level of care required for remedy.

Appendix 4 provides a summary table of the WA health system SAC codes, which can be used to assist relevant staff involved in managing clinical incidents when they first occur.

Of note, the summary table is not a replacement for a clinical judgment when reviewing a potential clinical incident. It is meant to emphasise that the outcome of an incident needs to be based on the investigation of individual circumstances.

6.4. Investigation

The purpose of the analysis and investigation phase is to establish the course of events and to identify the contributing factors. A summary of the analysis during the investigation will be formalised into a clinical incident investigation report or equivalent. All clinical incidents require review by the relevant staff involved in the management of clinical incidents in the service to determine the SAC rating and the level of investigation and escalation required.

In most cases, priority will be given to SAC 1 investigations. All SAC 1 investigation reports must be completed and submitted to the PSSU within 45 working days. All SAC 2 and 3 investigations are to be completed within 60 working days.

The appropriate method is determined using a range of criteria. This decision is usually made jointly by the relevant staff, clinical leads, senior leaders, and others, as defined in the organisational policies and procedures. Each incident investigation method includes a systematic process to identify what, how and why the incident happened and what can be done to reduce the likelihood of recurrence, make care safer, and share learnings.

When reviewing a method to analyse clinical incidents, several criteria help to inform the type of analysis required. For guidance:

SAC 1	SAC 1 incidents require a comprehensive analysis or other analysis of similar rigorous methodology to be undertaken to identify contributory factors. This may include concise and/ or multi-incident analysis.
SAC 2	SAC 2 incidents require a clinical review or investigation using an appropriate methodology.
SAC 3	SAC 3 incidents require an investigation using appropriate investigation methodology.

During CIM, it is essential to consider the predominance of patient factors as they play a critical role in understanding and mitigating risks. Patient factors such as their health status, age, cognitive function, communication abilities, and level of engagement in their care can significantly influence the occurrence of clinical incidents. For example, patients with complex medical conditions or multiple comorbidities may require more intensive monitoring and personalised care, increasing the likelihood of errors if proper systems are not in place.

Language barriers, mental health issues, or physical impairments may also lead to misunderstandings between patients and healthcare providers, affecting the accuracy of care delivery. Additionally, patients' adherence to treatment plans, informed consent processes, and ability to communicate symptoms can affect outcomes and contribute to the risk of clinical incidents. Acknowledging and addressing these patient factors in CIM allows healthcare teams to identify appropriate methods of investigation.

Where a WHS hazard is identified as a causal or contributing factor to the clinical incident, the investigation of the clinical incident should continue separate from the notification and investigation of the WHS incident. The WHS team should manage such incidents in a manner consistent with local WHS policies and procedures. For more information, refer to the local WHS policies and procedures or contact the relevant WHS team.

6.4.1. Selecting a method of incident investigation

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

- severity of the incident
- probability of recurrence
- the 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).

The table below contains a list that can be used as a starting point for understanding the general categories of analysis. One incident analysis method is not necessarily appropriate for all types of incidents.

Table 2: General Categories of Analysis

General Categories of Analysis			
	Comprehensive	**Concise**	**Multi incident /Aggregated**
Use?	Used for complicated complex incidents, resulted in serious harm, death.	Used for incidents with less complexity.	Used to analyse several incidents, grouped in themes to look for common causes. Can be used in any situation and level of harm.
Resources?	Significant time and resources. Multiple sources information, subject matter experts.	Targeted local analysis, generally where the care was delivered or with local units/programs involved with incident.	Variable – can be small and targeted all the way through to a large scale multi analysis.
Report detail?	Report will be detailed regarding the events, contributing factors, recommendations.	Brief report with facts, contributing factors, actions, and plans.	Variable – can be brief or detailed.

6.4.2. Investigation Methods

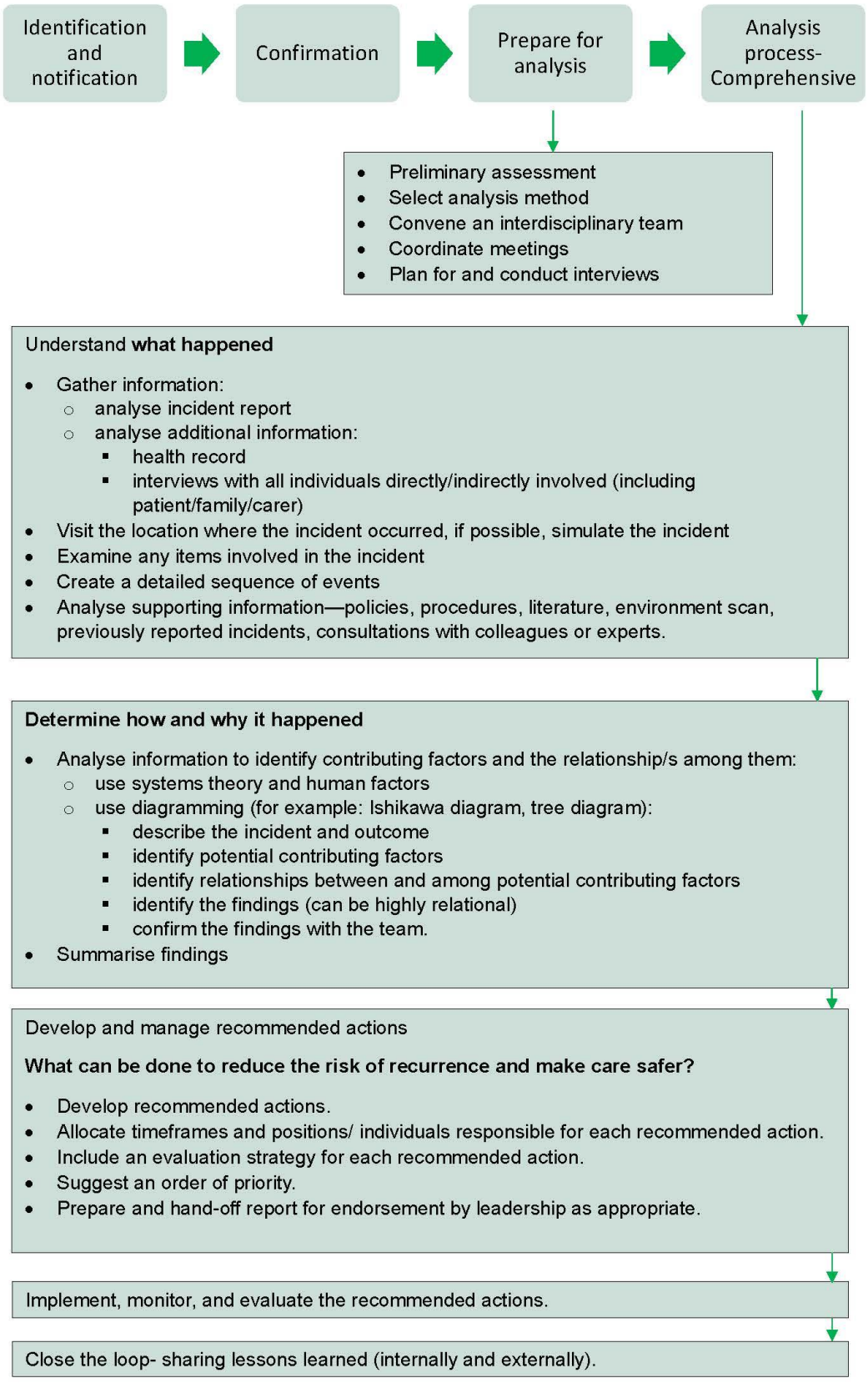
There are several different methods available to investigate a clinical incident. It has been acknowledged that healthcare is more complex compared to aviation and other high-risk industries given the dynamic nature of the interactions between multiple clinicians, vulnerable

patients, and complex care processes[10]. The PSSU does not stipulate to WA health entities what type of method/analysis must be undertaken to investigate a clinical incident. This decision remains at the discretion of the WA health entity in terms of what type of review methodology is best suited for the type of incident. This guideline mainly focuses on 3 approaches - Comprehensive, Concise and Multi-incident analyses.

Comprehensive analysis is usually used for complicated and complex incidents that result in catastrophic/major harm or the significant risk thereof[10]. Multiple sources of information are consulted, including interviews with those directly or indirectly involved in the incident and 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 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[10]. Members of the organisation's senior leadership need to be kept apprised of progress and may be directly involved in the process. A comprehensive or detailed analysis of a single incident is generally undertaken when permanent harm or death has occurred (or a significant risk thereof).

A comprehensive analysis can be conducted using several methodologies, including but not limited to a root cause analysis (RCA), the London Protocol and the Human Error and Patient Safety (HEAPS). Of these, more than 40 RCA techniques are described in the literature. Different agencies have modified the London Protocol and HEAPS to suit their requirements. Refer to Figure 2 for a flow diagram of comprehensive analysis.

Figure 2: Comprehensive Analysis Flow chart[10]



Adapted from QLD Best Practice Guide to Clinical Incident Management

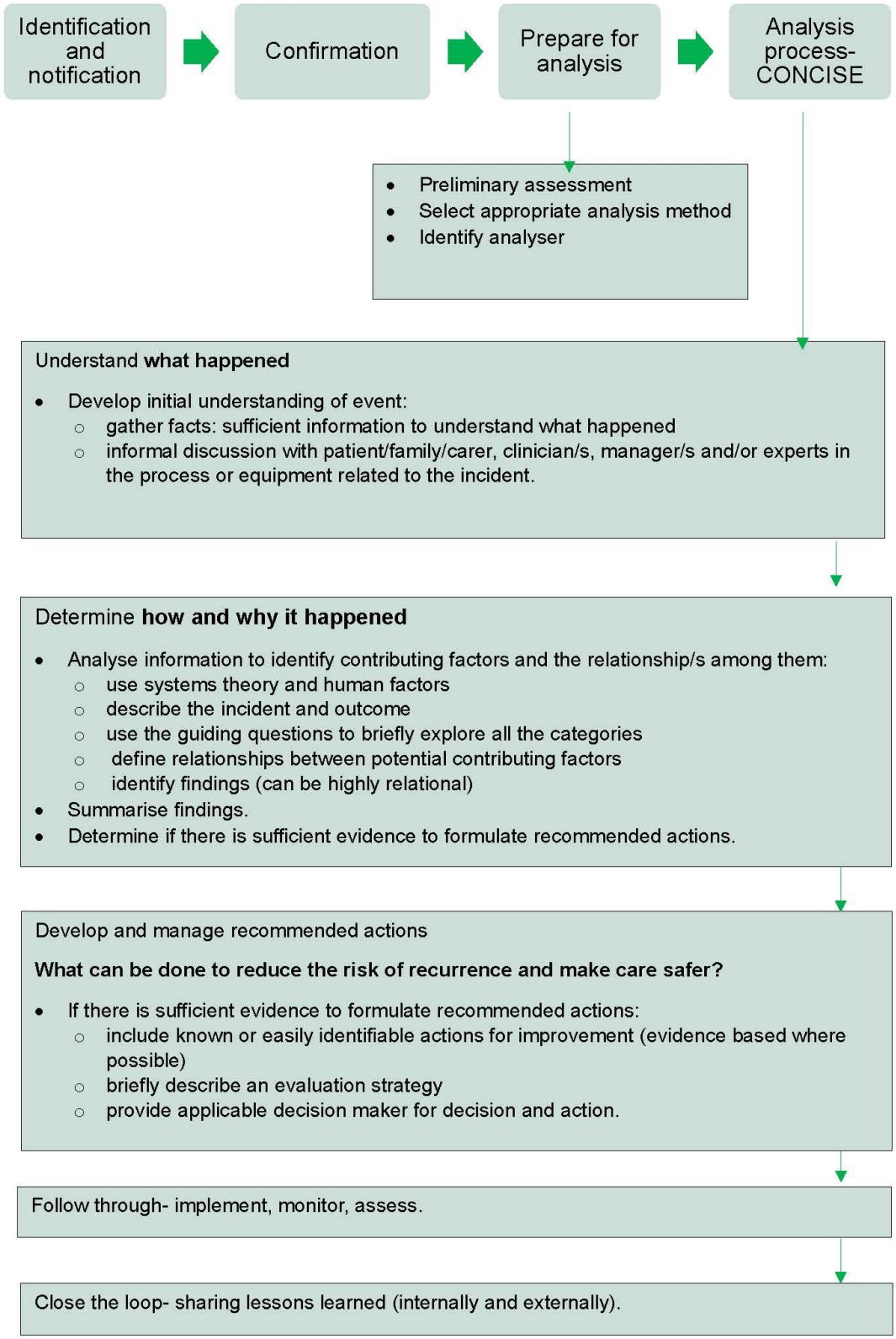
Concise analysis is a succinct yet systematic way to analyse incidents with low complexity. It may also focus on a recent incident for which a comprehensive analysis was completed. Other incident analysis tools may not lend themselves to use in a concise approach or be used in a limited way (e.g., sequence of events, constellation diagram, etc.)[10]. Generally, the incident and analysis process are 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[10]. The analysis is completed in a short interval of time by 1 or 2 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 a plan for evaluation and dissemination. Refer to Figure 3 for a flow diagram on concise analysis.

Table 3: Characteristics of concise and comprehensive incident analysis

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.	√	X
Conducted by a multidisciplinary 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).	X	√
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	√	√

Adapted from QLD Best Practice Guide to Clinical Incident Management

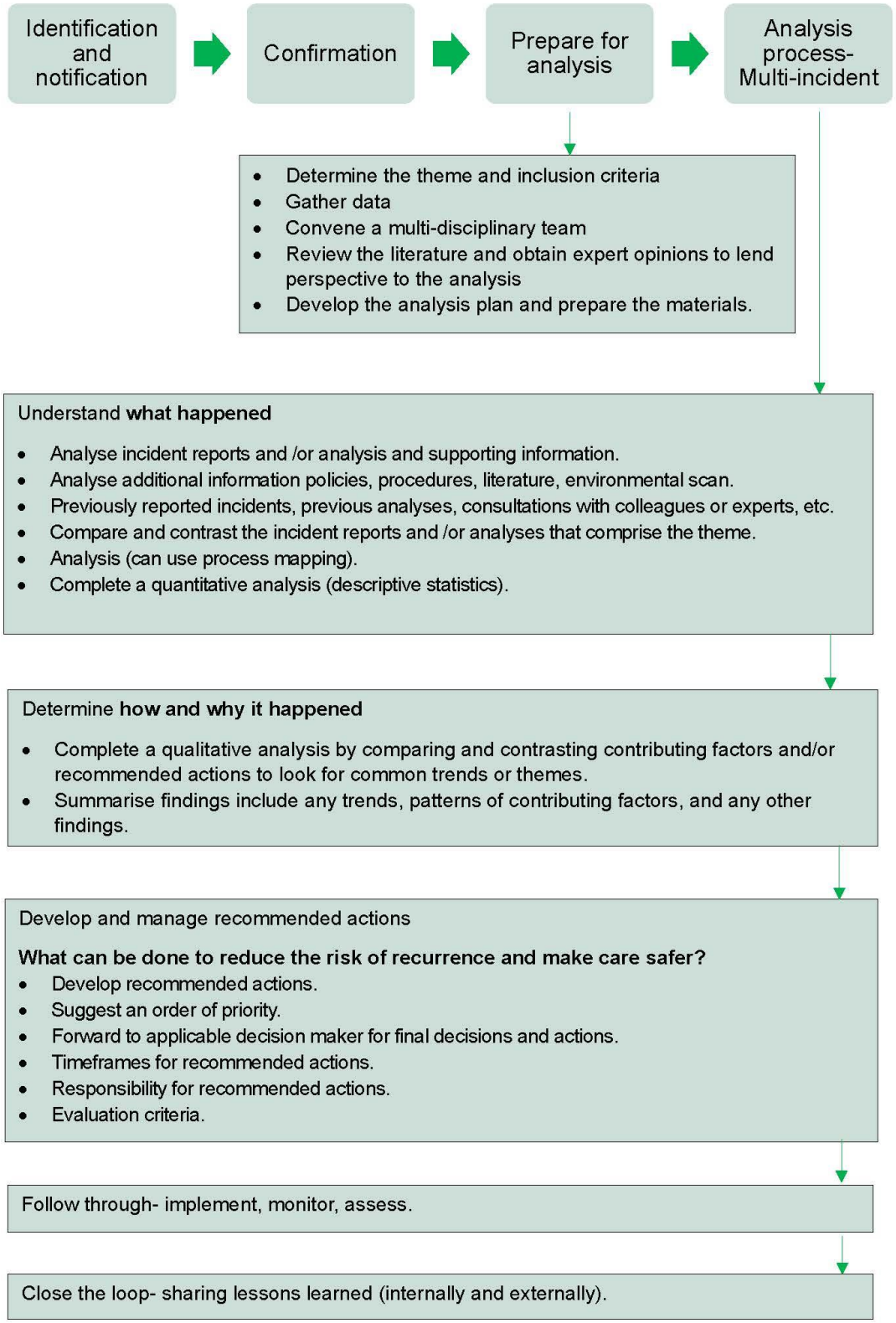
Figure 3: Concise Analysis Flow chart[10]



Adapted from QLD Best Practice Guide to Clinical Incident Management

Multi-incident analysis is a method for analysing several incidents simultaneously instead of one by one by grouping them into themes (in terms of composition or origin)[10]. 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 time). It can also be used to analyse a group of comprehensive and/or concise analyses. Multi-incident reviews can also be referred to as cluster reviews. This analysis method can generate valuable organisational and/or sector-wide learning that cannot be obtained through the other methods[10]. 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. Refer to Figure 4 for a flow diagram of multi-incident analysis.

Figure 4: Multi-incident/ Cluster Analysis Flow chart[10]



Adapted from QLD Best Practice Guide to Clinical Incident Management

6.4.3. Identify the team and the team approach

Depending on the methodology chosen, setting up an analysis and investigation team may be required. The WA health entity is to ensure that an appropriate incident investigation team with relevant subject matter expertise and independence is established. Typically, a local investigation team facilitator and panel chair share the responsibility for conducting, coordinating, and reporting on a SAC 1 clinical incident. The investigation team members within the analysis team are expected to have the following key skills:

- Ability to determine the appropriate methodology for the investigation based on the circumstances of the clinical incident.
- Ability to review, analyse and consider clinical concerns, systems factors, and human factors to identify contributing factors to the clinical incident.
- Facilitation skills to involve patients/families, clinicians involved in the incident, external consultants, and executive leaders as required.
- Skills in report writing and documentation.
- Skills in writing SMARTA recommendations.
- Appropriate mechanisms for communication and sharing lessons.

In addition to the above key skills, the investigation team members are expected to have the knowledge of:

- Relevant principles that support CIM as highlighted in Table 1 Clinical Incident Management Principles.
- Relevant legislation, regulatory processes, and policies are relevant to CIM.
- Relevant policies and procedures related to confidentiality, integrity, and performance management in CIM.
- Incident review methodologies.

An investigation 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 but are not limited to the following:

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

Note that there are several types of analysis teams. In keeping with best practice, this may include:

- Internal: members are employed by the organisation.
- Internal with external support: most are internal staff, and few are external.
- External: members are from outside the organisation.
- Consumer: drawn from the relevant lived or cultural experience

For further guidance see SAC 1 clinical incident investigations Roles and Responsibilities.

- Cultural knowledge and cultural responsiveness are key skills for a panel aiming to ensure a fair investigation and to effectively meet the principles of transparency and support partnering with consumers.

- Where appropriate, WA health entities should include an Aboriginal staff member on the investigation team where the incident involves an Aboriginal patient. For more information, please refer to the NSQHS Standards User Guide for Aboriginal and Torres Strait Islander Health.

6.4.4. Partnering with consumers during clinical incident investigation

Partnering with consumer representatives in clinical incident investigations can be a valuable approach to improving healthcare safety, transparency, and trust[27]. Their involvement ensures that patient perspectives are integrated into the investigation process, offering insights that might not be obvious to clinical staff. While the PSSU encourages WA health entities to engage with consumers in clinical incident investigations, it is at the discretion of the WA Health entity to decide which clinical incident would benefit from involving consumers in clinical incident investigations.

There are several ways of involving consumers in a clinical incident investigation, including but not limited to:

- Interviewing affected patients, family, and carers.
- Involving a consumer representative in the clinical incident investigation panel.
- Consider including an Aboriginal staff member on the investigation team when an incident involves an Aboriginal person.

Some key benefits for engaging consumers in clinical incident investigation include[27] but are not limited to:

- Enhanced patient-centred care: Consumer perspectives bring the patient's voice into investigations, ensuring that the concerns, expectations, and experiences of patients and their families are prioritised.
- Improved trust and transparency: Meaningful engagement with consumer representatives builds trust between the healthcare provider and the community, demonstrating openness and accountability.
- Unique personal and cultural perspectives: Consumer representatives can offer a non-clinical, unbiased personal and cultural perspective, helping to identify factors that may be overlooked or not considered by the investigation team.
- Education and advocacy: Involving consumers in these processes can increase awareness about patient safety issues within the broader community and create advocates for improved practices.
- Systems-level improvement: Consumer input can help identify systemic issues that affect multiple patients, leading to broader improvements in care.

Affected patient/family interview

Conducting interviews with the patients and families directly affected by the incident can provide valuable insight into their experiences, perceptions, and expectations regarding care. This can be conducted in the form of an open disclosure process[10, 27]. This information can form part of the investigation team discussion to develop meaningful recommendations. First-hand accounts can reveal system-level issues, communication breakdowns, and missed opportunities that may not be visible from the clinical perspective alone. However, a sensitive approach is to be considered, where patients feel heard and respected, especially in emotionally charged situations. Additionally, it is important to note that affected patients/families have the right to refuse to participate in the interview or the open disclosure process. If this occurs, this should be respected.

Please note that consumers can be supported in these interviews by a family member or an independent advocate. If required, the Health Consumer Council can be contacted for support if required by the family and to support the cultural safety of representatives from Aboriginal and multicultural backgrounds.

Involving consumer representatives in the investigation team

Consumer representatives can be a beneficial source of advice and insight for health services when investigating clinical incidents. Consumer representatives reflect and represent the consumer's voice. They may not have lived experience of the type of clinical incident, but they can provide an objective consumer view and ask questions from this perspective. Individuals can often be motivated to become consumer representatives after receiving care from a health service or from being a carer or a relative of a patient. To act as a consumer representative, an individual must be independent of the clinical incident under investigation. That is, they cannot be the affected patient, a relative, or a carer of a person directly affected by the incident under review.

If the WA health entity plans to engage with consumer representatives in a panel, the following considerations are to be taken:

- Training and Support: Consumer representatives should be given adequate training, which may include 'just in time' training on investigation processes and the role of the investigation team to ensure they are well-prepared and effective. If this is not feasible, WA health entities are to ensure that consumer representatives are supported throughout the investigation process. This includes identification and management of psychological safety risks from participating in a clinical incident investigation.
- Privacy and Confidentiality: Maintaining confidentiality and adhering to privacy principles is crucial. Consumer representatives should understand the importance of privacy and handling sensitive information appropriately. This may include signing relevant confidentiality declarations.
- Recruitment and onboarding: Consumer representatives should be selected carefully, ensuring they can offer constructive feedback, understand the scope of their involvement, and communicate effectively with clinical staff.
- Clear role definition: The role of the consumer representative must be well-defined, so they understand their boundaries, expectations, and the level of influence they have over the outcomes.
- Inclusivity and diversity: Consumer representatives should reflect the diversity of the patient population to ensure that different perspectives, especially those from underserved groups, are heard. Noting that this may only sometimes be feasible, consumer representatives with appropriate knowledge and experience over lived experience are to be considered.
- Payment for participation: WA health entities are to ensure that consumer representatives are informed and agree on appropriate compensation for their valuable time in the investigation team. Refer to the Department of Health Consumer, carer and community paid participation in engagement activities Policy.

6.4.5. Plan for and conduct interviews

WA health entities are encouraged to conduct interviews as part of the investigation. Interviews are key to collecting information for investigation and also help to support those directly involved in the incident. An interview is often the first opportunity for a patient/family/carer or healthcare practitioner 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. Additionally, cultural safety considerations are important for patient and family interviews.

Some key considerations during the interview include but are not limited to:

- Where appropriate, interviews occur with all staff involved in the incident and individual or group interviews with the patient and family members.
- A cooperative approach is encouraged, using open-ended questions where individuals should be asked to 'tell their story' and possibly re-enact the incident or portions of the incident.
- Ask individuals 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).
- Where possible, interviews are to 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.
- 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.

When interviewing staff involved in a clinical incident, the principles of open disclosure can be used to assist in implementing the principles of a restorative, just culture. For example, beginning the interview with the expression, 'I am sorry you were involved in the clinical incident; how do you think we can prevent this from happening again?'.

It is up to the WA health entity to identify the most appropriate staff to conduct interviews with individuals. For more information refer to SAC 1 clinical incident investigations – Roles and responsibilities.

6.4.6 Contributing factors

The goal of an investigation is to uncover and articulate contributing factors related to the incident and thus provide the 'backbone' for developing recommended actions. Clinical incidents may have more than one contributory factor.

Contributory factors are the 'circumstances, actions or influences which are thought to have played a part in the origin or development of a clinical incident or to increase the risk of a clinical incident. Examples are human factors such as behaviour, performance, or communication; system factors such as work environment; and external factors beyond the organisation's control, such as the natural environment or legislative policy'[18]. These factors during analysis are then articulated via statements of findings or causal statements, and each methodology can have differing terms.

The WA health system reports the following categories of contributing factors within CIMS:

- Communication
- Knowledge Skills Competence
- Work Environment/Scheduling
- Patient Factors
- Equipment, Information Systems/Applications
- Policies, Procedures, Guidelines
- Safety Mechanisms
- Other Factors

6.5 Reporting of final investigation outcomes

A summary of the investigation and analysis of the clinical incident is to be formalised either into a clinical incident report (for SAC 1 clinical incidents) or via equivalent local processes (for SAC 2 and 3 incidents). All clinical incidents require the completion of the clinical incident form when reporting final investigation outcomes in the CIMS.

WA health entities are to ensure that investigation reports or equivalent meet minimum standards of quality, which includes following recognised methodologies for investigations, ensuring that there has been an appropriate level of investigation conducted and that any areas for system improvement have been addressed in the recommendations and evaluations.

6.5.1. SAC 1 clinical incident investigation report

Final SAC 1 investigation reports with recommendations are to be signed off by the panel Chair and panel Facilitator and endorsed by the Chief Executive or their delegate(s) as per the approved delegation schedule. Once an investigation report has been finalised, SAC 1 investigation findings are submitted to the PSSU within 45 working days of the date of notification and completed within the CIMS. The report should also be communicated to other relevant stakeholders at the service level that manage and govern clinical incidents.

6.5.2. SAC 2 and SAC 3 investigation outcomes

SAC 2 and SAC 3 investigation reports are not submitted to the PSSU; however, equivalent local processes for the reporting and follow-up of SAC 2 and SAC 3 clinical incidents are required. All SAC 2 and SAC 3 clinical incidents require the completion of an investigation within 60 working days of the clinical incident's date of notification. The completion of the CIMS clinical incident form (notification and investigation sections) is required and can constitute a final investigation report.

6.5.3. Declassification and inactivation of clinical incidents

If a clinical incident investigation determines that there are no healthcare contributing factors and the event was not preventable, then declassification and inactivation processes are to be initiated.

- **Declassification** relates to a SAC 1 incident whereby the SAC 1 incident is reviewed, and it is determined that the incident does not meet the definition of a clinical incident in accordance with the policy.
- **Inactivation** of a clinical incident is a process used when the event does not fit the definition of an SAC 1,2, or 3 clinical incidents. Whilst inactivated clinical incidents can still be found within the system, because they do not meet the definition of a clinical incident, they are omitted from PSSU reporting of clinical incidents (unless specified within any report produced by PSSU).

6.5.3. Declassification of a SAC 1 clinical incident

WA health entities are to submit a request for declassification to the PSSU. The PSSU will review against the policy requirements and definitions and approve where appropriate. If approved, it will be noted within the CIMS that the clinical incident is declassified. Following approval to declassify a SAC 1 clinical incident, services are still required to implement any recommendations developed from the investigation and monitor and evaluate these at a local level for quality improvement purposes.

If the submitted request for declassification is rejected by PSSU, WA health entities must develop recommendations to address the contributing factors identified. These recommendations must be entered into the services CIMS and evaluated at 12 months.

Where appropriate, WA health entities are encouraged to communicate the declassification of a clinical incident with the affected patient and family. This includes sharing the findings of the incident investigation.

6.5.3.2. Inactivation of a SAC 2 and 3 clinical incidents

After appropriate investigation of a SAC 2 or 3 clinical incident, the investigation team may review and determine that no system factors contributed to the patient's outcome and that the clinical incident was not preventable. The relevant local staff involved in the management of clinical incidents can inactivate these types of SAC 2 or 3 clinical incidents within the CIMS. This includes the inactivation of duplicate records. If inactivated, the event is not regarded as a clinical incident but can still be identified via search processes in the CIMS.

6.6. Closing the loop

Closing the Loop is a term used to describe a focus on enhancing the components of CIM during the development, implementation, and evaluation of recommendations, with an objective to prevent harmful events from re-occurring, identify risks before they eventuate and share the lessons learned to promote a patient safety culture[21].

For all SAC 1 clinical incidents, a progress report discussing recommendations arising from clinical incident investigations is to be submitted to PSSU within 6 months (182 calendar days) of the investigation report submission.

Closing the Loop involves some key steps:

- Ensuring changes arising from clinical incident investigations are implemented 'on the ground'.
- Evaluating their effectiveness in altering practice and behaviour and preventing the recurrence of clinical incidents.

Following the investigation and analysis of a clinical incident, it is crucial to provide feedback, information, and recommendations to the healthcare system at various levels in multiple forms (e.g. changes in processes and procedures, staff education and newsletters, patient safety alerts and notifications, relevant committees, etc.). A key aspect also includes ensuring the notifier and management involved in the CIM process are aware of the investigation outcomes. Appropriate feedback, learnings, and recommended actions should be shared with the patient, family, carer, guardian, and enduring guardian. Where possible, WA health entities are encouraged to consider external communications to share lessons learned from clinical incident investigations with the public.

The development of recommendations is a fundamental component of clinical incident management. It aims to determine the most appropriate plan of action to reduce the risk identified during an investigation and make care safer. Recommendations provide the framework for improving or preventing recurring clinical incidents. The recommendations' success depends on the quality of the findings identified in the previous steps. Processes for developing and evaluating recommendations are to follow recognised methodologies in goal setting. They are to include action strengths to ensure the effectiveness of altered practices in preventing the clinical incident from reoccurring.

Recommendations should:

- clearly identify the recommended action.
- address the contributory factors and lead to system improvements.
- be assigned to a particular position (i.e. Nurse Unit Manager) responsible for the implementation and monitoring.

- have a specified timeframe for completion and evaluation – a progress report is due to PSSU within 6 months (182 calendar days) for SAC 1 clinical incidents, noting that progress for long-term quality improvement projects is appropriate to discuss as part of the timeframe.
- be signed off by the panel Chair and panel Facilitator.
- be endorsed by the WA health entity's Chief Executive (or relevant) or by their delegate as per the approved delegation schedule.

6.6.1.1. Developing and managing recommendations

Developing and managing recommendations arising from a clinical incident investigation involves a series of activities at several levels of the organisation. The investigation team has a fundamental role in the development of recommended actions. Findings identified in the previous investigation step (how and why it happened) are analysed by the team, and actions are proposed to address the contributing factors that allowed the incident to occur. The investigation team is generally responsible for proposing recommended actions, suggesting an order of priority, proposing timeframes and responsible positions, and consulting with others, such as treating clinicians. The relevant executive team is responsible for approving the recommendations from clinical incident investigation.

Table 4 illustrates some effective key features identified when developing recommendations.

Table 4: Key features of recommendations

Key Features	Description
1. Appropriate	Addresses the risk associated with findings
2. Reasonable	Uses the most effective solution that is reasonable or possible given the circumstances (see recommendations hierarchy below).
3. Long term	Solutions are long term to the problem
4. Right system level	Actions are at the right level in the system
5. Right responsibility level	Assign responsibility at the appropriate level in the organisation.
6. Consequences are thought through	Ensure there is a greater positive response on other processes – balance any consequences (unintended or otherwise) which may come out of the action.
7. Evidence based	Consider research literature, other jurisdictional evidence if appropriate that shows the impact of any similar recommendations.
8. Context	Provide enough context to ensure that during implementation, the rationale for the change is well understood.
9. SMARTA	Utilise well known goal setting methods such as the SMARTA format.

SMARTA

The WA health system uses the SMARTA system[1] of goal setting when creating recommendations. This uses the recognised SMART system of goal setting but also incorporates the 'Action strength' of a recommendation (SMARTA) to highlight that focusing on a few high-strength recommendations is ultimately more effective than multiple low-impact actions. When developing recommendations, following the SMARTA goal setting system ensures the greatest likelihood of producing sustainable improvements in health care delivery.

SMARTA[1] recommendations features include:

1. Specific: The recommendation must be specific.
2. Measurable: The recommendation must be measurable.
3. Accountable: State who will be responsible for implementing and evaluating this recommendation.
4. Realistic: Recommendations need to be realistic to ensure that the outcome goal can be achieved.
5. Time-related: It is imperative to state a deadline by which the goal will be achieved.
6. Action Strength: Ensure recommendation/s are created with the highest strength in mind.

Where possible, a consultation step may be beneficial to ensure that the recommendations are appropriate and feasible, the identified risks have been addressed, and there is a high probability to reduce the recurrence of this or similar incidents. Appropriate staff and experts from the area where the incident occurred should also be consulted.

Additionally, relevant staff within the WA health entity are to inform the recommendation owner when a recommendation action is assigned to them.

6.6.1.2. Recommended Hierarchy (Action Strength)

The Recommendations/Action hierarchy (refer to Appendix 6) was developed by the Veterans Affairs National Centre for Patient Safety and is also used within the WA health System for clinical incident recommendation development[20]. The Recommendations Hierarchy is a valuable tool that can assist staff in identifying and creating stronger recommendations and, thus, actions to ensure effective system change. Recommendations fall into three categories – stronger, intermediate, and weaker actions.

1. Stronger Actions: **Best at removing the dependence on the human** to 'get it right.'
2. Intermediate Actions: **Reduces the reliance on the human** to get it right but does not fully control for human error.
3. Weaker Actions: **Support/clarify the process but rely solely on the human**. These actions do not necessarily prevent the event/cause from occurring.

Based on the principles of human factors, the most effective actions accommodate or control the limitations of human behaviours and how they interact with the systems around them. Stronger recommendations focus on physical rather than procedural and permanent solutions rather than temporary ones. Note that within the hierarchy, tangible involvement by leadership refers to actions where senior leadership has extended past their usual responsibilities within their patient safety role and been involved specifically with an intervention.

For detailed information, refer to Appendix 6 and Appendix 7 for Recommendations/Actions Hierarchy[20] and Effectiveness of recommendation action strength[19], respectively.

6.6.1.3. Implementation of recommendation

Recommendations arising from clinical incident investigations should have a plan to be implemented and evaluated subsequent to the finalised investigation report submission. For all SAC 1 clinical incidents, services should communicate to relevant staff involved in the management of clinical incidents in the service.

6.6.1.4. Evaluation of Recommendations

When recommendations have been implemented, the service is to evaluate the effectiveness of the strategies progressed and implemented within those 12 months (365 calendar days) to validate that improvements have been made.

Implemented recommended actions should be monitored and evaluated to determine if the implemented changes have made the health system safer, had any impact on the system or, in

the worst case, actually made the system unsafe. Monitoring means there is an ongoing, systematic collection of information to assess if there is progress (or lack thereof) towards the intended outcome. It requires measurement of what is happening during the implementation of recommendations. Informal and formal process measurement methods can be used, including:

- surveying, asking staff on observed changes (has this policy been implemented?)
- utilising data from existing databases (has the incidence of falls reduced in this unit?)
- a simple audit tool to review if changes are being implemented (audit a local hospital fortnightly to check if a faulty device has been replaced with a new device or a checklist has been used).

Examples of some common Quantitative/Qualitative evaluation methods include:

- Clinical audit, which uses a systematic approach to demonstrate that standards for patient care are being met/improved (e.g. clinical audit to review IV dressing changes).
- Surveys which are used when you want to identify data patterns or trends. Survey methods are used to systematically collect information, which can be done through self-administered questionnaires, interviews, or observations. The data sources used can range from inpatient data, medical records, resuscitation logs, etc.
- Aggregate review is a method for analysing a group of similar clinical incidents (e.g. falls of patients within a rehabilitation ward) to determine common causes, which then allows for coordinated actions/strategies to be implemented.
- Interviews which can be face to face or via telephone/internet etc. In-depth interviews are undertaken to obtain the lived experience of that patient/carer for a particular issue/disease/procedure, etc.
- Focus groups are used to obtain patients' views, beliefs, experiences, attitudes, or motivations on a particular issue (e.g., issues with living with kidney disease).

Evaluation complements monitoring as the next step in CIM. The final assessment focuses on whether the implemented action has made a difference. In CIM, this generally relates to whether this had the intended outcome of increasing patient safety in the long term. Evaluation also requires measurement. It can use the same tools as the monitoring step but builds on monitoring activities to make a final judgement on a certain initiative and its effectiveness.

This is to ensure that:

- the contributory factors identified have been addressed
- recurrences have been reduced or eliminated
- lessons have been learned and communicated
- identified barriers to change have been removed
- the loop is closed to ensure organisational learning.

WA health entities are to provide PSSU with a progress report of SAC 1 clinical incident recommendations within 6 months (182 calendar days) of the investigation report submission. In the instance of long-term recommendations that cannot be completed within 6 months, it is reasonable to provide evidence of a quality improvement project and the progress of the project to address the recommendation. For SAC 2 and SAC 3 clinical incidents, the responsibility for implementation, evaluation and monitoring of recommendations is managed at a service level within 12 months (365 calendar days) of the investigation being completed.

6.6.1.5. Establishing measures for monitoring recommendations

The most useful measures of recommendation are those that assess outcomes. These provide direct evidence of the effectiveness of an action, not just the completion of a preventative

measure. However, other measures such as process and balancing are also helpful as a suite of evidence to assess if improvements have been made.

Table 5: Establishing measures

Measures	Actions
Outcome Measures	Best level of measurement as it demonstrates change that is attributable to an intervention or series of interventions. • Clinical incident outcome measure – measures the improvement the action has on eliminating the clinical incident. Example: the number of incidents of patient violence on the behavioural health unit resulting in injury to staff or patients will be reduced by 50 percent. The numerator will be the number of incidents of patient violence on the behavioural unit.
Process Measures	Complements outcome measures as a way to monitor implementation. It does not measure the effectiveness of an action, only the completion. Example: 95 percent of staff on the unit will have completed the training by June 2013. (This outcome measure informs that staff completed the training; however, it is uncertain if the training has improved patient care safety or not.)
Balance Measures	Assessing the system from other directions/dimensions to ensure that improving one part of the health system has not caused issues in others. There will always be intended (or unintended) effects, but a risk assessment should be done to weigh up the benefits and consequences of the outcomes. Example: When reducing a patients' length of stay in the hospital: Make sure readmission rates for the same issue are not increasing

6.6.2. Sharing lessons learned

The final step of the CIM process is where information on the recommendations is shared within the organisation to promote continuous organisational learning. Learning from an incident, understanding, and articulating what can be done to prevent its recurrence and heal relationships are the ultimate goals of the clinical incident management process. It is of utmost importance that the learning is fed backwards and forwards through multiple communication channels. This information may be shared in multiple ways, including memoranda, storytelling, huddles, or any other modality the organisation 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.

Sharing the lessons assists in systemic change to prevent the recurrence of similar healthcare-related errors and ultimately increases patient safety. Sharing what was learned is the ultimate objective of clinical incident investigation and is represented as the last element of the continuum in the guidelines and aims to close the loop. Sharing the learnings both within the organisation and outside the organisation is key to preventing additional harm and making care safer. It is recommended that the findings and outcome of a SAC 1 clinical incident is shared with the notifier once the investigation is complete, to promote a safety culture.

6.6.2.1. Synopsis report

A synopsis report is essential for learning lessons from clinical incident investigations, as it distils the key findings and outcomes in a clear and concise format. By summarising the

contributing factors, allowing healthcare professionals to quickly grasp important insights without the need to delve into the full investigation details. This enables the dissemination of knowledge across teams, promoting shared learning and fostering a culture of safety. Ultimately, it helps prevent similar incidents, improve clinical practices, and enhance patient care across the WA health system.

Where the PSSU identifies relevant lessons for other providers, PSSU may request the WA health entity for a synopsis of the incident and lessons learnt for wider dissemination. Refer to Appendix 5 for a synopsis report template.

6.6.2.2. Feed-forward communication

Feed-forward communication is concerned with sharing information externally to ensure that other external organisations can learn and review similar incidents. Alerts, advisories, and memos can be common tools. Some organisations have repositories (patient safety alerts) or summaries in regard to clinical incidents.

WA health entities are to disseminate de-identified information on learnings from clinical incidents, including the actions taken in response, in accordance with their local processes at various system levels.

6.6.3. Feedback

The success of clinical incident management is also dependent on feedback to all stakeholders involved in the clinical incident and should be done in a timely and appropriate manner. When an analysis has been completed, timely feedback to the notifier and relevant staff within the WA health entity is very important to prompt improvements in safety. Feedback should also be given to the patient/family/carer/guardian/enduring guardian involved. Equally, the patient/family/carer/guardian/enduring guardian should be given an opportunity to provide feedback to the organisation in accordance with open disclosure processes. Acknowledging the sensitive nature of the CIM process, providing feedback is to be handled with restorative just culture principles in mind.

Although this section on feedback is located at the end of the process, feedback is important at all parts of the CIM process. Feedback fulfils several functions with CIM and can be divided into several modes (corrective, informational, motivational). Stakeholders include staff involved (including the notifier), patients and their families and the wider health service organisation on what was acted upon, outcomes of investigations and what actions had the greatest impact.

Lack of feedback from incident reporting has been associated with inhibiting the willingness of staff to report incidents.

Upon receipt of an endorsed investigation report, the SAC 1 investigation report may be reviewed at a system level to provide feedback on:

- whether the appropriate level of investigation has been conducted relative to the nature of the clinical incident.
- whether all potential areas for system improvement have been identified, and
- whether recommendations made to address all contributing factors are likely to achieve the intended outcomes.

Table 6: Five modes of feedback for incident reporting systems

Mode	Type	Content and examples
A. Bounce back	Information to reporter (i.e. notifier)	• Acknowledge report filed (e.g. automated response). • Communicate to patient and families. • Debrief reporter/notifier. • Provide advice from safety experts. • Outline issue process (and decision to escalate).
B. Rapid response	Action within local work systems	• Measures taken against immediate threats to safety or serious issues that have been marked for fast-tracking. • Temporary fixes/workarounds until in-depth investigation process can be completed (withdraw equipment, monitor procedure, alert staff). • Communicate to family and patient as appropriate (open disclosure as appropriate).
C. Raise risk awareness	Information to all front-line personnel	• Safety-awareness publications (posted/online bulletins and alerts on specific issues, periodic newsletters with example cases and summary statistics). • Highlight vulnerabilities and promote correct procedures.
D. Inform staff of actions taken	Information to notifier and wider reporting community	• Report back to reporter/notifier on issue progress and actions resulting from their report. • Widely publicise corrective actions taken to resolve safety issue to encourage reporting. • Communicate to family and patient as appropriate on actions taken and impact it has had.
E. Improve work systems safety	Action with local work systems	• Specific actions and implementation plan for permanent improvements to work systems to address contributory factors evident within reported incidents. • Changes to tools/equipment/working environment, standard working procedures, training programs, etc. • Evaluate/monitor effectiveness of solutions and repeat.

6.7. Review

6.7.2. Clinical Risk Management

Risk management is a routine practice in many industries, including healthcare. Clinical risk management is specifically concerned about minimising risks and harm to patients and consumers by focussing on all aspects of clinical care through:

- identifying what can and does go wrong during patient care
- understanding the factors that influence this
- learning lessons from clinical incidents and poor outcomes
- ensuring actions are taken to prevent recurrence
- putting systems in place to reduce risks.

Each of the five steps above has been detailed within the WA Health Clinical Risk Management Guidelines, which was developed in reference to the Australian/New Zealand Standard AS/NZS ISO 31000:2018 Risk Management – Principles and Guidelines and the Clinical Risk Management Guidelines. WA Health currently utilises an approved enterprise risk management system (ERMS) to identify, record, review, and report against potential risks.

6.7.3. Quality Improvement

Quality improvement in healthcare is an important strategy for keeping patients safe and improving the care provision[21]. Organisations with strong leadership enable clinicians to think critically, reflect and monitor their own performance, display integrity in open, honest, ethical behaviour, see the big picture and learn from experience[21]. Key areas to supporting quality improvement include but are not limited to:

- Enhancing a just culture.
- Explaining how human factors impact the way organisations work.
- Discussing the importance of teams as the focal point for improvement.
- Identifying clinical issues and monitoring improvement.
- Undertaking regular clinical practice improvement projects[21].

All five areas can be built into the way organisations work. Every clinician can be part of the change and can individually make a difference[21]. If a system-related issue that needs fixing is identified, staff are to speak with their line manager about the issue identified and possible solutions that lend to quality improvement activities[21].

Models for Improvement: Plan Do Study Act Cycle

Adopting known frameworks to create, implement and evaluate recommendations provides good guidance for health services to enable change in a system. The Plan Do Study Act (PDSA) is one well-known model for improvement, but there are others that can be utilised depending on the aims. It provides a framework for new change ideas to be tested on a small scale, to establish if it will work prior to a large-scale implementation.

7. Key Considerations During Clinical Incident Management

7.6. Investigation of clinical incidents across WA health system boundaries

For clinical incidents that involve more than one organisation, it is best practice to consult with all health service organisations involved with the care of the patient. All WA health entities identified as being involved with a clinical incident are recommended to participate in a collaborative investigation, recommendation, and evaluation plan. This may include health

services such as (but not limited to) non-government organisations, for example St John Ambulance or Royal Flying Doctor Service. Facilitating a shared, systems approach to investigation and arising recommendations and learnings from clinical incidents is important, as failure within healthcare is usually complex with multiple system factors. It enables the whole patient journey to be captured, avoids unnecessary duplication of resources, ensures a coordinated approach at multiple points across the health system and reduces unnecessary variation of patient safety strategies.

Services should endeavour to seek patient consent for information disclosure to fulfil clinical investigation requirements. For further advice on the matter of patient confidentiality and the release of patient information for the purposes of clinical incident investigations, services should consult with their own Legal and Legislative Services as appropriate.

Where an incident involves multiple services, typically the last service providing care (including but not limited to a rural or metropolitan hospital, Mental Health Service, transport providers, Hospital in the Home, or Rehabilitation in the Home programs) will be responsible for initiating the clinical incident review and engaging other organisations involved in the care of the patient in establishing the investigation.

There are several investigation options to be considered when multiple services are involved in the care of the patient, including:

- Joint investigation involving all services.
- Investigation by the service where the clinical incident occurred.
- Independent review to ensure objectivity and/or obtain expert opinion.

The last service providing care is to:

- inform the transferring health service of the patient outcome in relation to the clinical incident.
- clinically review the care of the patient to identify any factors that may have contributed to the patient's outcome.
- provide the transferring health service with any issues recommended to be taken into consideration as part of their investigation.

For further details on the management of incidents across WA health system boundaries, refer to the Guideline for the Investigation of Multi-Site clinical incidents.

7.7. Education and Training

WA health entities are required to implement processes and systems to ensure staff receive an induction into and appropriate training for those aspects of the CIM process for which they are responsible. This includes ensuring staff have the required skills to participate, facilitate or chair a clinical incident investigation. Relevant staff are to also be proficient in monitoring and assessing the effectiveness of recommendations. WA health entities are to also ensure the processes implemented for training are evaluated to ensure the training provided is effective in preparing staff to participate in such processes.

Some key actions to consider for training and education include:

- Ensuring governing bodies (including senior leaders, board chair, and board members) are orientated to the roles and responsibilities required of them for safety and quality.
- Staff involved in clinical incidents are to be trained in appropriate and recognised systems-based investigation and evaluation methodologies.

- Within training, an awareness of the principles of clinical incident management with a focus on system issues rather than individual mistakes is included, and a learning culture is emphasised.
- Training systems that assess competency and implement training programs that have minimum competency standards. Ideally, services should monitor competency and evaluate training effectiveness.

7.8. Staff support and engagement

An important aspect of patient safety is also staff safety. When a clinical incident occurs, it is important to acknowledge not only the harm that has occurred for the patient but also the impact for others involved, including clinicians. Studies have demonstrated that there is a significant emotional impact on frontline staff involved, which may result in both short and long-term physical effects[22,24]. This can lead to staff fatigue, injury, or stress, which may further increase the risks of human error. The term 'second victim' has been used to describe the impact on staff when a clinical incident occurs; the first and obvious victim is the patient, but it is also acknowledged that the second victims are the clinicians who work in a health system and feel different forms of moral distress from the unintentional error that they are part of[22,24].

WA health entities are required to implement local processes to:

- identify appropriate and accessible internal and external staff supports available.
- target staff support to areas of greatest need. This may include critical times such as participating in an open disclosure process.
- ensure that during the closing-the-loop process that shared learnings put an emphasis on how an incident has occurred due to identified systemic issues and that a no-blame culture is re-iterated.

7.9. Accessing Post-Mortem Reports for the Investigation of Clinical Incidents

If a Post-Mortem Report (PMR) is required for clinical governance purposes (e.g., completing a mortality review or investigation of a SAC 1 clinical incident), a request may be submitted directly to the Coroner's Court of Western Australia. All requests require the consent of the deceased person's senior next of kin, which authorises the release of the post-mortem report to the requesting hospital or health care provider. Where appropriate, refer to relevant WA health entity business rules on accessing PMRs.

The clinical incident investigation should not be delayed pending receipt of a PMR, as this would result in lost information and a delay in the implementation of outcome measures. If the PMR provides any additional information following the investigation, this can be addressed subsequently.

8. Other actions

8.6. Statutory reporting requirements

The WA health entity should seek legal advice regarding the release of documents generated from a clinical incident investigation in accordance with MP 0023/16 Obtaining Legal Advice Policy and MP 0015/16 Information Access, Use and disclosure Policy. Other reporting requirements may also include the following but are not limited to:

- Statutory medical notifications are to be reported to the Chief Health Officer. These include but are not limited to:
    - maternal deaths
    - perinatal and infant deaths
    - deaths of persons under anaesthesia

- Reportable deaths are to be reported to the Office of the State Coroner. The Coronial Liaison Unit also provides guidance, as does the Death in Hospital form.
- Notifiable incidents are to be reported to the Office of the Chief Psychiatrist.
- Radiation incident reporting in a medical setting - incidents involving radiation are required to be reported to the Radiological Council.
- Reporting requirements for the recording and review of patient deaths in MP 0098/18 Review of Death Policy.
- Reporting requirements in relation to the Therapeutic Goods Administration.

8.7. Mandatory reporting of medical devices

On 21 March 2023, the *Therapeutic Goods Act 1989* (Cth) was amended with the intent of improving the reporting of adverse events related to medical devices to the Therapeutic Goods Administration (TGA). The TGA is working with the Australian Commission on Safety and Quality in Health Care and Australian hospitals, peak bodies, and state, and territory governments to improve and increase rapid information sharing about medical device safety and effectiveness[25].

The legislation will require mandatory reporting of information that describes three broad groups of adverse events related to medical devices.[26]

- A medical device was used in a healthcare facility and resulted in the death or serious deterioration in the health of a person.
- A medical device was not used in a healthcare facility. However, if used, it would (or would likely) result in the death or serious deterioration in the health of a person.
- Treatment was provided in a healthcare facility for a serious deterioration in the health of a person resulting from the use of a medical device (regardless of where that medical device was used).

Regulations to support implementation are currently in development and are due by 22 March 2025, when the mandatory reporting requirements are expected to commence. The mandatory reporting requirements will apply to both public and private hospitals as well as any other facilities described in the regulations.

Clinical incident data has been identified as a potential source of information for adverse events related to medical devices. Clinical staff may require guidance to ensure that clinical incidents related to medical devices are captured in incident management systems in a consistent manner that supports the mandatory reporting requirements.

8.8. Data Quality

The enterprise data system to capture clinical incidents in Western Australia is the CIMS. The Custodians of the CIMS and nominated data quality staff are to ensure they have implemented operational procedures and guidelines to ensure data quality is managed effectively. This includes ongoing, regular review of the data and data quality improvement efforts. For more information, refer to MP 0178/23 Information Quality Policy.

8.9. Retention and Disposal of clinical incident forms

There may be circumstances where hard copy clinical incident forms are used to capture analysis of a clinical incident. It is expected that these will be entered into the CIMS as soon as possible. For information on the retention and disposal of State records, refer to MP 0144/20 Information Retention and Disposal Policy and General Disposal Authority for State Government Information.

8.10. Qualified Privilege

The *Health Services (Quality Improvement) Act 1994 (QI Act)* is a method to facilitate the investigation of clinical incidents through an approved committee established under the QI Act. The QI Act governs the State Qualified Privilege scheme. To operate under this scheme, a committee is to be formally established and approved as a registered committee by the Minister for Health. However, no such committees currently exist within the WA health system.

9. Private Facilities, Non-Government Licensing and Contractual Processes

9.6. Guidance on Policy and Guideline interpretation

When a private facility or CHE has a license requirement or contractual agreement detailed about clinical incidents or requirements specifically with a SAC, the private facility or CHE should follow the applicable sections of the policy and guidelines. As each agreement may differ, refer to the license or contract to confirm clinical incident reporting requirements.

Currently, private hospital licensing requirements to the Department of Health are applicable to SAC 1 CIM processes only. SAC 2 and 3 requirements are not required to be reported to the Department of Health unless it has been specified within the contract/licence agreement. Private facilities should follow any local reporting requirements to manage clinical incidents as per local health service organisation guidelines to manage clinical incidents. This may be via their local organisation-wide clinical incident management system (e.g. Riskman). If the licensing or contractual requirements have been amended, please review the policy and guidelines for any requirements applicable to the license/contract.

9.7. Clinical Incident Management Systems

In order to maintain consistent approaches, WA health entities are to utilise an approved clinical incident management system for all clinical incidents. For private facilities, this means managing this within their own local organisation-wide incident management system to support their workforce in recognising, investigating, and analysing clinical incidents to improve safety and quality within the service[26]. The WA health system's electronic clinical incident management system used for public clinical incidents is the Clinical Incident Management System. Private facilities submit notifications, investigations, and evaluations to the PSSU to be entered into the CIMS on their behalf for SAC 1 clinical incidents.

9.8. Roles and Responsibilities

Licensed and Private Facilities are to ensure for CIM processes:

- All SAC 1 clinical incidents are notified to the PSSU within 7 working days of the event's occurrence or where the incident is not identified until after this time, within 7 working days of the site becoming aware of the clinical incident. The SAC 1 clinical incident notification form is submitted to the PSSU via the email: Events.SAC1@health.wa.gov.au
- All SAC 1 clinical incidents are investigated using an appropriate investigation methodology.
- All SAC 1 investigation findings are submitted to the PSSU within 45 working days of the event notification using the SAC 1 clinical incident investigation report or equivalent.
- The completed SAC 1 clinical incident progress report is submitted to PSSU within 6 months (182 calendar days) of the investigation report submission date.
- An evaluation report is provided to the PSSU within 12 months (365 calendar days) with evidence of completed recommendation actions.

- When clinical incidents occur across WA health system boundaries, services are to facilitate and ensure collaboration occurs to investigate with other health service providers, unless directed otherwise by their health service organisation executives. Services should endeavour to seek patient consent for information disclosure to fulfil clinical investigation requirements.
- Ensure any other applicable licensing, statutory reporting requirements, and contractual agreements are met.

10. Definition

Absent Without Leave	Under the *Mental Health Act 2014* (MHA 2014) section 97 Absence without Leave (AWOL) relates to involuntary inpatients, involuntary community patients, patients on an order for assessment, and referred patients that meet the following criteria: i. any forensic patient who leaves the hospital or other place where the person is detained without being granted leave of absence under MHA 2014 s105(1). ii. any detained involuntary or patient referred for examination who leaves from an authorised hospital, a general hospital, including emergency departments, or other place without being granted leave of absence under MHA 2014 s 105(1). iii. the failure of an involuntary patient to return from a period of authorised leave following expiry of leave or on cancellation under MHA 2014 s 110(1). iv. any patient referred for examination who leaves from an authorised hospital, general hospital, including emergency departments, or other place under MHA 2014 s 97(1)(a). v. any involuntary community patient who leaves the place where they are detained under MHA 2014 s 130(2)(b).
Breach of discipline	Included in MP 0127/20 Discipline Policy and in accordance with section 161 of the Health Services Act: An employee commits a breach of discipline if the employee – (a) disobeys or disregards a lawful order; or (b) contravenes – (i) any provision of this Act applicable to that employee; or (ii) any public sector standard or clinical risk, code of ethics; or (iii) a policy framework; or (c) commits an act of misconduct; or (d) is negligent or careless in the performance of the employee's functions; or (e) commits an act of victimisation within the meaning of the Public Interest Disclosure Act 2003 section 15.
Carer	An individual who may provide personal care, support, or other assistance to another individual due to disability, medical condition, including terminal or chronic illness, mental illness or is frail and aged. This may be, but not necessarily a nominated relative.

Clinical incident (or near miss)	An event or circumstance resulting from health care provision (or lack thereof) which could have or did lead to unintended or unnecessary physical or psychological harm to a patient. This includes patients who are participating in a clinical trial.
Clinical incident management (CIM)	The process of effectively managing clinical incidents with a view to minimising preventable harm.
Clinical Incident Management System (CIMS)	The CIMS refers to an organisation's approved nominated information system used to notify, report, and investigate clinical incidents. It may also include functions to record the implementation and evaluation of recommendations.
Clinical Risk	Refers to risks associated with delivering clinical functions.
Clinician	For the purpose of this document, clinician refers to all health professionals providing clinical care, including but not limited to medical officers, nurses, midwives, and allied health professionals.
Comprehensive Analysis	Used for complicated and complex incidents that resulted in serious harm, or the significant risk thereof.
Concise Incident Analysis	A succinct, yet systematic way to analyse incidents with no, low or moderate severity of harm.
Consumer	A person who uses (or may use) a health service, or someone who provides support for a person using a health service. Consumers can be patients, carers, family members or other support people.
Contracted Health Entity (CHE)	A non-government entity that provides health services under a contract or other agreement entered into with the Department CEO on behalf of the State, a Health Service Provider, or the Minister.
Contributing factors	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increasing the risk of an incident.
Custodian	Implements MP 0152/21 Information Management Governance Policy on behalf of the steward and has the delegation authority for granting access, use and disclosure of information from Information Assets in line with legislation and policy.
Date of Notification	For SAC1 incidents, there is the date of notification to PSSU, which is the date PSSU is notified of the SAC1 incident. Within the clinical incident management system this is currently the date within step 1 of the SAC 1 action chain. For SAC 2/3 incidents, the date of notification is the date the incident was entered (notified) into the CIMS. This is the CIMS date of notification field.

Declassification	Declassification is in relation to a SAC 1 incident and means that it has been determined that the incident is not a clinical incident resulting from health care delivery.
Hazard	Any source of potential harm or situation that may cause loss or injury to a person.
Health Record Review	A retrospective approach which can be used to investigate multiple or singular clinical incidents. Also called medical record or case record review.
Health Service	A health service is a service for maintaining, improving, restoring, or managing peoples' physical and mental health and wellbeing.
Health Service Provider	HSPs are governed by Health Service Boards and/or a CE. Each HSP is responsible and accountable for the delivery of safe, high quality, efficient and economical health services to their local areas and communities. Currently they include: 1. Child and Adolescent Health Service 2. North Metropolitan Health Service 3. South Metropolitan Health Service 4. East Metropolitan Health Service 5. WA Country Health Service 6. PathWest 7. Quadriplegic Centre
Human Factors	The scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data, and methods to design in order to optimise human wellbeing and overall system performance. Human Factors and Ergonomics (HFE) employs 3 substantive drivers of intervention: a) it takes a systems approach. b) it is design-driven; and c) it focuses on optimising two closely related outcomes, performance, and wellbeing. HFE can be described as a trans-disciplinary, user-centric 'bundling science,' in that it integrates and applies theory, principles, and data from many relevant disciplines to the design of work systems, considering the complex interactions between the human and other humans, the environment, tools, and equipment, and technology[31].
Inactivation	A process used for events which are deemed as not within the definition of a SAC 1,2,3 clinical incident and are not used within PSSU for reporting purposes (unless specified). Note that a SAC 1 undergoes declassification and then inactivation. A SAC 2 or 3 is deemed not a clinical incident and then inactivated.

Just Culture	A culture that identifies opportunities for systemic learning from systemic failures. This is a culture that focuses on patient safety, trust, fairness, learning and accountability. Within this culture, staff, patients, carers, and families feel encouraged to speak up and report when a clinical incident occurs.
London Protocol	A methodology which aims to take a systems approach to incident investigation and offers a structured approach to interviews and the pursuit of information.
Maternal death	Maternal death as 'the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes.'[23,24]
Missing Person	Any voluntary psychiatric patient at high risk of harm who is missing from a mental health service, general hospital, or emergency department, without the agreement of or authorisation by staff.
Near miss	An incident that may have, but did not result in harm, either by chance or through timely intervention.
Notifiable and reportable conduct	Included in MP 0127/20 Discipline Policy notifiable and reportable conduct means conduct by a staff member that: • may be suspected on reasonable grounds to constitute or may constitute Professional Misconduct or Unsatisfactory Professional Performance as defined in accordance with section 5 of the Health Practitioner Regulation National Law (WA) Act 2010 (National Law) (reportable to the Department CEO pursuant to section 146(1) of the HS Act and/or • relates to a charge for a Serious Offence (reportable to the Department CEO pursuant to HS Act: Section 146(2): or • may concern a suspected breach of discipline sections 160, 161 & 162 of the HS Act and/or • may concern Suspected Minor or Serious Misconduct as defined in accordance with section 4 of the CCM Act (notifiable to the Corruption and Crime Commission or the Public Sector Commission pursuant to section 28 or 45D of the CCM Act.)
Open disclosure	Open disclosure is the open discussion of incidents that result in harm to a patient while receiving health care with the patient, their family, carers, and other support persons. The elements of open disclosure are an apology or expression of regret (including the word 'sorry'), a factual explanation of what happened, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

Patient	Refers to any person receiving health care in a health service organisation.
Patient Safety	Patient safety is the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum.
Patient Safety Surveillance Unit (PSSU)	A part of the Patient Safety and Clinical Quality Directorate, Department of Health, WA. It is responsible for state-wide patient safety policy and reporting on consumer complaints, clinical incidents, clinical risk management and mortality review.
Qualified Privilege	The legal prohibition which may restrict the disclosure of information and documentation created for the purpose of investigations into clinical incidents in accordance with the provisions of the Health Services (Quality Improvement) Act 1994.
Relevant staff	Within a health service, the delegated team and structures which govern clinical incident management. This may be (but not limited to): • a line manager • delegated authority such as a Risk Manager or Safety, Quality and Performance teams • staff who oversee quality improvement activities.
Review of Death (ROD)	ROD refers to the mandatory mortality review process described in MP 0098/18 Review of Death Policy, the purpose of which is to ensure a consistent approach to the review of death process across the WA health system. The review of death process aims to identify: • Potentially preventable deaths • Opportunities for improvement in the delivery of health services, including the quality of end-of-life care. Potentially preventable deaths identified via a review of death process must be notified as SAC 1 clinical incidents and investigated under the CIM Policy.
Sentinel events	A subset of serious clinical incidents that has resulted in or could have resulted in serious harm or death of a patient. It refers to preventable occurrences involving physical or psychological injury, or risk thereof.
Serious misconduct	Included in MP 0125/19 Notifiable and Reportable Conduct Policy and pursuant to sections 3 and 4(a) (b) and (c) of the Corruption, Crime and Misconduct Act 2004, is conduct by a public officer who – a) acts corruptly or corruptly fails to act in the course of their duties; or b) corruptly takes advantage of their office or employment to obtain a benefit or to cause a detriment to any person; or c) acting in the course of their duties or while deliberately creating the appearance of acting in the course of their duties,

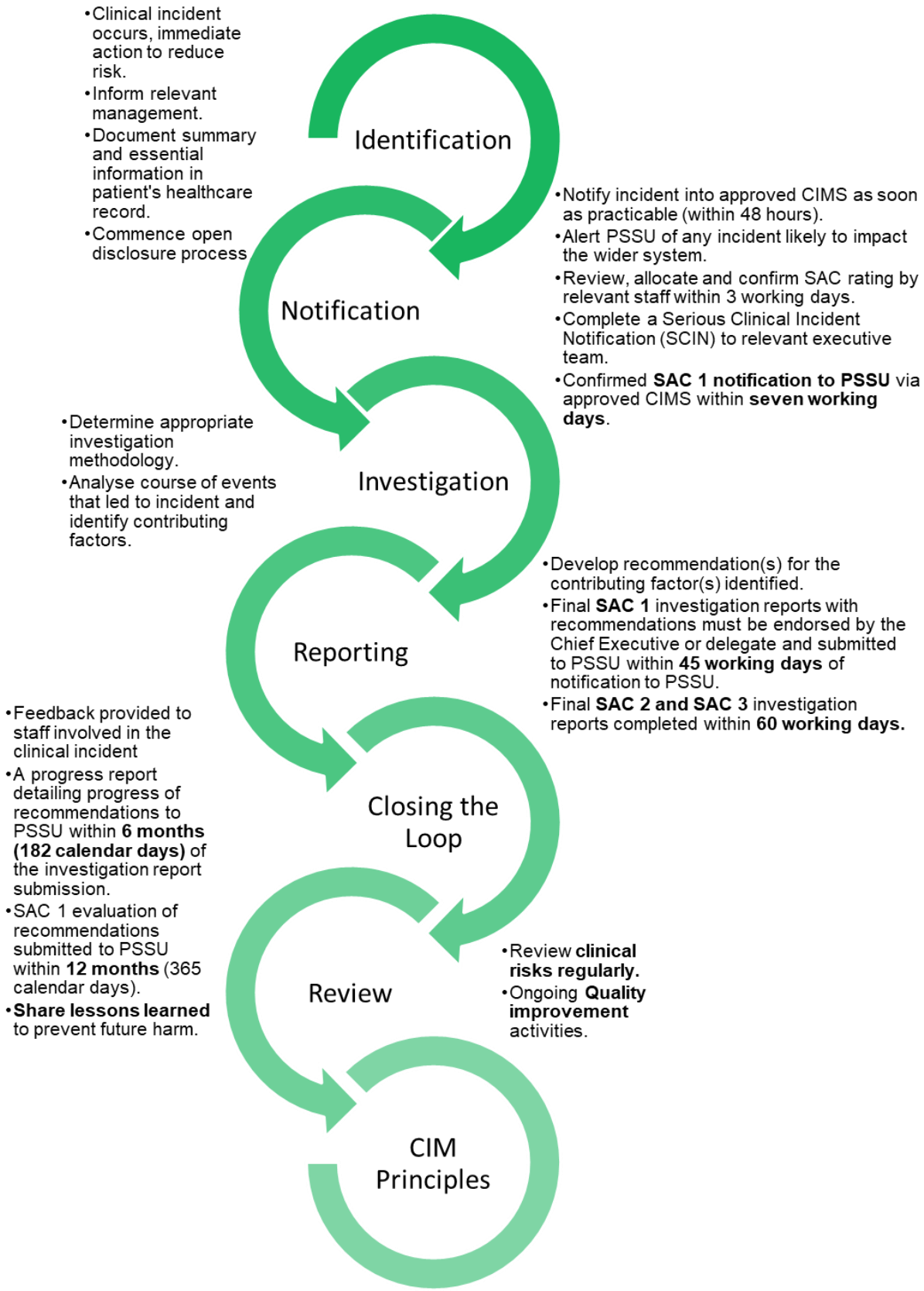
	commits an offence punishable by two or more years imprisonment. Corrupt conduct tends to show a deliberate intent for an improper purpose or an improper motivation. Corrupt conduct may involve an exercise of a public power or function, but for private benefit. It may involve conduct such as the deliberate failure to perform the functions of office properly, or the exercise of a power or duty for an improper purpose.
Severity Assessment Code (SAC) rating	The SAC rating is the way clinical incidents are rated in the WA health system. Clinical incidents are categorised using the SAC rating to determine the appropriate level of analysis, action, and escalation.
Steward	The delegated authority for the information assets outlined within the associated delegation schedule.
Synopsis report	A brief summary which gives readers an overview of the main points.
WA health entities	WA health entities include: (i) HSPs as established by an order made under section 32 (1)(b) of the Health Services Act 2016. (ii) Department of Health as an administrative division of the State of Western Australia pursuant to section 35 of the Public Sector Management Act 1994.
WA health system	The WA health system is comprised of: (i) the Department. (ii) HSPs (North Metropolitan Health Service, South Metropolitan Health Service, Child and Adolescent Health Service, WA Country Health Service, East Metropolitan Health Service, PathWest Laboratory Medicine WA, Quadriplegic Centre, and Health Support Services); and (iii) CHEs, to the extent they provide health services to the State.

Appendix 1. Roles and Responsibilities

Role	Responsibilities
Individual staff	• Notify clinical incidents into the CIMS. Notification can be done anonymously. • Adhere to Policy principles
WA health entity	Clinical Incident Management Processes: Ensure • Compliance to the Policy requirements is met. • All clinical incidents are recorded in the CIMS. • All SAC 1 clinical incidents are submitted to the PSSU via email using the prescribed templates or equivalent (private facilities and contracted health entities), which will then be recorded in the CIMS. Supporting staff: Ensure • There is staff awareness of their responsibilities to participate in CIM processes. • Relevant employees have had education and training in clinical incident management and investigation methodologies, including report writing, contributing factors, developing recommendations and evaluation processes. This includes an awareness and understanding of CIM and quality improvement principles which focus on system theory and human factors. • Executive support such as the Board, Chair and Safety and Quality Executive Director are inducted and aware of their roles and responsibilities with CIM and actively support a patient safety culture. • Support to staff in undertaking critical components such as the Open Disclosure Process with patients and any relevant stakeholders is available. • Support to staff following a clinical incident by encouraging participation in debriefing sessions and/or use of appropriate counselling services (both internal and external). • Staff are also recognised as the victims of unsafe systems who may also be harmed or experience moral distress as a result of a clinical incident. • Adequate feedback mechanisms are in place to maximise the effectiveness of quality improvement strategies and share lessons learned across the health service. They should also ensure that the notifier is involved with the CIM process as appropriate and aware of outcomes of the investigation. • When there has been a breach in CIM Principles and the CIM investigation is misused, there is investigation and implementation of remedial actions as necessary. Supporting the Patient: Ensure • There is an awareness and an understanding of their rights, responsibilities, and cultural considerations.

	• There is awareness and involvement in the CIM Process as appropriate (patient, family, carer, guardian). • Facilitation of an appropriate level of open disclosure to the patient, their family, and carers/guardians as soon as practical when a clinical incident occurs. • Adequate feedback mechanisms are in place to inform the patient and their family/carer/guardian of any outcomes. • SAC 1 investigation reports are offered/shared with patients/families/carers/guardians, noting that investigation reports are subject to Freedom of Information requests if not shared. Other • Analysis of local clinical incident data is undertaken to monitor quality improvement strategies and the PSSU is advised if adverse trends are detected within the health service. • Appropriate frameworks are in place to enable staff to work collaboratively to investigate clinical incidents with other health care providers when incidents occur across health service boundaries. • There is awareness of statutory and reporting requirements relevant to clinical incident management. • Processes and resources are in place to manage clinical incidents that result in legal proceedings.
Patient Safety Surveillance Unit	• Review, amend and monitor MP 0122/19 Clinical Incident Management Policy • Oversight of the clinical incident management process • Sharing lessons learned at a system level • Analyse and report aggregate data at a system level • Production and publication of clinical incident management reports • Business engagement of the CIMS database.

Appendix 2. Clinical Incident Management Steps



Appendix 3. Serious Clinical Incident Notification Template

SERIOUS CLINICAL INCIDENT NOTIFICATION			
CIMS		**Date of SCIN**	
Date of incident		**Datix notification**	
Location of incident		**Patient UMRN**	
Raised by	☐ CIMS ☐ Complaint ☐ Audit ☐ Death review ☐ Other _____		
Statutory reports completed	☐ Coroner ☐ Perinatal/infant death ☐ Maternal death ☐ Chief Psychiatrist ☐ TGA ☐ WHS ☐ Other _____ ☐ N/A		
Open Disclosure details			
Open Disclosure Lead	**Please complete before approval**		
Open Disclosure recorded	☐ Yes ☐ No Reason _____		
Incident details			
SAC 1 Incident Type			
Summary of incident ***Patient age, sex, and brief description of the event***			
Actions taken ***List immediate actions taken to ensure risk is reduced for all patients and any planned interim actions including seeking external advice or input into the SAC 1 investigation.***			
Patient outcome			
Panel			
Chair		**Facilitator**	
Independent member		**Consumer**	
Panel members			
Approvals (as per WA health entity's delegated schedule)			

Signature	Date

Current and relevant diagnosis

Description of actual or potential clinical incident

Treatment/investigations required as a result of the clinical incident

Additional information

Appendix 4. WA health system Severity Assessment Codes (SAC) – Summary

<table>
<tr><th></th><th>SAC 1</th><th>SAC 2</th><th>SAC 3</th></tr>
<tr><td>Actual/potential consequence to patient</td><td colspan="2">Physical/psychological serious harm or death (including near miss); that has or could have been attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness.</td><td>Physical/psychological Moderate harm (including near miss) that has or could have been attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness.</td><td>Physical/psychological Minor or no harm (including near miss) that has or could have been attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness.</td></tr>
<tr><td>Type of event/ incident</td><td colspan="2">SAC 1 clinical incidents include (but not limited to):
• National Sentinel Event Categories
• Any other clinical incident which results in serious harm (physical or psychological) or death of a patient
• Escalation of care to a higher level of care within the inpatient setting
• Increased length of stay greater than 7 days
• Near miss that could have resulted in serious harm or death.
National Sentinel Event Categories
1. Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death.
2. Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death.
3. Wrong surgical or other invasive procedure performed on a patient resulting in serious harm or death
4. Unintended retention of a foreign object in a patient after surgery or other invasive procedure resulting in serious harm or death.
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility resulting in serious harm or death.
6. Suspected suicide of a patient in an acute psychiatric unit or acute psychiatric ward.
7. Medication error resulting in serious harm or death
8. Use of physical or mechanical restraint resulting in serious harm or death.
9. Discharge or release of an infant or child to an unauthorised person.
10. Use of an incorrectly positioned oro-or naso-gastric tube resulting in serious harm or death.</td><td>SAC 2 clinical incidents include, but are not limited to the following:
• Increased length of stay (More than 72 hours to 7 days)
• Additional investigations performed
• Referral to another clinician
• Surgical intervention
• Medical intervention
• Increased frequency of mental health clinician review
• Near miss that could have resulted in moderate harm.</td><td>SAC 3 clinical incidents include, but are not limited to the following:
• No harm
• Only first aid treatment required
• Minor harm resulting in increased length of stay of up to 72 hours
• Increased frequency of mental health clinician review
• Near miss that could have resulted in minor harm.</td></tr>
<tr><td>Actions – During Notification, Analysis, and Investigation</td><td colspan="2">• Implement any preliminary actions to mitigate further risk of harm to the patient, staff, or others
• Document summary, essential information, actions in patient's healthcare records notes by end of notifier's workday or as soon as practicable (within 48 hours).
• Submit information via CIMS or equivalent as soon as possible (within 48 hours).
• Inform relevant manager/appropriate executive within 24 hours, follow any local processes.
• Within 3 working days review and confirm SAC rating.
• After confirmation of the SAC rating into the CIMS, complete the SCIN
• Complete a SAC 1 notification to PSSU via CIMS within 7 working days.</td><td>• Implement any preliminary actions to mitigate further risk of harm to the patient, staff, or others
• Document summary, essential information, actions in patient's medical notes by end of notifier's workday.
• Submit information via CIMS or equivalent by end of notifier's workday.</td><td>• Implement any preliminary actions to mitigate further risk of harm to the patient, staff, or others
• Document summary, essential information, actions in patient's medical notes by end of</td></tr>
</table>

	• Implement a **higher-level open disclosure response** for incidents causing serious harm or death, or a lower-level response for near miss incidents**. • Notify the local WHS team if a WHS hazard is suspected or identified as a causal or contributing factor to the incident. • Undertake SAC 1 investigation by **comprehensive analysis or other appropriate methodology.**	• Notify the local WHS team if a WHS hazard is suspected or identified as a causal or contributing factor to the incident. • Within 3 working days, **confirm** SAC rating. • After confirmation of the SAC rating into the CIMS, commence **initial investigation** to identify human errors and system failures. • Investigate at a local level using an appropriate methodology. • Implement an **appropriate level of open disclosure**.**	notifier's workday or as soon as practicable (within 48 hours). • **Submit** information via CIMS or equivalent by end of notifier's workday or as soon as practicable (within 48 hours). • Notify the local WHS team if a WHS hazard is suspected or identified as a causal or contributing factor to the incident. • Within 3 working days, **confirm** SAC rating • After confirmation of the SAC rating into the CIMS, commence **initial investigation** to identify human errors and system failures. • Investigate at a local level using appropriate methodology. • Implement an **appropriate level of open disclosure**.**
Reporting requirements	• Final investigation reports with recommendations must be endorsed by the Chief Executive or by their steward(s) as per the approved delegation schedule. • Submit completed investigation reports which are due within 45 working days of notification to PSSU.	• Complete investigation within 60 working days of incident notification*.	• Complete investigation within 60 working days of incident notification*.
Recommendations	• All SAC 1 progress report must be submitted to the PSSU within six months (182 calendar days) of the investigation report submission. • An evaluation report is also be forwarded to PSSU within twelve months (365 calendar days) of the investigation report submission. • Lessons learned are to be shared at all levels of the service and the system where appropriate.	• Progress report of recommendations managed at a service level within 6 months (182 calendar days) of the investigation being completed. • Evaluation report managed at a service level within 12 months (365	• Progress report of recommendations managed at a service level within 6 months (182 calendar days) of the investigation being completed.

		calendar days) of the investigation being completed. • Lessons learned are shared at all levels of the service	• Evaluation report managed at a service level within 12 months (365 calendar days) of the investigation being completed. • Lessons learned are shared at all levels of the service.
*The completion of the CIMS clinical incident form (notification and investigation sections) can constitute a final report. ** in accordance with the Australian Open Disclosure Framework.			

Appendix 5. Synopsis Report - Template

Use the template text in red to create a synopsis of the clinical incident.

Summary	Provide a summary of the clinical incident. What happened?
Incident type	Provide the type of incident (for example- SABSI/ Fall/ Unexpected death of a MH patient)
Investigation Methodology	Include the methodology used
Findings	Summarise the findings from the clinical incident investigation
Recommendation actions	What were the recommendation actions that arose from the clinical incident investigation.
Valuable lessons learned	Provide information regarding lessons learned as part of the incident investigation process that could be applied across the WA health system.
Relevant Resources	
Provide links/ guidance to relevant tools and resources for considerations.	
Approvals	

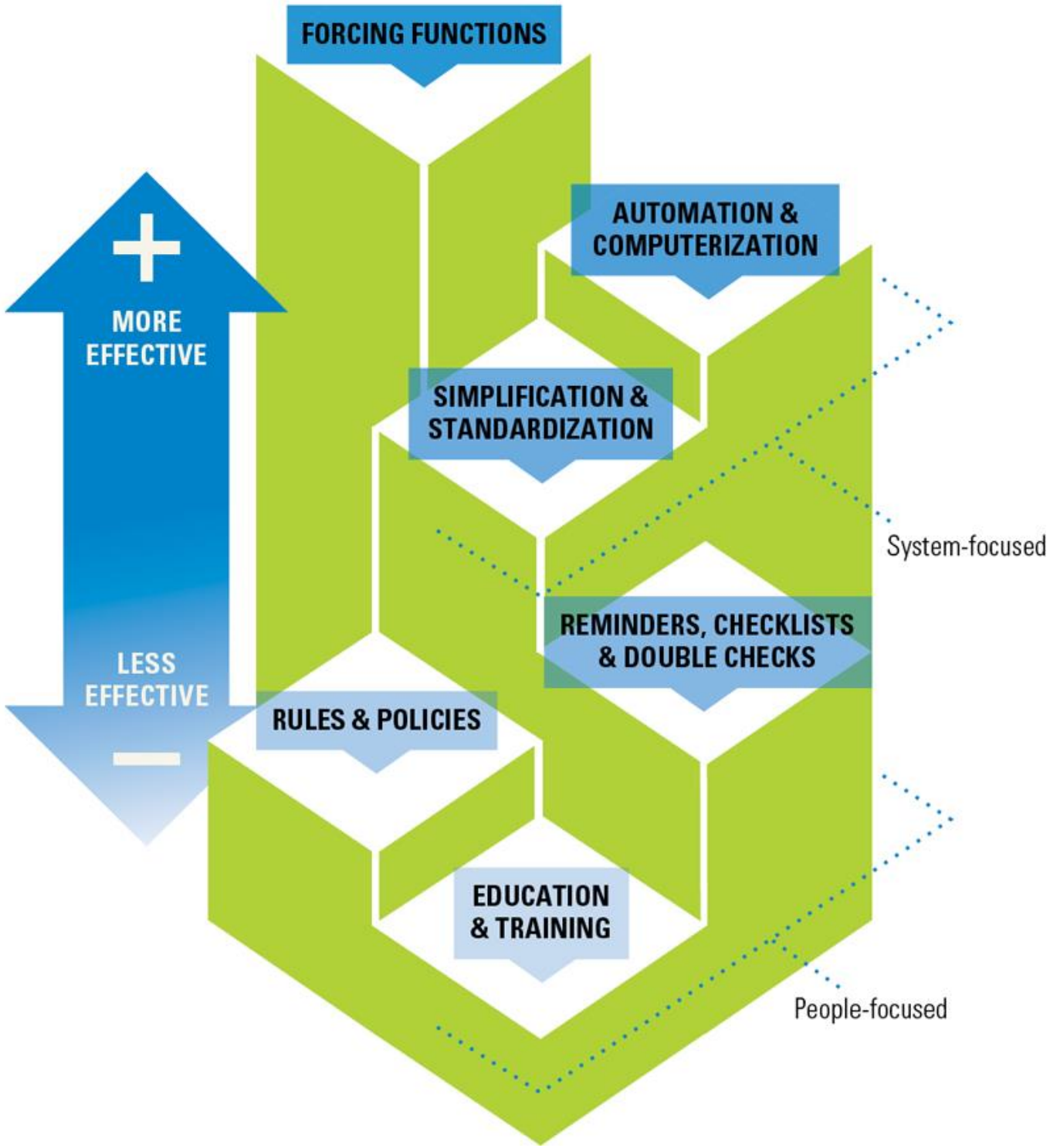
WA health entity	Name: Position:	Signature:
DOH	Name: Position:	Signature:

Appendix 6. Recommendations/Actions Hierarchy

Action Strength	Recommendation/Actions Category	Example
Stronger Actions	Architectural/physical plant changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fittings that can only be connected the correct way (e.g., IV tubing and connectors that cannot physically be connected to sequential compression devices or SCDs).
	Simplify process	Remove unnecessary steps in a process. Standardize on equipment or process. Standardize on the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.
	Tangible involvement by leadership.	Participate in unit patient safety evaluations and interact with staff; support the RCA[2] process; purchase needed equipment; ensure staffing and workload are balanced.
Intermediate Actions	Redundancy	Use two RNs to independently calculate high-risk medication dosages.
	Increase in staffing/decrease in workload	Make float staff available to assist when workloads peak during the day.
	Software enhancements, modifications	Use computer alerts for drug-drug interactions.
	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.
	Education using simulation-based training, with periodic refresher sessions/observations	Conduct patient handovers in a simulation lab/environment, with after action critiques and debriefing.
	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fibre optic endoscopes.
	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the unit medication room. Introduce tall-man lettering to differentiate between look- and sound-alikes.
	Standardized communication tools	Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handover format.
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.
Weaker Actions	Double checks	One person calculates dosage, another person reviews their calculation.
	Warnings	Add audible alarms or caution labels.
	New procedure/ memorandum/policy	Remember to check IV sites every 2 hours.
	Training	Demonstrate the hard-to-use defibrillator with hidden door during an in-service training.

Appendix 7. Hierarchy

The Hierarchy of Intervention Effectiveness



Appendix 8. Sentinel events

All SAC 1 clinical incidents, which include sentinel events, must be notified.

Please see Appendix 2 for other examples of other clinical incidents which may be notified as SAC 1.

SAC 1 Clinical Incident Notification List (Sentinel events)	
Category	**Clinical incidents (category 1-10 sentinel events)**
1	Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death.
2	Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death.
3	Wrong surgical or other invasive procedure performed on a patient resulting in serious harm or death.
4	Unintended retention of a foreign object in a patient after surgery or other invasive procedure resulting in serious harm or death.
5	Haemolytic blood transfusion reaction resulting from ABO incompatibility resulting in serious harm or death.
6	Suspected suicide of a patient in an acute psychiatric unit or acute psychiatric ward. Note: Mental Health Services are required to report to the Chief Psychiatrist and to the State Coroner (for involuntary patients) episodes of unexpected death.
7	Medication error resulting in serious harm or death.
8	Use of physical or mechanical restraint resulting in serious harm or death.
9	Discharge or release of an infant or child to an unauthorised person.
10	Use of an incorrectly positioned oro-or naso-gastric tube resulting in serious harm or death.

Appendix 9. SAC 1 notification list

SAC 1 includes a clinical incident that has, or could have (near miss), resulted in serious harm or death and which is attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness.

Note that this list is NOT EXHAUSTIVE. If unsure of whether to notify of an incident, contact relevant staff involved in the management of clinical incidents.

SAC 1 Clinical Incident Notification List (Other)
Medication error (not resulting in death or serious harm) may include: • The inappropriate administration of daily oral methotrexate • The intravenous administration of epidural medication • Wrong gas being administered.
Fetal or Neonatal complications associated with health care delivery: • Unrelated to congenital abnormality in an infant causing death, or serious and/or ongoing perinatal morbidity. • Complications not anticipated yet arose and were not managed in an appropriate/timely manner • Delivery at a site other than where labour commences which requires transfer to another facility for a higher level of care resulting in death, or serious and/or ongoing morbidity. *Note that for clinical incident reporting a fetus is from conception to birth. Please note this may differ to clinical service*
Misdiagnosis and subsequent management (refer to physical and mental health)
Psychological deterioration of a mental health patient resulting in serious harm (physical, verbal, or sexual); or serious harm or death to staff, other patients, or other persons. *Consider the seriousness of the outcome (whether that be patient harm or harm to others) which may assist in understanding the level of patient deterioration. For example: if a patient commits homicide, this should suggest a high level of deterioration and thus serious harm to the patient.*
Complications of resuscitation: • Events in which staff experienced problems in managing an emergency situation or resuscitation resulting in death, or serious and/or ongoing morbidity. • Failed resuscitation where resuscitation guidelines could not be followed due to a deficiency of equipment, communication, or staffing resulting in death, or serious and/or ongoing morbidity.
Complications of anaesthetic management: • Unintended intra-operative awareness. • Anaesthetic events resulting in death, or serious and/or ongoing morbidity
Complications of surgery: • Intentional retention of foreign material for treatment which is found to have resulted in harm • Pulmonary embolism • Injury to major blood vessels
Complications of a fall within a health service
Delay in recognising/responding to physical clinical deterioration.
Hospital Acquired Pressure Injuries
Hospital/Service process issues: • Events in which hospital or other health service processes such as triaging, assessment, planning or delivery of care e.g. miscommunication of test results, response to abnormal test results contributed to death, or serious and/or ongoing morbidity • Transport or transfer – Events in which delays in transport or transfer contributed to death, or serious harm • Misidentification of patients.
Intravascular gas embolism resulting in death or neurological damage.
Infection control breach (e.g., IV cannula related bacteraemia infections)
The unexpected death of a mental health client: • suspected suicide which occurs in a location other than an acute psychiatric unit or acute psychiatric ward • unnatural or violent death *Note an unnatural or violent death involving mechanical or physical restraint in a health service, should be categorised as a sentinel event.*

Maternal death: The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes.[23,24]
Missing or Absent Without Leave of any high-risk mental health patient/consumer. *Note the assessment of a mental health patient as high risk is based on the patient's mental health condition and is determined using clinical judgement. High risk mental health patients include those patients determined to be at high risk of causing significant harm to themselves or others or being harmed by others.*
Patient missing or Absent Without Leave with adverse outcome
Equipment use resulting in unintended harm

Appendix 10. Key concepts in Safety and Quality relevant to CIM

1. A Safe and Just Culture

Safety culture is frequently defined as 'the product of individual and group values, attitudes, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of an organisation's health and safety programs'. Organisations with a positive safety culture are characterised by communications founded on mutual trust, shared perceptions of the importance of safety, and confidence in the efficacy of preventative measures[1].

A safe and just culture has many aspects, including the above CIM best practice principles. Organisations that embrace these principles at a foundational level are well placed to create a culture of safety and learning to ensure reliability, improvement, and sustainability[2,3].

The clinical incident investigation process is most effective when it is being conducted within a safety culture, as clinicians understand that the organisation's focus is on system learning, not individual blame. The term 'just culture' describes a culture that successfully achieves that balance where wider systemic issues are learned from without fear of retribution and accountability[4].

1.1. Restorative Just Culture

Moving from a just culture to creating 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[5,6]. A restorative just culture creates a healing, learning, and improving approach. 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'[5,6]. It asks 3 questions:

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

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 to be involved in the review process. Acknowledging who is hurt and what their needs are is the first step towards becoming truly 'just'.

The goals of a restorative just culture include but are not limited to:

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

1.2. Improving Patient Safety Culture

Safety culture is enacted when the emphasis on safety is translated into meaningful practice by front-line healthcare workers, including the willingness of frontline staff to disclose and report errors, including near misses and to communicate their concerns upward in the organisation[7,8]. Interventions that support enacting a safety culture focus on improving the capability of healthcare professionals to identify and proactively address potential safety threats, including complex healthcare delivery models and latent conditions. In enacting a safety culture, threats to safety are highlighted and resolved through effective interpersonal processes[8,9]. These processes include but are not limited to:

- Leadership walks round.
- Multidisciplinary safety rounds.
- Building resilience at the team level through mindful organising[2].
- Working towards a shared goal of delivering safe and quality patient care through relational coordination[3].
- Team training.
- Comprehensive Unit-Based Safety Programs.
- Quality improvement activities focused on safe and quality healthcare provision.

Figure 5: Conceptual framework for improving patient safety culture[8]

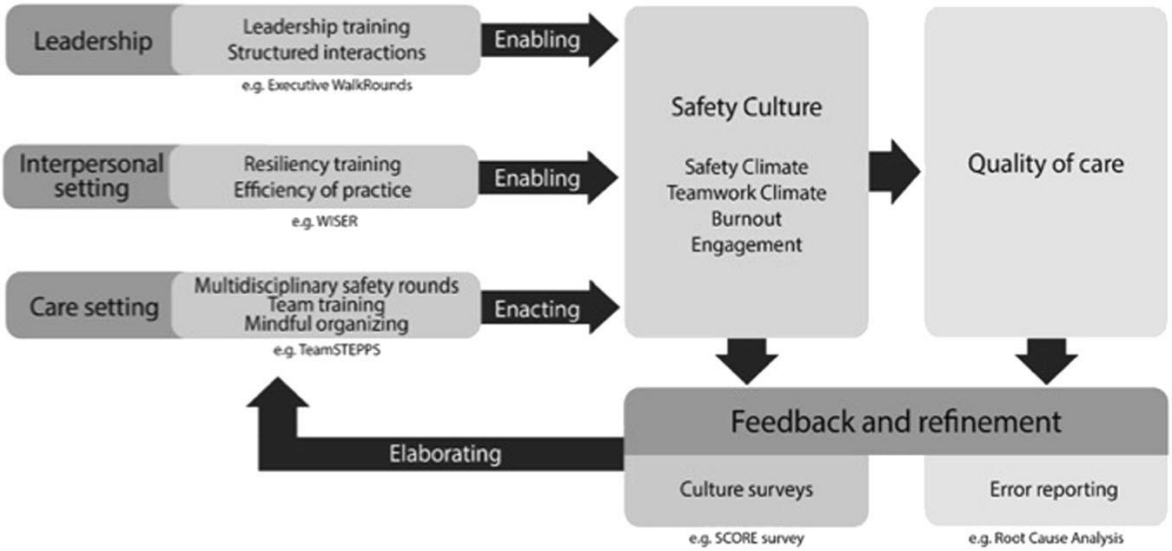


Figure 2: Conceptual framework relating drivers, outcomes, and feedback mechanisms relevant to safety culture. Drivers such as leadership and specific interventions such as Executive Walk Rounds enable and help enact safety culture. Surveys and error reporting provide feedback and help reinforce safety culture[8].

1.3. Role of Leadership in improving safety culture

Positive safety cultures in healthcare 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[9].

The NSQHS 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. Building high-reliability health organisations and systems for a strong patient safety culture that protects patients daily from harm requires strong leadership at all levels. Leaders of organisations should commit to creating and maintaining a culture of safety. An engaged and skilled leadership team is paramount to improving patient safety. Having board members who are skilled in quality and safety can play a positive role in influencing safety.

Organisations with positive safety cultures have[9, 10]:

- strong leadership to drive the safety culture
- strong management commitment, with safety culture as a key organisational priority

[2] the patterns of interactions between staff to create resilience at a team level that is anchored by an understanding of both the context of the work and the capabilities of all members of the team.
[3] a mutually reinforcing process of communicating and relating for the purpose of task integration

- a workforce that is engaged and always aware that things can go wrong
- acknowledgement at all levels that mistakes occur
- just accountable culture
- ability to recognise, respond to, give feedback about, and learn from clinical incidents.

1.4. Cultivating a reporting culture

A positive safety culture is closely linked with organisations that have implemented a sound reporting culture. All staff are responsible for identifying and reporting incidents. If incidents are **not** reported, learning cannot be made, and there is a high chance of a recurrence. There are several key aspects when adopting this approach that organisations need to consider, including[11] but not limited to:

- **Establishing trust to improve reporting:** Leaders can help to create an environment where it is psychologically safe to report. Psychological safety is crucial in terms of ensuring people feel safe to speak up. Programs that acknowledge or give positive recognition for reporting (i.e. 'Good Catch programs') reinforce the trust being built.
- **Eliminate fear:** Establishing trust also means establishing that the clinical incident management process is for the purpose of identifying and addressing systemic failures and systems-level changes.
- **Examine Near misses:** This assists in developing more mature processes to respond to poorly detected clinical risks and helps to provide information on active or potential system weaknesses.
- **Encourage reporting with leadership engagement:** Leaders who are accountable are strong role models for staff to report incidents.

2. System thinking and human factors

A system can be described as the coming together of parts and purpose. The health system is one example, where many parts have come together for the purpose of ensuring the wellbeing of an individual. The science of human factors examines how humans interact with the world around them and how aspects can influence human performance. Human factors play a crucial role in CIM by influencing how healthcare professionals perform tasks, communicate, and make decisions under pressure. These factors encompass the interactions between individuals, their work environment, tools, and organisational systems. In the context of clinical incidents, the HALT model[28] stands for Hunger, Anger, Late, and Tired and highlights key human factors that can affect performance and decision-making. Effective CIM involves recognising and addressing these human elements to prevent errors, improve patient safety, and optimise the delivery of safe and quality healthcare.

A systems approach understands that humans are fallible, and errors are to be expected, even within the best organisation. This view assesses the individual's actions within a wider context of circumstances that occurred at the time, and deeper analysis will uncover more system-based contributing factors.

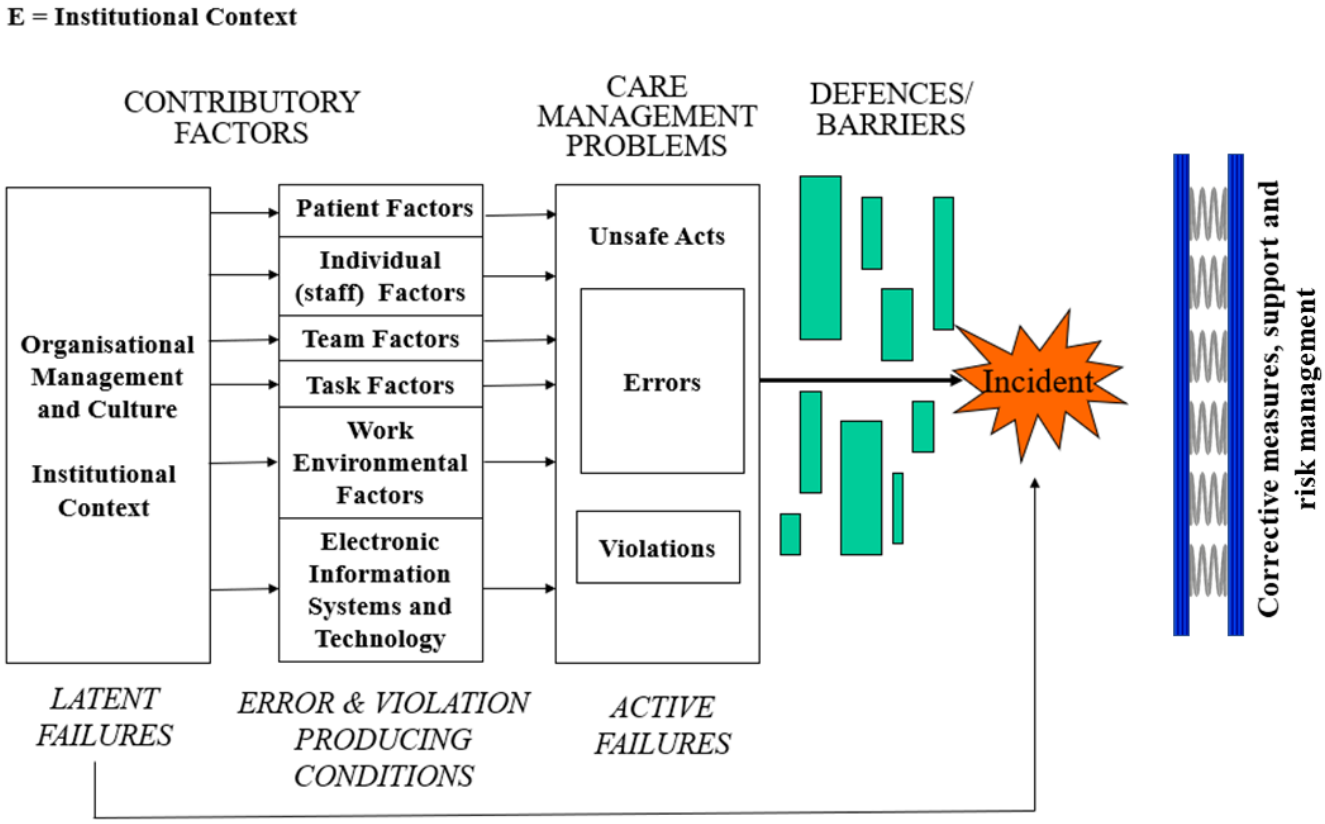
The role that human factors and systems thinking can have in enabling organisations to learn from incidents is well acknowledged. A systems approach can help organisations focus less on individual fallibility and more on setting up resilient and safe systems. Systems thinking, in its simplest, is appreciating both the explicit and tacit processes that surround a system of work. Embracing systems thinking is almost synonymous with embracing the complexity of healthcare and appreciating that incidents in healthcare may not follow a linear causation process.

2.1. System Analysis of Clinical Incidents: London Protocol 2024

The London Protocol 2024 provides a structured approach to incident investigation, focusing on comprehensive analysis and reflection, rather than assigning blame or identifying “root causes.” Building on prior versions, it encourages active thinking, reflection, and exploration of incidents within the broader context of the healthcare system[29]. The protocol is designed to support both full investigations and quicker, more focused analyses and is adaptable to different settings. It emphasises learning from systemic issues rather than individual fault, aiming to improve safety and restore trust. Disciplinary actions, if necessary, should be separate from the investigation process. The goal is to foster a culture of fairness, learning, and safety enhancement.

For a detailed guide, please refer to System Analysis of Clinical Incidents: London Protocol 2024.

Figure 6: Extension of James Reason’s Organisational Accident Causation Model, adapted from Reason[30].



2.2. System Engineering Initiative for Patient Safety model

Models have emerged to incorporate the science of HFE to understand how humans interact with the complex systems in which they work, referred to as work systems[4]. HFE is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data, and methods to design in order to understand human well-being and overall system performance[14].

The System Engineering Initiative for Patient Safety (SEIPS) model illustrates that patient safety risks may develop from several work system factors and the interactions between them[14].

[4] A work system is a system in which humans or machines perform processes or activities using information and technology.

These interactions affect the processes (admission to the intensive care unit, flow in and out of the postoperative care unit) required to deliver safe care. This influence on the processes can produce different outcomes, which can be patient (clinical incidents), staff or organisation-related (medication safety, staff well-being, organisational reputation).

The SEIPS model focuses on five core components:

1. **Work system:** This includes the people (e.g., clinicians, patients), tasks (e.g., clinical procedures), technologies and tools, organisational factors (e.g., policies), and the physical environment (e.g., hospital layout) involved in care delivery[14]. By analysing clinical incidents through this lens, healthcare organisations can better understand the factors contributing to incidents in relation to a person, tasks, tools, technologies, and environment.
2. **Processes:** It addresses the care processes that occur within the work system, such as diagnosis, treatment, and patient interactions. During clinical incident investigation, this would identify specific process failures (e.g., lack of double-checking medication orders, unclear communication between teams) and use this analysis to develop recommendation actions to improve the workflow and prevent similar incidents in the future[14].
3. **Outcomes:** This includes the outcomes for patients (e.g., health improvements, patient safety), healthcare professionals (e.g., job satisfaction, burnout), and organisational outcomes (e.g., reputation risk, efficiency)[14]. Applying these outcomes to clinical incident management helps assess both the immediate and long-term effects of the incident.
4. **Interactions:** The model highlights how different components of the work system interact with one another and affect the processes and outcomes. For example, if a nurse is overworked (person), working in a poorly designed unit (environment), with insufficient staffing (organisation), the likelihood of an incident increases[14]. Understanding these interactions is key to developing effective recommendation actions and preventative strategies.
5. **Feedback loops:** SEIPS emphasises the importance of feedback for continuous improvement, with outcomes influencing future adaptations to the work system and processes. After analysing the incident, healthcare organisations should implement changes and monitor their effectiveness.

Figure 7: SEIPS 2.0 Model[15]

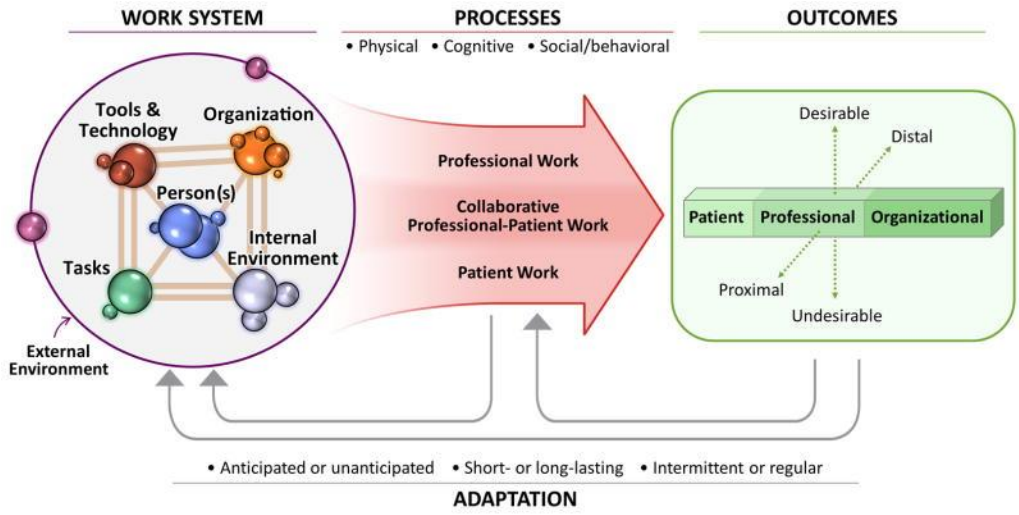


Figure 3: The general structure of the model is that the sociotechnical work system (left) produces work processes (middle), which shape outcomes (right).

2.3. Swiss Cheese Model

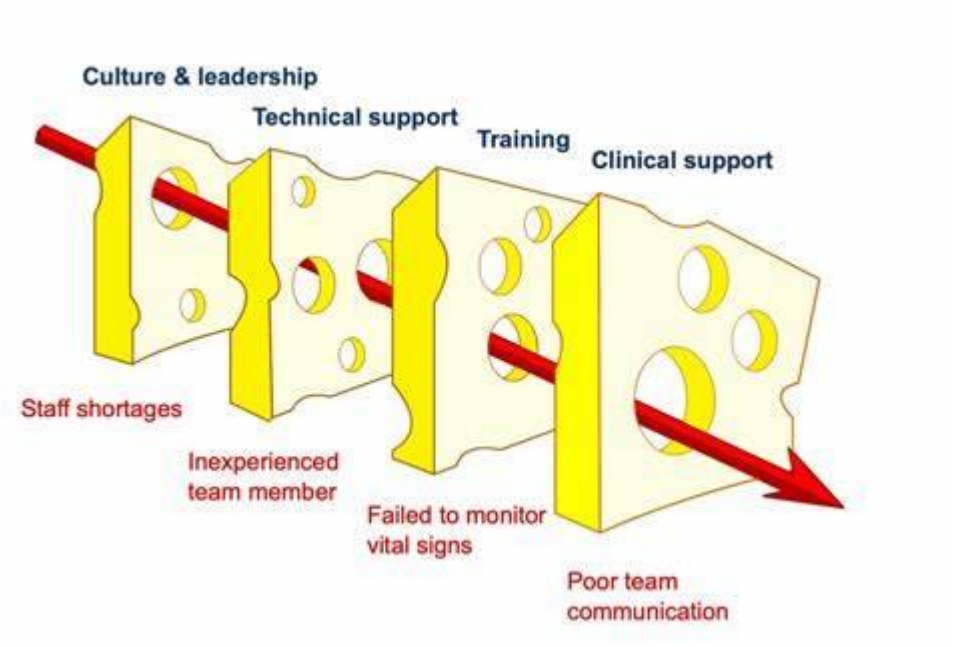
The Swiss Cheese Model of organisational accidents, developed by James Reason in the 1980s, is one of the key foundational concepts that supports aspects of clinical incident management[12]:

- The model proposes that defences, barriers, and safeguards that exist are not impermeable and can occur when active failures (productive activities) and latent conditions (defences and decision makers) combine to create the 'perfect' opportunity for an incident.
- Active failures are the unsafe acts committed by people who are in direct contact with the patient or system and tend to take a variety of forms, such as slips, lapses, fumbles, mistakes, and procedural violations.
- Latent conditions arise from decisions made by designers, builders, procedure writers, and top-level management.
- Unlike active failures, whose specific forms are often hard to foresee, latent conditions can be identified and remedied before a clinical incident occurs[12].

Understanding this leads to proactive rather than reactive clinical risk management. The basic understanding of this model is that one cannot "change the human condition, but we can change the conditions under which humans work", and this encourages a 'find and fix' philosophy[12, 13].

The limitation of the model is that to be effective, the event must have occurred in a linear system, and healthcare is not a linear system but rather complex and adaptive. The core questions to ask when a clinical incident happens are how and why the defences in the system failed and review the system as a whole rather than solely the actions of individuals.

Figure 8: Swiss Cheese Model in Healthcare[12]



2.4. Relationship between Safety I and Safety II

Historically, the Safety I approach defined safety as a state, whereas few things as possible go wrong. The assumption was that things go wrong due to identifiable failures or malfunctions of specific components, including technology, procedures, human workers, and organisations. A Safety I investigation is retrospective and reactive in that it identifies the causes and contributory factors of adverse outcomes and puts measures in place to prevent a repeat

incident from occurring. The downside of Safety I is that it fails to consider why human performance primarily always goes right[10].

By comparison, Safety II looks forward and focuses on 'as many things as possible going right' and relates to the system's ability to succeed under varying conditions. The focus of Safety II is to learn where things work well, understand the challenges, and develop and implement systems-based patient safety approaches and principles to ensure patients flow through the system safely[16]. Table 2 shows the difference between Safety I and Safety II concepts[12].

Table 7: Safety I and Safety II concepts[10]

	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 and are a problem to be fixed.	Humans are seen as a resource necessary for system flexibility and resilience and 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 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.	The purpose of an investigation is to understand the conditions where performance variability can become difficult or impossible to monitor and control.

3. Partnering with consumer

Partnering with consumers in a clinical incident investigation is a vital aspect of improving healthcare safety and quality. By partnering with patients and their families in the review and analysis of clinical incidents, healthcare organisations gain valuable insights into the patient experience and identify areas for improvement. Engaging consumers in these investigations fosters transparency, builds trust, and ensures that care delivery is patient centred. It also helps organisations address the concerns of those directly affected by the incident, promoting learning and accountability within the healthcare system. As a result, consumer engagement is increasingly recognised as a key element in driving improvements in clinical outcomes and enhancing patient safety.

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

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

Detailed information on engaging consumers and consumer representatives during a clinical incident investigation is set out in Section 6.4.4.

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