# Clinical Incident Management Toolkit 2019

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**About this Toolkit**

The toolkit and resources are accurate at the time of publication. Please check the WA health CIM website and links in the further resources and templates for any updated processes or templates since the time of this publication.

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**Suggested Citation:**

Department of Health, Western Australia. Clinical Incident Management Toolkit. (2019). Perth: Patient Safety Surveillance Unit, Patient Safety and Clinical Quality, Clinical Excellence Division.

**Document Control:**

| Version | Published date | Effective from | Review date | Amendment(s) |
|---------|----------------|----------------|-------------|--------------|
| 1.0 | 1 November 2019 | 1 November 2019 | November 2022 | Original version |
| 2.0 | 19 July 2023 | 19 July 2023 | November 2022 | Replaced broken hyperlinks. |

# Contents

# 1. Clinical Incident Management in WA: Introduction and Background

Clinical Incident Management (CIM) is a process which aims to:

1. Identify hazards before they cause patient harm, treat them and review clinical risks.
2. Identify when patients are harmed and implement strategies to minimise harm.
3. Ensure lessons are learned; provide opportunities to share lessons and taking action to reduce the risk of similar events occurring.

**Note: how to use the suite of CIM documents**

The CIM Toolkit is part of three documents which guide the WA health system when managing clinical incidents.

| Document | Example |
|---|---|
| 1. **The Policy** sets out requirements which are binding under the Health Services Act 2016[i]. The language used within the Policy include terms such as 'must' and 'shall' which indicate a mandated action. | This requirement can be very precise ("A final investigation report must be submitted to PSSU in 28 working days") or general ("An investigation must follow recognised methodologies"). |
| 2. **The Guideline** is supporting information, a non-mandatory document which provides detailed information to inform services ways to meet these Policy requirements. Whilst they are not mandated to follow a certain method, the Guideline provides a sure methodology to meet the requirements. | A final investigation report may utilise a root cause analysis however the Guideline also indicates using FMEA or HEAPS will be just as accepted as a recognised methodology. <br><br> The Policy states CIM must be managed in accordance with CIM Principles. There is further descriptions of what these principles entail within the Guideline. |
| 3. **The Toolkit** is further supporting information which provide a further range of patient safety and incident management literature. | Discusses what sort of criteria can be used to determine an investigation method and further international resources for implementation. |

For ease of use, requirements within the Policy may be repeated in the appropriate section. The only statements within this document which have the term 'must' or 'shall' are the same requirements within the Policy.

The CIM Toolkit (the Toolkit) complements the above package as a resource which provides HSPs a suite of practical advice on current methodologies, templates to use for CIM implementation. The Toolkit does not seek to duplicate resources, only offering clarifications if the WA health system has adapted a resource or provide further resources and recommendations at each stage of the CIM Process to utilise. It is encouraged that staff utilise this toolkit as a starting point and use the 'further resources and templates' section to deepen knowledge on in the areas of Patient Safety and CIM.

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[i] Health Services Act 2016 s26(2) (a) (c) (d)

## 1.1. WA health definitions

- **Clinical Incident**: 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[ii].

Clinical incidents include:

- **Near miss:** an incident that may have, but did not cause harm, either by chance or through timely intervention.
- **Sentinel events:** a subset of serious clinical incidents that has caused, or could have caused serious harm or death of a patient. It refers to preventable occurrences involving physical or psychological injury, or risk thereof. This includes the list of nationally endorsed sentinel event categories. **Please note** there is a list of nationally endorsed sentinel event categories however the WA health system and scope for sentinel events is broader then the national list.

**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.[iii]

| SAC 1 | a clinical incident that has, or could have (near miss), caused serious harm or death; and which is attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness. |
| --- | --- |
| SAC 2 | a clinical incident that has, or could have (near miss), caused moderate harm; 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 (near miss) caused minor or no harm; and which is attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness. |

**Datix CIMS System**
Health Service Providers must ensure they maintain systems and processes that provide a consistent approach to the management of clinical incidents, including utilising the approved incident management system. The WA health system's electronic approved clinical incident management system used for public clinical incidents is the Datix Clinical Incident Management System (CIMS).

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[ii] The term adverse event may be used in non WA health resources to refer to incidents that result, or could have resulted in harm to a patient. Within WA health the term clinical incident is used. The WA definitions are adapted from international and national resources. Each jurisdiction may have a slightly different scope and/or definitions.
[iii] For further SAC detail and requirements refer to the CIM Policy and Guideline

## 1.2.  Key steps: The Clinical Incident Management Process

Although a very big focus in CIM is investigation and analysis of a clinical incident, it is one of many components within the CIM process. Each health service organisation may have slightly different actions however the major key steps are outlined as below in Figure 1.

**Figure 1: Clinical Incident Management Process**

**A Safety Culture**
CIM Principles
Key concepts

**Identification**
Immediate Action
Notification
Confirmation

**Review**
Clinical risk management
Quality Improvement

**Closing the Loop**
Implementation
Monitoring & Evaluation
Sharing Lessons Learned

**Analysis**
Investigation
Recommendations

# A Safety Culture

## 2. A Safety Culture

### 2.1.   CIM Principles and Key Concepts

The Policy has been created on principles which relate to key concepts that underpin the area of patient safety. Organisations should embed, support and communicate these principles on an ongoing basis.

**Table 1: Clinical Incident Management Principles**

| Principle | |
|---|---|
| Transparency | Full and open communication is to occur as part of clinical incident management. As appropriate, patients, staff and visitors notifying clinical incidents will receive feedback on findings of any investigation and preventative actions carried out. |
| Accountability | Services have a duty to take reasonable care to avoid harm to patients, staff and visitors. Individuals understand they may be held accountable for their actions. |
| Probity/Fairness | Staff and patients involved in clinical incidents will be entitled to fair treatment.<br><br>Analysis of an incident should focus on 'what happened?', 'why did it happen?' and 'how could it be prevented from occurring again?' Implementation and evaluation of recommendations is essential. |
| Patient centred care | The patient, their family and carers who are associated with the incident are asked to contribute to the CIM process as appropriate, particularly during the investigation. Outcomes of an investigation are to be shared and communicated openly. |
| Open 'just' culture | The focus of an analysis and investigation of clinical incidents focuses on identifying and correcting underlying system problems rather than focusing on an individual. The workforce is supported when systems break down and errors occur. |
| Obligation to act | The responsibility to take action to correct problems is clearly accepted. |
| Prioritisation | Resources are directed to areas where improvements to prevent harm are possible. It must also be directed to the areas of high clinical risk. |

### 2.1.1.  A Safe and Just Culture

Safety culture is frequently defined[5] 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 organization's health and safety programs. Organizations with a positive safety

culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventative measures."

A safe culture has many aspects which include the CIM principles of transparency, fairness and accountability. The incident analysis process is the most effective when it is being conducted within a safety culture as clinicians understand that the organisation will focus on system learning, not individual blame. There are of course times when in rare cases an individual healthcare staff member has acted deliberately with gross negligence which needs to be addressed. The term 'just culture' describes a culture which successfully achieves that balance where wider systemic issues are learned from without fear of retribution and accountability[6].

### 2.1.2. Cultivating a Reporting Culture

Linked closely to safety culture is also implementing a sound reporting culture within the organisation and has some key aspects which organisations need to consider[7]:

**1. Establishing trust to improve reporting:** leaders help to create an environment where it is psychologically safe to report. Psychological safety is very important in terms of ensuring people feel safe to speak up[8]. Programs which acknowledge or give positive recognition for reporting (ie "Good Catch programs") reinforce the trust being built.

**2. Eliminate fear of negative consequences:** Tied with the above establishing trust also means establishing that reporting will not have negative consequences to the clinician reporting or the clinicians involved.

**3. Examine Near misses:** This assists in developing more mature processes to respond to poorly detected risks. It helps to provide information on potential system weaknesses in the environment.
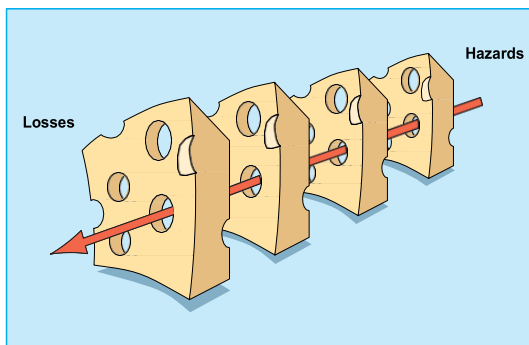
## 2.2.    Other Key Concepts

### 2.2.1. Swiss Cheese

The Swiss Cheese Model[9], developed by James Reason is one of the key foundational concepts which supports all aspects of clinical incident management:

- The defences, barriers and safeguards that exist are not impermeable and can occur when active failures (unsafe acts) and latent conditions (dormant system conditions) combine to create the 'perfect' opportunity for an incident. Latent conditions can be identified and corrected.

### Figure 1: Swiss Cheese Model



- The basic understanding is that one cannot "change the human condition, but we can change the conditions under which humans work."[9]

- The core queries to ask when a clinical incident happens are how and why the defences in the system failed; review the system as a whole, rather than just at the actions of individuals.

### 2.2.2. Systems Thinking, 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 examine how humans interact with the world around them and also how aspects can influence human performance- these aspects can include the task itself, the individual and the organisation they operate in.

Historically, when a clinical incident occurred, individual human error was identified as the main cause. The outcome of such an analysis may have then included the creation of new procedures, additional training, disciplinary action or increased personal vigilance – approaches which focus almost exclusively at identifying an individual's failure. This approach was likely unsuccessful in preventing the same or similar incident from occurring again due to human factors.

A different approach for analysing clinical incidents is now to adopt the view that human error is a symptom of broader issues within a poorly designed system. 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 which occurred at the time and deeper analysis will uncover more system based contributing factors.

# Identification

## 3. Identification

### 3.1.    Immediate Action & Notification

A clinical incident can be a very stressful experience for all stakeholders involved. Care and support for the patient, immediate family members as well as the clinician should be managed.

The incident will usually trigger internal protocols on how to manage a clinical incident and in most cases, notification into an incident reporting system. The WA health system utilises Datix CIMS[10] as the clinical incident management system which assists in the appropriate notification steps within each service provider.

### 3.2.    Confirmation

A determination of what may have contributed to the event occurs next and in this step, will determine what sort of analysis the organisation may embark on. Incident Decision Trees[11] are an example of a tool which can be used to assist relevant staff involved in managing clinical incidents when they first occur. It helps to determine a fair and consistent course of actions, ascertaining if a systems method of analysis is required or other, separate management actions such as. It is important to note that incident decision trees are not a replacement for a manager's 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.[12]

In the WA health system, the Severity Assessment Code once assigned helps to determine what level of analysis is required for the clinical incident. Key factors which are considered for the severity categories can be extent of injury, length of stay, level of care required for remedy. If the event is a near miss, the severity is based on a reasonable 'worst case' system level scenario.

# Analysis

## 4. Analysis

### 4.1.     Investigation

When reviewing a method to analyse clinical incidents, a number of criteria help to inform the type of analysis required. There are stricter mandatory requirements for SAC 1's however clinical incidents which do not result in death or serious harm need to take in other factors prior to determining the best type of analysis:

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

The below table is not an exhaustive list but can be used as a starting point in understanding what general categories of analysis. One method of incident analysis 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 with low harm | Used to analyse several incidents, grouped in themes<br><br>Can be used in any situation and level of harm |
| **Resources?** | Significant time and resources<br><br>Multiple sources information, 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 |

### 4.1.1. Investigation Methods

Once an initial investigation is completed, the next steps can be determined in terms of the type of investigation methodology is needed.

**Setting up analysis teams**

The service ensures that an appropriate incident investigation team is established. Typically, a local analysis team facilitator and an executive leader share a responsibility for conducting, coordinating and reporting on a clinical incident. Key skills which team members within the analysis team should have include:

- Knowledge of an effective systems based investigation with skills to lead and deliver
- Skills in report writing, documentation
- Facilitation skills to involve - Patient/family , clinicians involved in, external consultants , executive leaders as required
- Appropriate mechanisms for communication and sharing lessons

Note that there are several types of analysis teams which can occur:

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

**Methodologies**

This section introduces briefly several systems based methods which can be used to investigate clinical incidents. Many of these methods described share common features across data collection, analysis and recommendations development. Many organisations will use a mixture of methods depending on the clinical incident. Further reading, resources and links for these methodologies can be found in the resources appendix at the end of the CIM toolkit.

**Root Cause Analysis (RCA)**

A root cause analysis is a comprehensive type of analysis. It is based on the idea that a core issue ultimately leads to a problem and within the health system- a clinical incident. It is one of the most widely used analysis tools in healthcare to detect and analyse patient safety issues. Many organisations have adopted this approach to assist in analysing clinical incidents which result in serious harm or death.[13, 14]

It attempts to answer three questions about something that has gone wrong:

1. What happened?
2. Why did it happen?
3. How can we prevent it happening again?

Effective RCA investigations feature the following characteristics[15]:
- Identifying underlying problems and not individual mistakes – the focus is on **how and why,** not on the who.
- Ensures it uses approaches which peel away at the surface layers of the event and reviews the fundamental causes (ie.,' the root')
- Reconstruct an event through a variety of approaches including records review and interviews
- The team is interdisciplinary in nature with involvement from a variety of stakeholders
- Identify changes to be made in the system to reduce recurrence of events

**Common approaches used in RCA investigations**

These approaches assist in brainstorming and clustering factors within a clinical incident and also identifying the reason for the system failure in healthcare provision.

- **Cause and Effect Diagrams**

The Cause and Effect Diagram, also called the "fishbone' or Ishekawa diagram[16] can be used as a way to generate possible causes of a clinical incident. The general process is to identify a problem, then contributing factors which may have caused the problem. Other variations of this include a tree diagram or constellation diagram.[5]

- **Five Whys**

The Five Whys[17] originated within Toyota and formed a critical component of their problem solving methodology. Repeatedly asking the question "why?" allows for the layers of an issue to be examined leading to the root cause of a problem. The Five Whys can be used independently or as part of a Root Cause Analysis when developing a cause and effect diagram. The Five Whys assists investigation teams to drill down and explore all potential or real causes which contributed to a clinical incident, in turn identifying the root causes.

- **Five Rules of Causation[14,15,18]**

After understanding what has happened and why, causal statements can be written to describe how the root causes or contributing factors led to the clinical incident. The Five Rules of Causation was developed by the Department of Veterans Affairs, Veterans Health Administration. These statements which are accurate, precise and unemotional lead to a more objective understanding of the events. Causal statements are written to describe (1) Cause, (2) Effect, and (3) Event. Something (Cause) leads to something (Effect) which increases the likelihood that the incident will occur.

As an example: A high volume of activity and noise in the emergency department led to (cause) the resident being distracted when entering medication orders (effect) which increased the likelihood that the wrong dose would be ordered (event).

## Table 3: The Five Rules of Causation

| THE FIVE RULES OF CAUSATION | |
|---|---|
| **Rule 1: Clearly show the "cause and effect" relationship.** | |
| Incorrect | A resident was fatigued. |
| Correct | Residents are scheduled 80 hours per week, which led to increased levels of fatigue, increasing the likelihood that dosing instructions would be misread. |
| **Rule 2: Use specific and accurate descriptors for what occurred, rather than negative and vague words e.g. Poor; Inadequate; Wrong; Bad; Failed; Careless.** | |
| Incorrect | The manual is poorly written. |
| Correct | The pumps user manual had 8 point font and no illustrations; as a result nursing staff rarely used it, increasing the likelihood that the pump would be programmed incorrectly. |
| **Rule 3: Human error must have a preceding cause.** | |
| Incorrect | The resident selected the wrong dose, which led to the patient being overdosed. |
| Correct | Drugs in the Computerized Physician Order Entry (CPOE) system are presented to the user without sufficient space between the different doses on the screen, increasing the likelihood that the wrong dose could be selected, which led to the patient being overdosed. |
| **Rule 4: Violations of procedure are not root causes, but must have a preceding cause.** | |
| Incorrect | The techs did not follow the procedure for CT scans, which led to the patient receiving an air bolus from an empty syringe, resulting in a fatal air embolism. |
| Correct | Noise and confusion in the prep area, coupled with production pressures, increased the likelihood that steps in the CT scan protocol would be missed, resulting in the injection of an air embolism from using an empty syringe. |
| **Rule 5: Failure to act is only causal when there is a pre-existing duty to act.** | |
| Incorrect | The nurse did not check for STAT orders every half hour, which led to a delay in the start of anticoagulation therapy, increasing the likelihood of a blood clot. |
| Correct | The absence of an assignment for designated RNs to check orders at specified times increased the likelihood that STAT orders would be missed or delayed, which led to a delay in therapy. |

## London Protocol

The London Protocol[19] was refined in 2004 and is also a systems based methodology to investigate clinical incidents. The protocol has a framework which identifies 'care delivery problems' and the contributory factors which influence practice and outcomes. Comprehensive interviews are also a key process in identifying what has occurred in the clinical incident. The key questions of "What happened?" (the outcome and chronology); "How did it happen?" (the care delivery problems) and "Why did it happen?" (the contributory factors) frame this methodology.

## Healthcare Failure Mode and Effect Analysis (HFMEA)

The traditional Failure Modes and Effects Analysis (FMEA) Method is an analysis technique which can be used during clinical incident investigations to identify all possible failures within a process. It combines steps to understand and assess the root cause of an issue as well as a risk assessment (a 'risk priority number'- RPN) in order to prioritise actions.

FMEA has also been adapted for health care by the National Center for Patient Safety (NCPS), named the Healthcare Failure Modes and Effects Analysis (HFMEA)[20]. It can be used as both a retrospective or prospective analysis technique when reviewing clinical incidents. It adapts the FMEA to health care settings and uses a decision tree and replaces the RPN with a Hazard Matrix Table.

## Health Record Review

Health record reviews[21] which are tailored specifically to identify contributing factors and other criteria help to improve the quality and safety in health care delivery. A health record review (sometimes labelled as a medical record, case record review), is a retrospective approach which can be used to investigate multiple or singular clinical incidents. It can be a comprehensive or

concise, short analysis. It typically follows a systematic set of review criteria - firstly a set of predefined criteria (eg. reviewing hospital acquired infections) which is flagged for further critical review to identify the causes and issues detailed within the incident.

**Concise Incident Analysis**

A comprehensive analysis utilising traditional RCA methods for events which result in death or serious harm can take up major resources and timing. Adopting concise incident analysis[5] methods may be more appropriate for incidents with minimal complexity, being managed at a local level. These methods should still be consistent with CIM principles which include a systems approach and consideration of human factors. Concise incident analysis encompasses a range of approaches including conducting 'mini' RCA's, unit-based safety programs, or morbidity and mortality rounds. The Concise Incident Analysis[22] (CIA) methodology and tool is developed by the World Health Organization (WHO) Patient Safety Programme which bases much of the tool it on the methods within the Canadian Incident Analysis Framework.

**Aggregated/Multi- Incident Analysis (Aggregated)**

In addition to an individual incident analyses, organisations should have methodologies for analysing multiple incidents. Other terms within the literature also include cluster, aggregate meta-analyses. Typical features include a pre-defined scope, involve an inter-disciplinary team and uses a mixture of methods to analyse incidents. Multi incident analyses can have any type of theme, such as focusing on a particular unit, degree of harm or a type of clinical incident. The VA National Center for Patient Safety uses the Aggregate RCA[23] tool to identify trends and systems issues across groupings of similar events. Some organisations use the term 'Lookback Review' to define the process of reviewing retrospectively a series of events which have been flagged as potential clinical incidents.

### 4.1.2. Contributing Factors

The goal of an analysis is to uncover and articulate contributing factors which are related to the incident and thus provide the 'backbone' for the development of recommended actions.[5] Clinical incidents will generally have more than one contributory factor.

Contributory factors/hazards 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 control of the organisation, such as the natural environment or legislative policy".[3]

These factors during analysis are then articulated via statements of findings or causal statements- each methodology can have differing terms.

It is important to acknowledge that human factors play a part in a clinical incident, and can be a contributing factor, but this is to inform and approach analysis, recommendations and interventions with a systems solution.[36]

The Conceptual Framework for the International Classification for Patient Safety (ICPS) has 6 categories – staff, patient, work/environment, organisational/service, external and other[3], of which many other analysis methods have adapted (the London Protocol will have an adapted predefined list).

The WA health system reports 7 standard categories within the electronic reporting system, Datix CIMS and 1 "other" category.

1. Communication

2. Knowledge Skills Competence
3. Work Environment/Scheduling
4. Patient Factors
5. Equipment, Information Systems/Applications
6. Policies, Procedures, Guidelines
7. Safety Mechanisms
8. Other Factors

## 4.2. Recommendations

The development of recommendations is a fundamental component in clinical incident management and aims to address the root causes identified during investigation. Recommendations provide the framework for action in improving or preventing clinical incidents from occurring. The success of the recommendations is dependent on the quality of findings identified in the previous analysis step.

### 4.2.1. Developing Recommendations

Some key features which have been identified as effective when developing recommendations include:

**Table 4: Key features of Recommendations**

Key Features

| | Key Feature | 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) |
| 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 organization. |
| 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. | **SMART** | Utilise well known goal setting methods such as the SMART format |

**SMARTA SYSTEM:**

The WA health system uses the SMARTA system of goal setting when creating recommendations. This uses the recognised SMART system of goal setting but also incorporates the 'Action strength' of a recommendation (SMART**A**) to highlight the principle that focussing on a few high strength recommendations is ultimately more effective than multiple low impact actions[5]. SMARTA recommendations features include:

**SMARTA SYSTEM (Continued)**

| S | clearly defined issue and have a clear scope |
|---|---|
| M | can demonstrate impact on process and outcomes |
| A | state who will be responsible for implementing and evaluating this recommendation |
| R | reality check ensure that the outcome goal will be accepted, implemented |
| T | state a deadline in which the goal will be achieved |
| A | created with the highest strength reasonable |

**ACTION STRENGTH:**

The Recommendations/Action hierarchy was developed by the Veterans Affairs National Center for Patient Safety[24] and is also used within the WA health System for clinical incident recommendation development. Based on the principles of human factors, the most effective actions accommodate or control for the limitations of human behaviours and how they interact with the systems around them. Stronger recommendations focus on the physical rather than procedural and permanent solutions rather than temporary. For example, using fittings that can only be connected the correct way in a machine (engineering control) is a stronger recommendation than implementing reminders to staff to use the right fitting (training). Note that within the hierarchy tangible involvement by leadership refers to actions where senior leadership has extended past their usual responsibilities[25] within their patient safety role and been involved specifically involved with an intervention.

## Table 5: 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 handoffs 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. |
| | 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 handoff 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. |

# Closing the Loop

## 5. Closing the Loop

Closing the Loop is a term used which focuses on enhancing the components of CIM during the development, implementation and evaluation of recommendations, with an objective to share the lessons learned. Sharing to the organisation within as well as outside is a key final element in the process to ensure that the incidents do not reoccur and ultimately promote a safer environment.

### 5.1. Implementation

As capacity and resources in front line staff to take on new improvement activities can sometimes be limited, successful implementation of recommendations can be a challenging process. Within the WA health system implementation and monitoring are required within a set timeframe of 6 months (182 calendar days). This is at the discretion of the Health Service Provider to view the SMARTA recommendations arising from the clinical incident and to judge when it is appropriate for implementation and evaluation to occur during that time period.

Use of change management principles and tools will support the success of implementing recommendations. Many of the adapted frameworks for health care are based on Dr John Kotter's[26] work on strategies for organisational change. The National Health Service (NHS) has a Change Model[27] developed to assist in leading large scale change and a hub to promote other tools which may be more appropriate for facilitating smaller, local changes[28]. The Canadian Patient Safety Institute (CPSI) has a *Safer Healthcare Now![29]* Program which assists frontline staff in implementing, measuring and evaluating major patient safety initiatives such as falls, rapid response teams.

The Australian Commission on Safety and Quality in Health Care (ACSQHS)[30] has also released the second edition of the National Safety and Quality Health Service (NSQHS) Standards with resources to assist services in implementing strategies for improvement which cover areas which are well known to cause clinical incidents. These resources  which may not specifically be created for the specific clinical incident which has occurred can be a starting framework to help align with best practices around known identified root causes and issues surrounding clinical areas.

### 5.2. Monitoring, Evaluation

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

Evaluation complements monitoring as the next step in CIM. It focuses on the final assessment if the implemented action has made a difference. In CIM, this generally relates to whether or not this has the intended outcome of increasing patient safety long term if the SMARTA principles of creating recommendations have been followed. 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 initiatives and its effectiveness.

**Establishing Measures**

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.[31]

**Table 6: Establishing Measures**

| Measures | |
|---|---|
| **Outcome Measures** | • Best level of measurement as it demonstrates change that is attributable to an intervention or series of interventions<br>　○ **Clinical incident outcome measure –** measures the improvement the action has on eliminating the clinical incident<br>　○ Example: *the number of incidents of patient violence on the behavioral 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.*<br>　○ **Root cause outcome measure-** Measures the impact the action will have on the root cause.<br>　○ Example: *Hourly rounds will show that 90 percent of patients, at high risk for falls will not ambulate independently for the next six months.* |
| **Process Measures** | • Complements outcome measures as a way to monitor implementation. It does not measure the effectiveness of an action, only the completion.<br><br>　○ Example: *95 percent of staff on the unit will have completed the training by June 2013. (This outcome measure just tells us that staff completed the training; we don't know if the training made care safer or not.)* |
| **Balance Measures** | • Looking that the system from other directions/dimensions to ensure that improving one part of the health system has not caused issues in others. There will be always be intended (or unintended) effects, but a risk assessment should be done to weigh up the benefits and consequences of the outcomes.<br>　○ Example: When reducing a patients' length of stay in the hospital: Make sure readmission rates for the same issue are not increasing |

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 source 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 a co-ordinated 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 patient's views, beliefs, experiences, attitudes or motivations on a particular issue (e.g. issues with living with kidney disease

**Models for Improvement: Plan Do Study Act (PDSA) Cycle**

Adopting known frameworks to create, implement and evaluate recommendations provides good guidance for health services to enable change in a system. The PDSA[32] is one well known model for improvement but there others which can be utilised[28] depending on the aims. It provides a framework for new change ideas to be tested on a small scale, establish if it will work prior to a large scale implementation.

## 5.3. Sharing Lessons Learned

Sharing what has been learned from the clinical incident is the final step. Learnings should be shared within the organisation as well as externally. Results should be communicated and shared at different levels of the system, implementing appropriate feedback and feedforward mechanisms.

**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. In particular, when an analysis has been completed, feedback to the notifier and other local hospital or health services is very important at this point in time in order to prompt improvements in safety.

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 a number of 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.

The five models of feedback outlined are based upon descriptions of effective feedback processes studied by Benn et al.[33]

**Table 7: Five modes of feedback for incident reporting systems**

| Mode | Type | Content and examples |
|------|------|----------------------|
| A. Bounce back | Information to reporter (ie. notifier) | • Acknowledge report filed (e.g. automated response).<br>• Communicate to patient and families<br>• Debrief reporter/notifier.<br>• Provide advice from safety experts.<br>• 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.<br>• Temporary fixes/workarounds until in-depth investigation process can be completed (withdraw equipment, monitor procedure, alert staff).<br>• 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).<br>• 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.<br>• Widely publicise corrective actions taken to resolve safety issue to encourage reporting.<br>• 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 plans for permanent improvements to work systems to address contributory factors evident within reported incidents.<br>• Changes to tools/equipment/working environment, standard working procedures, training programs, etc.<br>• Evaluate/monitor effectiveness of solutions and repeat. |

**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 regards to clinical incidents.

# Review

## 6. Review

### 6.1. Clinical Risk Management, Quality Improvement

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

It does this through:
1. identifying what can and does go wrong during care
2. understanding the factors that influence this
3. learning lessons from adverse events and poor outcomes
4. ensuring action is taken to prevent recurrence
5. putting systems in place to reduce risks

Each of the five steps above have been detailed within the WA health Clinical Risk Management Guidelines[34] which was developed in reference to the Australian/New Zealand Standard *AS/NZS ISO 31000:2009 Risk Management – Principles and guidelines* and the *Clinical Risk Management Guidelines[35].* WA health currently utilises an approved enterprise risk management system (ERMS) to identify, record, review and report against the potential risks.

Risk management is important as a process in conjunction with CIM as it proactively seeks to reduce identified clinical risks to an acceptable level. If harm has occurred, risk management processes review what can be implemented to reduce it from re-occurring and then ascertain if the residual clinical risk is acceptable. If it is not, this is the part of the cycle which aims to look at other quality improvement strategies which can be implemented to improve the quality of clinical care as part of a continuous improvement cycle.

Organisations are encouraged to periodically dedicate time to review and reflect on how the CIM Process functioned. This prompts teams to review and whether or not CIM principles and concepts had been adhered and what sort of leadership underpins the system to enable a safety culture as a whole. Other factors to review the quality of the CIM process within an organisation can also include

1. Timeliness of the analysis, evaluation, implementation phases
2. Quality of recommended actions
3. Effectiveness of the actions in reducing harm
4. Lessons learned are accessed and used

# Appendix 1: WA health Resources – Forms, Templates, further guidance

These forms and templates are up to date at the time of publishing. Please check the Department of Health webpage for any changes or revisions.

| SAC 1 Templates | |
|---|---|
| Severity Assessment Codes | https://ww2.health.wa.gov.au/Articles/S_T/Severity-assessment-codes |
| SAC 1 Clinical incident notification form | https://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/Quality/PDF/SAC-1-Notification-form.pdf |
| SAC 1 Clinical Incident Investigation Report | https://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/patient%20safety/PDF/SAC-1-Clinical-incident-investigation-report.pdf |
| SAC 1 Clinical Incident Evaluation of recommendations | https://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/patient%20safety/PDF/SAC-1-Clinical-incident-evaluation-of-recommendations-template.pdf |

| Closing the Loop | |
|---|---|
| Closing the Loop SMARTA score spreadsheet | https://ww2.health.wa.gov.au/Articles/A_E/Closing-the-Loop-Program |

| Multi Site Investigations | |
|---|---|
| Guidelines for the investigation of multi-site clinical incidents | https://www.health.wa.gov.au/~/media/Files/Corporate/general-documents/patient-safety/PDF/Guideline-for-the-investigation-of-multi-site-clinical-incidents.pdf |

| Clinical Risk | |
|---|---|
| Clinical Risk Management | https://ww2.health.wa.gov.au/Articles/A_E/Clinical-risk-management |
| WA health Integrated Corporate and Clinical Risk Analysis Tables in risk compliance audit tables | https://ww2.health.wa.gov.au/About-us/Policy-frameworks/Risk-Compliance-and-Audit |
| Enterprise Risk Management Systems (ERMS) | https://doh-healthpoint.hdwa.health.wa.gov.au/workingatdoh/Managing-Risks/Pages/default.aspx |

# Appendix 2: Further Resources and Templates

Please note this list is not exhaustive and should be used as a starting point. It is only current at the time of publication.

## A Safety Culture

- Leadership & Organisational Culture of Safety – Respectful Management of Serious Clinical Adverse Events (2nd Edition)
http://www.ihi.org/resources/Pages/IHIWhitePapers/RespectfulManagementSeriousClinicalAEsWhitePaper.aspx
- Developing a reporting culture – learning from close calls and hazardous conditions
https://www.jointcommission.org/sentinel_event_alert_60_developing_a_reporting_culture_learning_from_close_calls_and_hazardous_conditions/

## Principles and Concepts in Patient Safety

- Safer Healthcare: Strategies for the real world: https://link.springer.com/book/10.1007/978-3-319-25559-0
- Institute for Health care improvement – IHI Open School Online Courses. Courses and Certificates in Safety and quality: http://app.ihi.org/lmsspa/#/certificates/6cb1c614-884b-43ef-9abd-d90849f183d4

## Identification

Incident decision trees: https://www.ahrq.gov/downloads/pub/advances/vol4/meadows.pdf

## Analysis

- AHRQ System Focused Event Investigation and Analysis Guide
https://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/module4-guide.html
- Clinical Excellence Commission, New South Wales Government
https://www.cec.health.nsw.gov.au/Review-incidents/incident-management-policy-resources
- Safety and Quality, South Australian Health
https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/safety+and+quality/governance+for+safety+and+quality/root+cause+analysis+rca
- Institute for Healthcare improvement: RCA[2:] http://www.ihi.org/resources/Pages/Tools/RCA2-Improving-Root-Cause-Analyses-and-Actions-to-Prevent-Harm.aspx
- Failure Mode Effects Analysis (FMEA) – IHI resource – (log in for access)
http://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx
- Flow Chart Story : http://www.ihi.org/resources/Pages/Tools/Flowchart.aspx
- Five Whys: https://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/module4-guide-apa.html
- Understanding Contributing Factors (CF) : Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review
https://qualitysafety.bmj.com/content/21/5/369

**Closing the Loop**

- Implementation and Evaluation KINGS improvement science. The KIS guide to evaluation resources is helpful to review different methods and toolkits a service can use to evaluate. https://kingsimprovementscience.org/cms-data/resources/KIS_evaluation_guide_December_2018.pdf
- Program Evaluation The WA Department of Treasury has a resource assist in undertaking evaluation of programs of work. https://www.wa.gov.au/government/document-collections/program-evaluation

**Toolkits**

- NHS tools for improvement by project, task, approach, patient pathway https://improvement.nhs.uk/resources/quality-service-improvement-and-redesign-qsir-tools/
- Institute for of Healthcare Improvement – Quality improvement , Patient safety essentials Toolkits http://www.ihi.org/resources/Pages/Tools/default.aspx
- Standardised methodology by NHS to review case records https://www.england.nhs.uk/patient-safety/learning-from-deaths-in-the-nhs/

**Clinical Risk Management**
- The Australian Commission on Safety and Quality in Healthcare - https://www.safetyandquality.gov.au/standards/nsqhs-standards/clinical-governance-standard/patient-safety-and-quality-systems/action-110
- Clinical Risk Management - Enhancing Patient Safety- http://www.ihi.org/resources/Pages/Publications/ClinicalRiskManagementEnhancingPatientSafety.aspx

**Other International Agencies or Institutes for Patient Safety**

- US Department Veterans Affairs - VA National Center for Patient Safety https://www.patientsafety.va.gov/
- Canada - Patient Safety Education Program (PSEP) https://www.patientsafetyinstitute.ca/en/education/PatientSafetyEducationProgram/Pages/default.aspx
- USA – Agency for Healthcare Research and Quality  https://www.ahrq.gov/

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    *The Incident Analysis Collaborating Parties are Canadian Patient Safety Institute (CPSI), Institute for Safe Medication Practices Canada, Saskatchewan Health, Patients for Patient Safety Canada (a patient-led program of CPSI), Paula Beard, Carolyn E. Hoffman and Micheline Ste-Marie.*

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