



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

# Clinical Incident Management Guideline 2019

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## 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.

### For further details please contact:

Patient Safety Surveillance Unit  
Patient Safety and Clinical Quality  
Clinical Excellence Division  
Department of Health Western Australian  
189 Royal Street, EAST PERTH Western Australia 6004

**Email:** [PSSU@health.wa.gov.au](mailto:PSSU@health.wa.gov.au)

**Website:** [https://ww2.health.wa.gov.au/Articles/A\\_E/Datix-Clinical-Incident-Management-System-CIMS](https://ww2.health.wa.gov.au/Articles/A_E/Datix-Clinical-Incident-Management-System-CIMS)

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## Introduction

One of the critical factors in delivering a high standard of health care is a commitment in ongoing learning and quality improvement. Having systems which underpin the identification, review and analysis of clinical incidents to implement and evaluate system improvements, supports the provision of safer care to patients.

Clinical incidents refer to events resulting from health care provision which could have or did lead to unintended harm to a patient. Learning from clinical incidents is important to preventing future patient harm. Clinical incidents are complex and can have multiple contributing factors. The majority of errors are not due to individual failures but a result of human factors and flawed systems which create environments of risk where failures can occur. The aim then is not to focus just on the human or the system alone, but rather 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 hold no blame acknowledges this system thinking.

As part of continual efforts to support best practice in clinical incident management, the purpose of the Clinical Incident Management (CIM) Guideline (Guideline) is to provide more detailed information adapted from international and national resources for the WA health system on the CIM process to assist implementation of the Clinical Incident Management Policy (Policy).<sup>1</sup> The CIM Toolkit<sup>2</sup> is an additional resource which aims to provide examples of templates and resources which can be used within services.

The Australian Commission on Safety and Quality in Health Care have also released the second edition of the National Safety and Quality Health Service (NSQHS) Standards which assist Australian health services to improve the safety and quality of health care in their services. Likewise, the international ISO Australian Standards for Quality management systems (AS/NZS ISO 9000, ISO 9001) are accepted standards which health care systems may also be accredited to for clinical safety and quality. Following the CIM Policy, Guideline and Toolkit will support services to design patient safety processes which align with these best practices and principles, both nationally and internationally.

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

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

Document	Example
<b>1. The Policy</b> sets out requirements which are binding under the Health Services Act 2016 <sup>i</sup> . The language used within the Policy include terms such as 'must', 'shall', 'require' 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").
<b>2. The Guideline</b> is a non-mandatory Supporting Information document which provides supplementary information to assist services in meeting the Policy requirements.	The Policy states CIM must be managed in accordance with CIM Principles. There is further description of what these principles entail within the Guideline.
<b>3. The Toolkit</b> 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', 'shall', 'require' are the same requirements within the Policy. [Appendix 4](#) assists in mapping relevant sections together for the reader.

For private or contracted entities, please refer to [Section 8](#) of the CIM Guideline for further interpretation.

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<sup>i</sup> Health Services Act 2016 s26(2) (a) (c) (d)

## 1. Principles

The purpose of the Clinical Incident Management (CIM) Policy (Policy) is to ensure Health Service Providers implement consistent and accountable processes and systems for the management of clinical incidents with the goal to prevent harm to patients and improve patient safety.

The Policy promotes best practices in CIM to:

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

It is based on the following principles:

Principle	
<b>Transparency</b>	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.
<b>Accountability</b>	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.
<b>Probity/Fairness</b>	Staff and patients involved in clinical incidents will be entitled to fair treatment. 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.
<b>Patient centred care</b>	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.
<b>Open 'just' culture</b>	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.
<b>Obligation to act</b>	The responsibility to take action to correct problems is clearly accepted.
<b>Prioritisation</b>	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. Applicability

This Policy is applicable to all Health Service Providers and Contracted Health Entities to the extent that this Policy forms part of their contract. This Guideline provides further information in regard to clinical incident management processes to support implementation of the CIM Policy requirements.

### 2.1. Clinical Incident Management Systems (CIMS)

An approved CIMS helps health services to support their workforce in recognising, investigating and analysing clinical incidents to improve safety and quality within the service. 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 clinical 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 \(CIMS\)](#)<sup>ii</sup>.

When there has been a disruption to the Datix system which results in the inability to access to the system, Health Service Providers should implement local procedures in order to meet any policy requirement timeframes. This includes actions such as (but not limited to) local procedures to make clinicians awareness on how to access hard copy forms for clinical incident notification and contacting PSSU to submit forms/reports via other accepted methods.

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

- [Clinical Incident Management Policy and Toolkit](#)<sup>1,2</sup>
- [Clinical Risk Management Guideline](#)<sup>3</sup>
- [Closing the Loop Program Resources](#)<sup>4</sup>
- [Complaints Management Policy, Guideline and Toolkit](#)<sup>5</sup>
- [Datix CIMS Information Access and Disclosure Model](#)<sup>6</sup>
- [Datix CIMS User Guides and business rules](#)<sup>7</sup>
- [Guidelines for the investigation of Multi-Site clinical incidents](#)<sup>8</sup>
- [Policy for Mandatory Reporting of Notifiable Incidents to the Chief Psychiatrist](#)<sup>9</sup>
- [Qualified Privilege information](#)<sup>40</sup>
- [SAC 1 incident notification, investigation and evaluation forms and templates](#)<sup>10</sup>
- [The Australian Open Disclosure Framework](#)<sup>13</sup>
- [Western Australian Review of Death Policy and Guideline](#)<sup>11,12</sup>

## 3. Roles and Responsibilities

To be effective, clinical incident management needs a whole of organisation approach that fosters a no blame culture and incorporates the following responsibilities at each organisational level.

### 3.1. Responsibilities of individuals

Clinical staff are to:

- Notify clinical incidents into Datix CIMS. Notification can be done anonymously.
- Adhere to CIM Policy principles

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<sup>ii</sup> Refer to section 8 for more information on approved CIMS and private and NGO processes.



## 3.2. Responsibilities of Health Service Providers

Health Service Providers are to ensure that:

### Clinical Incident Management Processes

- Compliance to the CIM Policy requirements are met.
- All clinical incidents are recorded in Datix CIMS (public services).
- All SAC 1 clinical incidents are submitted to the PSSU via email using the prescribed templates or equivalent (private services), which will then be recorded in Datix CIMS.

### Supporting staff

- 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 evaluation. 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 and Chair 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 are available.
- Support to staff following a clinical incident by encouraging participation in debriefing sessions and/or use of counselling services (both internal and external).
- 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 are investigation and implementation of remedial actions as necessary.

### Supporting the Patient

- There is awareness and involvement in the CIM Process as appropriate (patient, family, carer).
- Facilitation of an appropriate level of open disclosure<sup>iii</sup> to the patient, their family and carers as soon as practicable when clinical incidents occur.
- Adequate feedback mechanisms are in place to inform the patient and their family of any outcomes.

### Other

- Undertake analysis of local clinical incident data to monitor quality improvement strategies and advise the PSSU if adverse trends are detected within the health service.
- Ensure 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<sup>iv</sup>
- Awareness of other statutory requirements relevant to clinical incident management<sup>v</sup>
- For clinical incidents that result in legal proceedings, or have the potential to, contact with the medico-legal staff and the appropriate relevant staff involved in the management of clinical incidents in the service may be required. Hospitals and health services are also required to notify/report incidents in accordance with other statutory, medico-legal and insurance requirements.

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<sup>iii</sup> Processes are to be in accordance with the Australian Open Disclosure Framework.

<sup>iv</sup> Refer to section 6.1 and Appendix 3 for more information about health service boundaries

<sup>v</sup> Refer to section 7.1 for more information about other and statutory requirements

### 3.3. Responsibilities of Private Facilities and Non-Government Organisations

Where a private health care facility or contracted agency has a licence requirement or contract requirement to comply with this Policy; clinical incidents must be notified and investigated. Facilities are to refer to their license or contractual agreement to confirm clinical incident management requirements to the Department of Health<sup>vi</sup>.

### 3.4. Responsibilities of the Patient Safety Surveillance Unit

The PSSU responsibilities include:

- Development of the 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.
- Clinical incident management annual reports are produced.
- Business engagement of the Datix CIMS database.

## 4. Definitions: Clinical Incidents, Sentinel Events and Severity Assessment Codes

Health Service Providers are to notify, investigate and implement recommendations for clinical incidents.

### 4.1. Definitions

- **Clinical Incident**<sup>14</sup>. 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<sup>vii</sup>.

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<sup>15</sup>. **Please note** there is a list of nationally endorsed sentinel event categories which can be reviewed in the CIM Guideline. The WA CIM Policy for reporting SAC 1 events is broader than the national list - near misses are also to be reported in the WA health system.

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<sup>vi</sup> Refer to section 8 on for Private Facilities, Non-Government Licensing and Contractual Processes

<sup>vii</sup> 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.

## Severity Assessment Codes

The SAC rating is the way clinical incidents are rated in WA's health system. Clinical Incidents are categorised using the following SAC ratings to determine the appropriate level of analysis, action and escalation.

<b>SAC 1</b>	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.
<b>SAC 2</b>	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.
<b>SAC 3</b>	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.

### 4.2. Determination of Severity Assessment Codes

#### 4.2.1. SAC 1, 2, 3 Clinical Incidents

When an event is a SAC 1, 2 or 3, the organisation is confirming that health care provision (or lack thereof) was a factor in the patient outcome. Health care provision encompasses the systems in place including but not limited to decisions, actions, policies and processes completed by health care professionals for the care of a patient. Clinical incidents also includes near misses where the incident did not reach the patient however if it did, would have caused harm. However, when an event results in death and during review there is any possibility that it was preventable, it must be notified as a SAC 1 and investigated as such.

The Review of Death (RoD) Policy is complementary in relation to clinical incident management processes as it assists in identifying preventable deaths. The [RoD flowchart](#) assists in determining the actions to undertake when a death occurs. It is a requirement within the ROD Policy to categorise all deaths (unless the death is already notified as a SAC 1 incident) within a hospital in terms of preventability using the Health Roundtable (HRT) <sup>viii</sup> tool and criteria. For CIM, any notified clinical incidents which result in death or serious harm Health Service Providers should endeavour as best practice to use the HRT criteria and tool.

#### 4.2.2. For Mental Health Patients

With regard to clinical incidents involving mental health patients, the focus should be on how health care delivery or the lack of health care delivery contributed to the clinical incident occurring. In addition to the factors discussed in section 4.2.1, 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 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.

As examples;

- If a mental health patient who is deemed at high risk of suicide goes missing from hospital, this should be notified as a SAC 1 clinical incident.
- If a mental health patient became increasingly agitated during the course of a shift, which resulted in the patient physically, verbally or sexually assaulting a staff member, it would be important to investigate this clinical incident to see if all appropriate health care

<sup>viii</sup> Refer to the [Review of Death Policy](#) for further detail on scales for categorisation.

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 Datix 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 health 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<sup>ix</sup>.

### 4.3. Incidents out of scope

#### Misconduct

If it is suspected that the clinical incident may contain elements of misconduct, the investigation team should refer the matter to the relevant stakeholders so it can be addressed using the appropriate management and governance processes<sup>48</sup>. The clinical incident investigation should continue separately to the misconduct processes unless advised to cease the investigation. For further information refer to the following:

- [Notifiable and Reportable Conduct Policy 0125/19<sup>17</sup>](#)
- [Discipline Policy 0127/20<sup>18</sup>](#)

#### Other

Incidents that should NOT be managed through the CIM process include but not limited to:

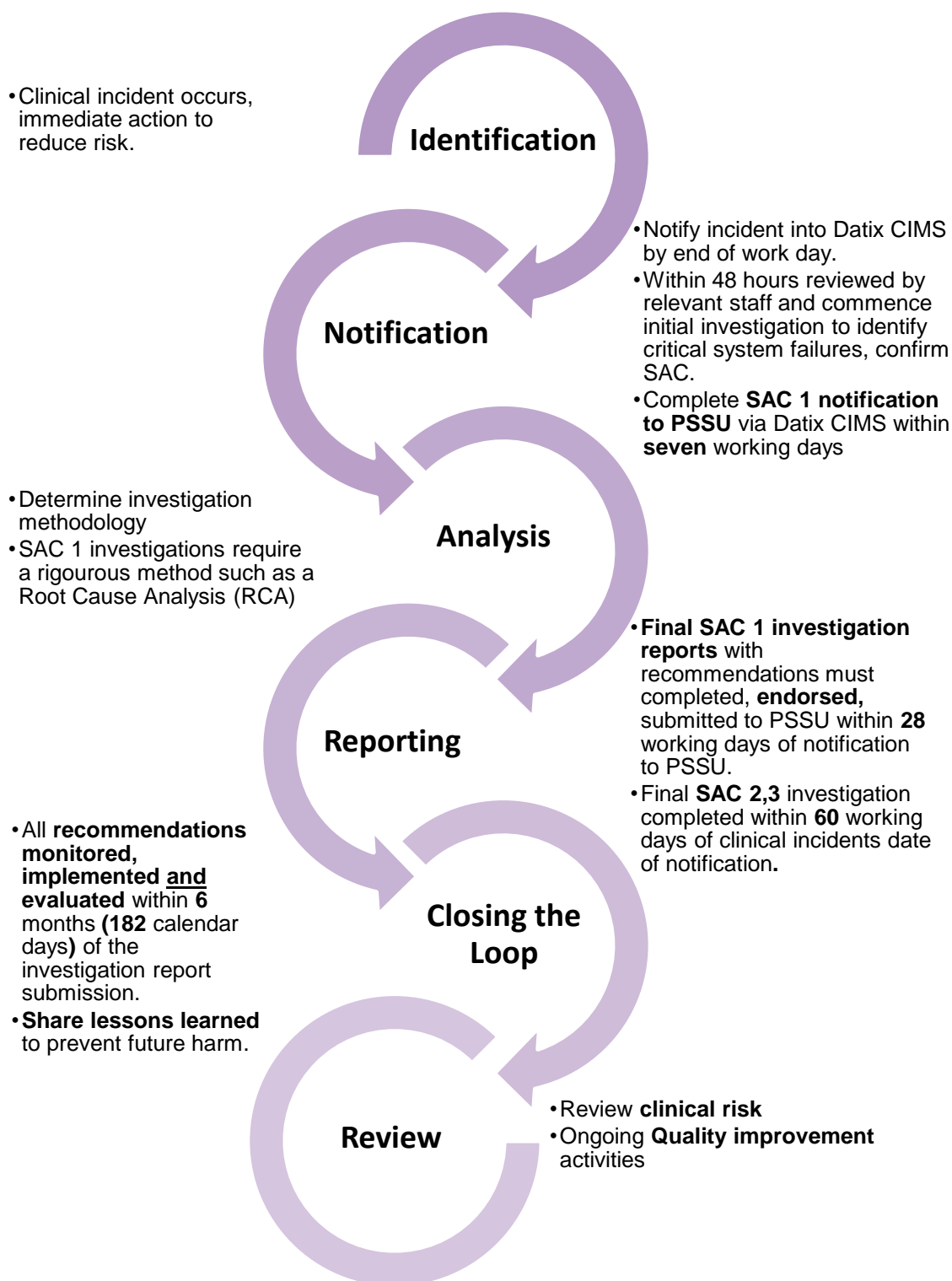
Other incidents	Example
Occupational Safety and Health incidents that involve staff only.	Staff tripped on carpet, hurting their back whilst transferring patients.
Incidents involving visitors unrelated to the provision of a health care service to a patient.	Visitor spilling hot drink on themselves.
Allegations or suspicions of: <ul style="list-style-type: none"> <li>• workplace aggression between staff e.g. rudeness, bullying</li> <li>• physical or verbal aggression from non-mental health patients or visitors toward staff where the patient is not harmed</li> <li>• suspected or alleged alcohol/substance use by a staff member/health care provider.</li> </ul>	For further information on Workplace Bullying refer to the current Policy <sup>19</sup> in the <a href="#">Employment Policy framework</a> .

<sup>ix</sup> For further detail refer to the OCP website <https://www.chiefpsychiatrist.wa.gov.au/monitoring-reporting/notifiable-incidents/>.

## 5. The Clinical Incident Management Process

A key function of clinical incident management is to optimise patients' safety when receiving health care. An important aspect of quality improvement is a systematic CIM process as it provides staff with standardised, necessary information and resources required to address, improve and evaluate their services. The key steps to effective clinical incident management in the WA health system are shown in Figure 1 below and are underpinned by CIM Principles.

**Figure 1: Clinical Incident Management Process**



## 5.1. Identification of a Clinical Incident and Immediate Action

A clinical incident may be identified:

- at the time (or later) of the incident by a patient, carer, visitor, clinician, staff member or student.
- through established consumer feedback or complaints mechanisms<sup>5</sup>.
- through other systems, such as audit, reviews of clinical outcomes, medical records or mortality reviews<sup>11</sup>.

When a clinical incident is identified, **immediate action** must be taken to reduce the risk to the patient. These actions include:

- ensuring 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.
- making the surroundings safe to prevent immediate recurrence of the incident
- removing malfunctioning equipment or supplies
- gathering essential information about a chain of events
- notifying a medical officer if a person suffers any harm or injury

## 5.2. Notification of Clinical Incidents

### 5.2.1. Who Can Notify?

Any staff member can identify that a clinical incident has occurred (including both salaried and non-salaried visiting medical officers). Notification can be done anonymously. Please note that the Department of Health's medical indemnity cover<sup>20,21,22</sup> will not be jeopardised by statements made by a doctor in the course of notifying activities to their employer, nor where the doctor has in good faith, implemented open disclosure in accordance with the Australian Open Disclosure Framework. Patients, carers or visitors can also notify clinical incidents. This may be via the Nurse Manager, Patient/Customer Liaison Unit or other appropriate avenues for the service.

### 5.2.2. How to Notify

Notification of a clinical incident is made via an online clinical incident form, completed within Datix CIMS, WA health system's electronic online clinical incident management system (CIMS). Notifiers are asked to provide as much factual/objective information as possible to assist with:

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

Documentation of the clinically relevant aspects of the clinical incident should also be made in the patient's medical record.

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 seven working days of the event's occurrence, or seven working days of the site becoming aware of the clinical incident. For private facilities, this is via the [SAC 1 Clinical incident notification form](#).

### 5.2.3. Notification Actions and Timeframes

For notification, staff must:

- Inform relevant management involved with clinical incidents and follow any other local processes.
- Document a summary and any essential information and any action(s) taken in the patient's medical record by the end of the notifiers work day.

- Notify the incident in the approved clinical incident management system (CIMS) by the end of the notifier’s work day.
- Review, confirm and allocate a WA Health Severity Assessment Code (SAC) rating within 48 hours of the incident being notified into the CIMS. This is to be done by the relevant staff involved in the management of clinical incidents within each HSP.

Where the event is not identified at the time as a clinical incident, notification must be within seven working days of the site becoming aware of the clinical incident.

HSPs must facilitate an appropriate level of open disclosure<sup>x</sup> to the patient, their family and carers as soon as practicable. They must also have processes in place to ensure support for the teams or individual staff involved in a clinical incident is provided.

Note that the above notifications apply to all. Further, all SAC 1 clinical incidents should be communicated to the appropriate health service executive as per health service guidelines. Confirmed SAC 1 clinical incidents must also be notified to the Department of Health Patient Safety and Surveillance Unit (PSSU) within seven working days, or seven working days of the site becoming aware of the clinical incident. For SAC 2 and 3 clinical incidents they must be informed to the relevant staff involved in the management of clinical incidents in the service within 24 hours and then a notification submitted via the approved clinical incident management system, Datix CIMS.

#### 5.2.4. Open Disclosure Process

Health Service Providers must facilitate an appropriate level of open disclosure to the patient, their family and carers as soon as practicable when clinical incidents occur. The decision to implement open disclosure for no-harm incidents and near misses should consider the potential to detect latent harm through discussion with 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 and carer trust in the service.

The Australian Open Disclosure Framework guides the appropriate level of open disclosure response.<sup>13</sup> Please note that the Department of Health’s medical indemnity cover<sup>20, 21, 22</sup> will not be jeopardised by statements made by a doctor in the course of notifying activities to their employer, nor by a doctor has in good faith, implemented open disclosure in accordance with the Australian Open Disclosure Framework.

### 5.3. Prioritisation of Investigation

Before an investigation of the clinical incident can take place, a severity assessment code (SAC) rating must be confirmed and allocated which will determine the prioritisation of the clinical incident investigation. The Severity Assessment Codes (SAC) are:

<b>SAC 1</b>	a clinical incident that has, or could have (near miss), caused serious harm or death; and which is attributed to health care provision rather than the patient’s underlying condition or illness.
<b>SAC 2</b>	a clinical incident that has, or could have (near miss), caused moderate harm; and which is attributed to health care provision rather than the patient’s underlying condition or illness.
<b>SAC 3</b>	a clinical incident that has, or could have (near miss) caused minor or no harm; and which is attributed to health care provision rather than the patient’s underlying condition or illness.

<sup>x</sup> In accordance with the Australian Open Disclosure Framework.

**Table 1: WA health system Severity Assessment Codes (SAC) – Summary**

	SAC 1	SAC 2	SAC 3
<b>Actual/potential consequence to patient</b>	<b>Physical/psychological serious harm or death;</b> that has, or could have (near miss), be attributed to health care provision (or lack thereof) rather than the patient’s underlying condition or illness.	<b>Physical/psychological Moderate harm</b> that has, or could have (near miss), be attributed to health care provision (or lack thereof) rather than the patient’s underlying condition or illness.	<b>Physical/psychological Minor or no harm</b> that has, or could have (near miss), be attributed to health care provision (or lack thereof) rather than the patient’s underlying condition or illness.
<b>Type of event/incident</b>	<p><b>SAC 1 clinical incidents include (but not limited to):</b></p> <ul style="list-style-type: none"> <li>National Sentinel Event Categories</li> <li>Any other clinical incident which results in serious harm (physical or psychological) or death of a patient</li> <li>Escalation of care to inpatient setting</li> <li>Increased length of stay greater than 7 days</li> <li>Near miss that could have resulted in serious harm or death.</li> </ul> <p><b>National Sentinel Event Categories</b></p> <ol style="list-style-type: none"> <li>Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death.</li> <li>Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death.</li> <li>Wrong surgical or other invasive procedure performed on a patient resulting in serious harm or death</li> <li>Unintended retention of a foreign object in a patient after surgery or other invasive procedure resulting in serious harm or death.</li> <li>Haemolytic blood transfusion reaction resulting in serious harm or death.</li> <li>Suspected suicide of a patient in an acute psychiatric unit or acute psychiatric ward.</li> <li>Medication error resulting in serious harm or death</li> <li>Use of physical or mechanical restraint resulting in serious harm or death.</li> <li>Discharge or release of an infant or child to an unauthorised person.</li> <li>Use of an incorrectly positioned oro-or naso-gastric tube resulting in serious harm or death.</li> </ol>	<p>SAC 2 clinical incidents include, but are not limited to the following:</p> <ul style="list-style-type: none"> <li>Increased length of stay (More than 72 hours to 7 days)</li> <li>Additional investigations performed</li> <li>Referral to another clinician</li> <li>Surgical intervention</li> <li>Medical intervention</li> <li>Increased frequency of mental health clinician review</li> <li>Near miss that could have resulted in moderate harm.</li> </ul>	<p>SAC 3 clinical incidents include, but are not limited to the following:</p> <ul style="list-style-type: none"> <li>No harm</li> <li>Only first aid treatment required</li> <li>Minor harm resulting in increased length of stay of up to 72 hours</li> <li>Increased frequency of mental health clinician review</li> <li>Near miss that could have resulted in minor harm.</li> </ul>
<b>Actions – During Notification, Investigation</b>	<ul style="list-style-type: none"> <li><b>Inform relevant management</b>/appropriate executive within 24 hours, follow any local processes.</li> <li><b>Submit</b> information via Datix CIMS or equivalent by end of notifier’s work day.</li> <li>Document summary, essential information, actions in <b>patient’s medical notes</b> by end of notifier’s work day.</li> <li>Within 48 hours, <b>review, confirm and allocate SAC</b> rating.</li> <li>Within 48 hours commence <b>initial investigation</b> to identify human errors and critical system failures.</li> <li>Complete a <b>SAC 1 notification to PSSU</b> via Datix CIMS within <b>seven</b> working days</li> <li>Implement a <b>higher level open disclosure response</b> for incidents causing serious harm or death, or a lower level response for near miss incidents***.</li> <li>Undertake SAC 1 investigation by <b>Root Cause Analysis (RCA)/ equivalent*</b>.</li> </ul>	<ul style="list-style-type: none"> <li><b>Inform</b> Unit Manager/Director within 24 hours.</li> <li><b>Submit</b> information via Datix CIMS and <b>document</b> the clinical incident in the patient’s medical notes by end of notifier’s work day.</li> <li>Within 48 hours, <b>confirm</b> SAC rating.</li> <li>Within 48 hours commence <b>initial investigation</b> to identify human errors and critical system failures.</li> </ul>	<ul style="list-style-type: none"> <li><b>Inform</b> Unit Manager within 24 hours.</li> <li><b>Submit</b> information via Datix CIMS and <b>document</b> the clinical incident in the patient’s medical notes by end of notifier’s work day.</li> <li>Within 48 hours, <b>confirm</b> SAC rating</li> </ul>



		<ul style="list-style-type: none"> <li>Investigate at a local level using clinical review as a minimum requirement or other appropriate methodology.</li> <li>Implement an <b>appropriate level of open disclosure</b>***.</li> </ul>	<ul style="list-style-type: none"> <li>Within 48 hours commence <b>initial investigation</b> to identify human errors and critical system failures.</li> <li>Investigate at a local level using aggregated analysis or other appropriate methodology.</li> <li>Implement an <b>appropriate level of open disclosure</b>***.</li> </ul>
<b>Reporting requirements</b>	<ul style="list-style-type: none"> <li>Final investigation reports with recommendations must be endorsed by the Chief Executive or from an approved delegation schedule.</li> <li>Submit completed investigation reports which are due within 28 working days of notification to PSSU.</li> <li>Refer to section 6.1 for any other applicable statutory reporting requirements.</li> </ul>	<ul style="list-style-type: none"> <li>Complete investigation within 60 working days of incident notification**.</li> </ul>	<ul style="list-style-type: none"> <li>Complete investigation within 60 working days of incident notification**.</li> </ul>
<b>Recommendations</b>	<ul style="list-style-type: none"> <li>All SAC 1 recommendations must be both implemented and evaluated within six months (182 calendar days) of the investigation report submission.</li> <li>An evaluation of SAC 1 recommendations must also be forwarded to PSSU within those six months (182 calendar days) of the investigation report submission.</li> </ul>	<ul style="list-style-type: none"> <li>Monitoring, implementation and evaluation of recommendations managed at a service level within 6 months (182 calendar days) of the investigation being completed.</li> <li>Lessons learned are shared at all levels of the service</li> </ul>	<ul style="list-style-type: none"> <li>Monitoring, implementation and evaluation of recommendations managed at a service level within 6 months (182 calendar days) of the investigation being completed.</li> <li>Lessons learned are shared at all levels of the service</li> </ul>
<p>* For other equivalent investigation methods and resources which can be used in place of an RCA please refer to the CIM Toolkit.  **The completion of the Datix CIMS clinical incident form (notification and investigation sections) can constitute a final report.  *** in accordance with the Australian Open Disclosure Framework.</p>			

## 5.4. Analysis of clinical incidents

### 5.4.1. Analysis and 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 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 thus level of investigation and escalation required.

During the first 48 hours after notification Health Service Providers must review a confirmed SAC and;

- Commence an initial investigation to identify human errors and system failures that may have led to the clinical incident occurring.
- Implement any preliminary actions to mitigate any further risk of harm to the patient and/or staff.
- Initiation as appropriate any open disclosure processes.

Where the event is not identified at the time as a clinical incident, initial investigation must be commenced within 48 hours of the site becoming aware of the clinical incident.

For especially complex incidents, obtaining an external investigator may be beneficial. To ensure that lessons are learnt especially from SAC 1 clinical incidents, every SAC 1 investigation includes recommendation/s for each contributing factor<sup>xi</sup>. Consideration should be given to providing patients and their families with the opportunity to contribute information about the clinical incident to assist with the investigation process and the development of patient-centred recommendations.

## 5.5. Reporting of Final Investigation Outcomes

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

Health Service Providers must ensure that investigation reports or equivalent meet minimum standards of quality which includes following recognised methodologies for investigations<sup>xii</sup>, 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.

### 5.5.1. SAC 1 clinical incident investigation report

Final SAC 1 investigation reports with recommendations must be endorsed by the Chief Executive or from an approved delegation schedule. Once an investigation report has been finalised, SAC 1 investigation findings are submitted to the PSSU within 28 working days of the date of notification as well as completed within Datix CIMS. The report should also be communicated to other relevant stakeholders at service level that manage and govern clinical incidents. SAC 1 incidents require a Root Cause Analysis (RCA) or other analysis of similar rigorous methodology<sup>xiii</sup> to be undertaken. Examples of other methodologies include the London Protocol, Failure Modes and Effects Analysis (FMEA), Human Error and Patient Safety (HEAPS) or Health Record Review<sup>2</sup>. It must also include recommendations.

### 5.5.2. SAC 2, SAC 3 investigation outcomes

Investigation reports are not submitted to the PSSU; however equivalent local processes for the reporting and follow-up of SAC 2, 3 clinical incidents are required. All SAC 2, 3 clinical incidents

<sup>xi</sup> Refer to Section 5.6.1 for further detail on development of recommendations.

<sup>xii</sup> Refer to the CIM Toolkit 2019 section 4.2 Investigation methods for more guidance.

<sup>xiii</sup> Refer to the CIM Toolkit 2019 section 4.2 Investigation methods for more detail

require the completion of an investigation within 60 working days of the clinical incident's date of notification. The completion of the Datix CIMS clinical incident form (notification and investigation sections) is required and can constitute a final investigation report. A SAC 2 clinical incident requires a clinical review or investigation using an appropriate methodology. A SAC 3 requires an investigation using an aggregated analysis or other appropriate investigation methodology.

Please note it is encouraged to analyse other SAC 2, 3 clinical incidents using comprehensive methodologies such as RCA if this is deemed appropriate. Refer to the CIM Toolkit for further resources which can assist Health Service Providers in investigation methodologies.

### **5.5.3. Feedback**

Feedback on submission of a notification should be given by the relevant staff involved in the management of clinical incidents in the service involved with the incident follow-up. The success of clinical incident management is dependent on timely feedback to all staff, including the notifier on the recommendations/outcome of investigations<sup>2</sup>. Lack of feedback from incident reporting has been highlighted as inhibiting the willingness of staff to report incidents<sup>23</sup>. Further, Health Service Providers must facilitate an appropriate level of open disclosure<sup>xiv</sup> and integral to this is feedback to the patient and nominated carer.

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

- if the appropriate level of investigation has been conducted related to the nature of the clinical incident;
- if 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.

### **5.5.4. Declassification of Clinical Incidents**

Following a clinical incident investigation, if it is determined that there are no health care contributing factors and the event was not preventable then declassification, inactivation processes must be initiated.

1. Declassification is in relation to a SAC 1 incident and is the process where a SAC 1 incident is reviewed and determined that the incident does not meet the definition of a clinical incident (harm resulting from health care delivery).
2. Inactivation is a process<sup>24</sup> used for events which are deemed as not within the definition of a SAC 1,2,3 clinical incident. Although they can still be found within the system, they are an event that does not meet the definition of a clinical incident and thus not used within PSSU reporting of clinical incidents (unless specified within the report). Note that a SAC 1 undergoes declassification and then inactivation. A SAC 2 or 3 is deemed not a clinical incident and then inactivated.

#### **Declassification of a SAC 1 Clinical Incident**

The Health Service Provider must submit requests of declassification of the incident to the PSSU. The PSSU will review against CIM Policy requirements and definitions and approve as appropriate. Once approved, it will be noted within Datix 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.

#### **Inactivation of a SAC 2, 3 Clinical Incident**

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 the clinical incident

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<sup>xiv</sup> in accordance with the Australian Open Disclosure Framework<sup>13</sup>

was not preventable. The relevant local staff involved in the management of clinical incidents in the health service organisation can inactivate these types of SAC 2 or 3 clinical incidents within Datix CIMS. If inactivated, it is not counted in the system as a clinical incident but can still be searched.

## 5.6. Closing the Loop (CLP)

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 share the lessons learned. The Health Service Provider must implement, monitor and then evaluate the effectiveness of recommendations made. Recommendations arising from clinical incident investigations must then be implemented and evaluated within 6 months (182 calendar days) of the investigation report submission.

### 5.6.1. Development of recommendations

Recommendations within investigation reports address the contributing factors of a clinical incident - what set circumstances have caused this to occur. These recommendations must be endorsed by the Chief Executive or as per the approved delegation schedule of the service. They are assigned to a particular position to be responsible for the implementation and have a specified timeframe for completion and evaluation. Processes for developing and evaluating recommendations must follow recognised methodologies<sup>xv</sup> in goal setting and must include action strengths to ensure the effectiveness of altered practices in preventing the clinical incident from reoccurring.

### Contributing Factors

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”.<sup>14</sup>

The goal during analysis is to articulate contributing factors which are related to the incident and thus provide the ‘backbone’ for the development of recommended actions. Clinical incidents will generally have more than one contributory factor.

### Recommendations should:

- Clearly identify the recommended action.
- address the contributory factors and lead to system improvements.
- be assigned to a particular position responsible for the implementation and monitoring.
- have a specified timeframe for completion and evaluation – this is within six months (182 calendar days) for SAC 1 incidents.
- be endorsed by the Health Service Provider Chief Executive or by their nominated delegate(s) as per the approved delegation schedule.

### SMARTA system

When developing recommendations, following the SMARTA<sup>xvi</sup> system of goal setting ensures the greatest likelihood of producing sustainable improvements in health care delivery.

1. **Specific:** The recommendation must be specific.
2. **Measurable:** The recommendation must be measurable.

<sup>xv</sup> Refer to the CIM Guideline 2019 section 5.6.1, Figure 2 and Table 2 and Toolkit 2019 for further guidance, resources and templates for recommendation development, including SMARTA and Action strengths.

<sup>xvi</sup> Refer to the CIM Toolkit for further resources and templates for recommendation development.

3. **Accountable:** State who will be responsible for implementing and evaluating this recommendation.
4. **Realistic:** Recommendations needs to be realistic to ensure that the outcome goal can be achieved.
5. **Time related:** It is imperative to state a deadline in which the goal will be achieved.
6. **Action Strength:** Ensure recommendation/s are created with the highest strength in mind.

### **Recommendation Hierarchy (Action Strength)**

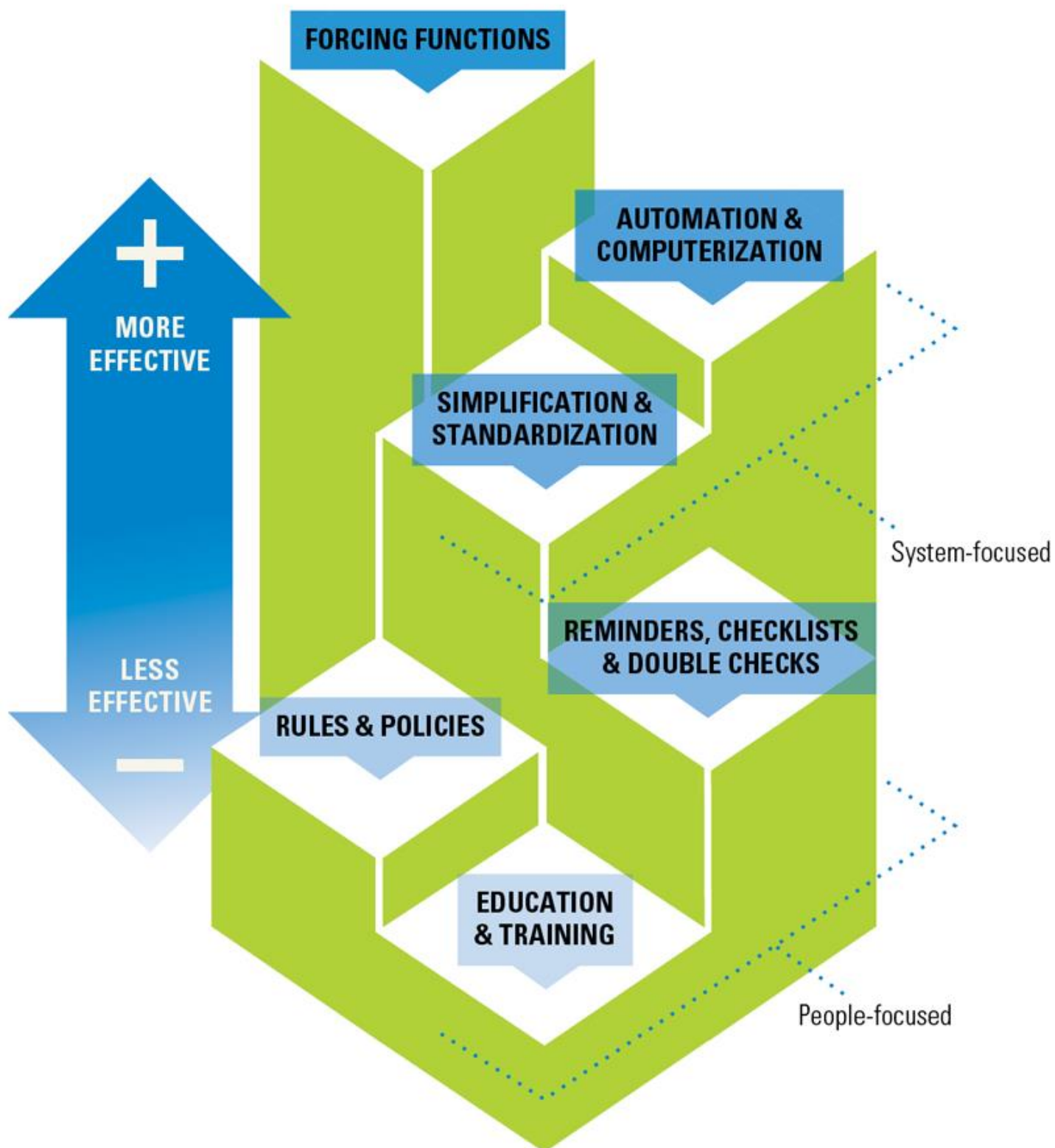
A Recommendation Hierarchy was developed by the Veterans Affairs National Center for Patient Safety<sup>25</sup> to assist in the development of actions that are more likely to succeed and achieve the desired outcomes. The Recommendations Hierarchy is a valuable tool that can assist staff in identifying 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 do 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 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. 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.

Figure 2: Effectiveness of Recommendation Action Strengths<sup>26</sup>

### The Hierarchy of Intervention Effectiveness



**Table 2: Recommendations Hierarchy<sup>25</sup>**

<b>Strength</b>	<b>Recommendation/Action Category</b>	<b>Example</b>
<b>Stronger Actions</b>	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 <sup>2</sup> process; purchase needed equipment; ensure staffing and workload are balanced.
<b>Intermediate Actions</b>	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.
<b>Weaker Actions</b>	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.

### 5.6.2. Implementation of Recommendations

Recommendations arising from clinical incident investigations must be implemented and evaluated within 6 months (182 calendar days) of 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<sup>xvii</sup>.

### 5.6.3. Monitoring, Evaluation of Recommendations

When recommendations have been implemented, the service must also evaluate the effectiveness of the strategies within those six months (182 calendar days) in order to validate that improvements have been made. This is to ensure that:

- the systemic problems 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.

Health Service Providers must provide to PSSU evaluation results of SAC 1 clinical incident recommendations within six months (182 calendar days) of the investigation report submission. For SAC 2 and SAC 3 clinical incidents the responsibility for implementation, evaluation and monitoring of recommendations is managed at a service level within 6 months (182 calendar days) of the investigation being completed.

### 5.6.4. Sharing Lessons Learned

The final step of the CIM process is where information of the recommendations is shared within the organisation. Health Service Providers must 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. Sharing the lessons assists in systemic change to prevent the recurrence of health care-related errors and ultimately increase patient safety.

Closing the Loop involves some key steps:

1. Ensuring that these changes are implemented 'on the ground'.
2. Evaluating their effectiveness in altering practice and behaviour and preventing the recurrence of clinical incidents.
3. Ensuring that information and recommendations are fed back into the health care system at various levels in multiple forms (e.g. changes in processes and procedures, staff education and newsletters, patient safety alerts and notification, relevant committees etc.) following the investigation and analysis of a clinical incident. A key step here also is to ensure that those involved such as the notifier, management is involved with the CIM process as appropriate and aware of outcomes of the investigation. Appropriate feedback, learnings and the recommended actions should be shared with the patient/family. External communications to inform the public should also be considered<sup>16</sup>.

## 5.7. Clinical Risk Management

Once clinical incident recommendations have been completed and evaluated it should be assessed if there are any ongoing clinical or corporate risks, particularly for SAC 1 clinical incidents. Health Service Providers should capture any ongoing clinical or corporate risk on their risk register and manage it at service level for continuous quality improvement<sup>xviii</sup>.

Please contact your relevant staff involved in the management of clinical incidents and risk in the service for further advice.

<sup>xvii</sup> Review the CIM Toolkit for more resources and methods for implementation

<sup>xviii</sup> Refer to the [WA Health Clinical Risk Management Guidelines](#) and [WA Health Risk Management Policy](#) for further guidance



## 6. Key Considerations during analysis and investigation

### 6.1. Investigation of clinical incidents across Health Service Provider boundaries

For complex clinical incidents involving a number of organisations, it is best practice to consult with all health service organisations involved with the care of the patient. All Health Service Providers identified as being involved with a clinical incident must participate in a collaborative investigation, recommendation and evaluation plan unless directed otherwise by their executives.<sup>xix</sup>. This may include health services such as (but not limited to) non-government organisations such as St John Ambulance, Royal Flying Doctor Service. A shared, systems approach to investigation and with arising recommendations and learnings from clinical incidents is important as failure within healthcare is usually complex with multiple causes and a solution is usually systemic. It avoids un-necessary duplication of resources and ensures a coordinated approach at multiple points across the health system and reduces 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 or the State Solicitor's Office as appropriate.

#### **Guide to investigate across boundaries<sup>8</sup>**

Where an incident involves multiple services, the last service providing care (including 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 a number of investigation options to be considered where multiple services are involved in the care of the patient including:

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

Note: The last service providing care should also:

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

### 6.2. Education and Training

Health Service Providers 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 must also be proficient in monitoring and

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<sup>xix</sup> In December 2018, it was communicated by DOHWA to each Health Service Provider's Chief Executive that investigations of clinical incidents across health service boundaries between public Health Service Providers, private entities and other contracted health entities are still under review and discussion. However Public Health Service Providers can still engage via service agreements in an investigation across health service boundaries. It is recommended that your Health Service Provider seek advice either from your General Counsel or from Legal and Legislative Services before performing multi-site clinical incident investigations involving private entities. Current good practice guidelines are located <https://ww2.health.wa.gov.au/-/media/Files/Corporate/general-documents/patient-safety/PDF/Guideline-for-the-investigation-of-multi-site-clinical-incidents.pdf>

assessing the effectiveness of recommendations. Health Service Providers must 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, members) are orientated to the roles and responsibilities required of them for safety and quality.
- Staff involved in clinical incidents must 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 critical. A learning culture is emphasised.
- Training systems should assess competency and implement training programs that have minimum competency standards. Ideally, services should monitor competency and evaluate training effectiveness.

### **6.3. Staff support and engagement<sup>28</sup>**

An important aspect of patient safety is also staff safety. When a clinical incident occurs, it is important to acknowledge not only the harm which has occurred for the patient but also the impact for others involved including clinicians. It has been shown that there is a significant emotional impact to frontline staff involved, which may result in both short and long term physical effects<sup>27</sup>. This can lead to staff fatigue, injury, 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 involved who operate in a health system and feel an emotional response from the unintentional error that they are part of.

Health Service Providers are required to implement local processes to:

- identify appropriate 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.
- investigate suspected breaches of the CIM Principles.

### **6.4. Accessing Post-Mortem Reports for the Investigation of Clinical Incidents**

If a PMR is required for quality improvement purposes (e.g. completing mortality review or investigation of a SAC 1 clinical incident), it may be requested via the service's nominated officer in accordance with the business rules for accessing a post mortem report<sup>29</sup>. In the event that the PMR is not available, clinical incident investigation should not be delayed as this would result in lost information and a delay in implementation of outcome measures. If the PMR provides any additional information following the investigation, this can be addressed subsequently.

## 7. Other Actions

### 7.1. Other and Statutory Reporting Requirements

The Health Service Provider should seek legal advice regarding the release of documents generated from a clinical incident investigation in accordance with the [WA health Obtaining Legal Advice](#)<sup>30</sup> policy. Other reporting requirements may also include the following but are not limited to:

- Statutory medical notifications must be reported to the [Chief Health Office](#).<sup>31</sup> These include but are not limited to:
  - maternal deaths
  - perinatal and infant deaths
  - deaths of persons under anaesthesia
- Reportable deaths must be reported to the [Office of the State Coroner](#).<sup>32</sup> The [Coronial Liaison Unit](#)<sup>33</sup> also provides guidance.
- Notifiable incidents must be reported to the [Office of the Chief Psychiatrist](#).<sup>9</sup>
- Medical incident reporting - incidents involving radiation are required to be reported to the [Radiological Council](#).<sup>34</sup>
- Reporting requirements for the recording and review of patient deaths in the [Review of Death Policy](#).<sup>11</sup>
- Reporting requirements in relation to the [Therapeutic Goods Administration](#).<sup>35</sup>

Please contact your relevant staff involved with the management of clinical incidents for further advice.

### 7.2. Data Quality

The enterprise data system to capture clinical incidents in Western Australia is Datix CIMS. The Data Custodians of Datix CIMS and nominated data quality staff must 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<sup>36</sup>.

### 7.3. 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 Datix CIMS as soon as possible. For information on retention and disposal of State records, refer to the [Information Retention and Disposal Policy](#)<sup>37</sup> and [General Disposal Authority for State Government Information](#)<sup>38</sup>.

### 7.4. Qualified Privilege (QP)

The Health Services (Quality Improvement) Act 1994 (QI Act)<sup>39</sup> is a method to facilitate the investigation of clinical incidents through an approved committee established under the QI Act. In some circumstances, documents and information created for the purpose of the committee's functions may be prohibited from disclosure.

The preferred approach is that services investigate outside of the framework established by the QI Act. There are many advantages of conducting quality improvement activities without QP. Clinical incident management requires a culture that promotes learning and sharing lessons learned from an incident is an integral part of this process. Without QP, sharing information across services can become quicker and more efficient. The investigation and information shared is also more complete and includes all details of what has occurred. This ensures clinical incident recommendations are addressed and communicated more quickly, effectively and developed with an understanding of all the system factors involved. This type of collaboration and sharing of information ultimately benefits the safety of the patient.

The QI Act governs the State Qualified Privilege<sup>40</sup> scheme. In order to operate under this scheme, a committee must be formally established and approved as a registered committee by the Minister for Health. Annual reports are also a requirement and the committee must be applied for and renewed regularly. Please note also that factual information regarding a clinical incident can still be obtained from other places that not protected by the legislation; for example, the patient's medical record is not protected.

For additional advice on the matter of patient confidentiality or release of patient information for the purposes of clinical incident investigations or otherwise, staff should consult with their relevant staff involved in the management of clinical incidents in the service within their service and/or the Department of Health's Legal and Legislative Services or the State Solicitor's Office, as appropriate.

## 8. Private Facilities, Non-Government Licensing and Contractual Processes

### 8.1. Guidance on Policy and Guideline interpretation

When the private or contracted facility has a license requirement or contractual agreement detailed about clinical incidents or requirements specifically with a SAC, then the facility needs to read those that are applicable to them within the CIM Policy and Guideline. 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 clinical incident management 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. Private facilities should follow any local reporting requirements into local systems to manage clinical incidents as per local health service organisation guidelines. 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 Guideline for any requirements applicable to the license/contract.

### 8.2. Approved clinical incident management systems

In order to maintain consistent approaches Health Service Providers must 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<sup>41</sup> to support their workforce in recognising, investigating and analysing clinical incidents to improve safety and quality within the service. The approved WA health system's electronic clinical incident management system used for public clinical incidents is the [Datix Clinical Incident Management System \(CIMS\)](#) which private facilities submit notification, investigation and evaluations to be entered into the Datix CIMS on their behalf for SAC 1 clinical incidents.

### 8.3. Roles and Responsibilities

#### Facilities are to ensure for Clinical Incident Management Processes

- All SAC 1 clinical incidents are notified to the PSSU within seven working days of the event's occurrence or where the incident is not identified until after this time, within seven working days of the site becoming aware of the clinical incident.
- The [SAC 1 clinical incident notification form](#)<sup>42</sup> is submitted to the PSSU via the email: [SAC1.events@health.wa.gov.au](mailto:SAC1.events@health.wa.gov.au)
- All SAC 1 clinical incidents are investigated using an appropriate rigorous investigation methodology.

- All SAC 1 investigation findings are submitted to the PSSU within 28 working days of the event notification using the [SAC 1 clinical incident investigation report](#)<sup>42</sup> or equivalent.
- The completed template [Evaluation of Recommendation Actions Following Investigation of SAC 1 Incidents](#)<sup>42</sup> or equivalents are submitted to PSSU within six months (182 calendar days) of the investigation report submission date.
- Recommendations from clinical incident investigations are implemented and evaluated within six months (182 calendar days) of completing the investigation report.
- When clinical incidents occur across health service boundaries, services must 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, contractual agreements are met.

## Appendix 1: SAC 1 Clinical Incident Notification List (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 a SAC 1

<b>SAC 1 Clinical Incident Notification List (Sentinel events)<sup>xx</sup></b>	
<b>Category</b>	<b>Clinical incidents (category 1-10 sentinel events)</b>
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.

<sup>xx</sup> As per the national Australian sentinel events list (version 2) - <https://www.safetyandquality.gov.au/our-work/indicators/australian-sentinel-events-list/>

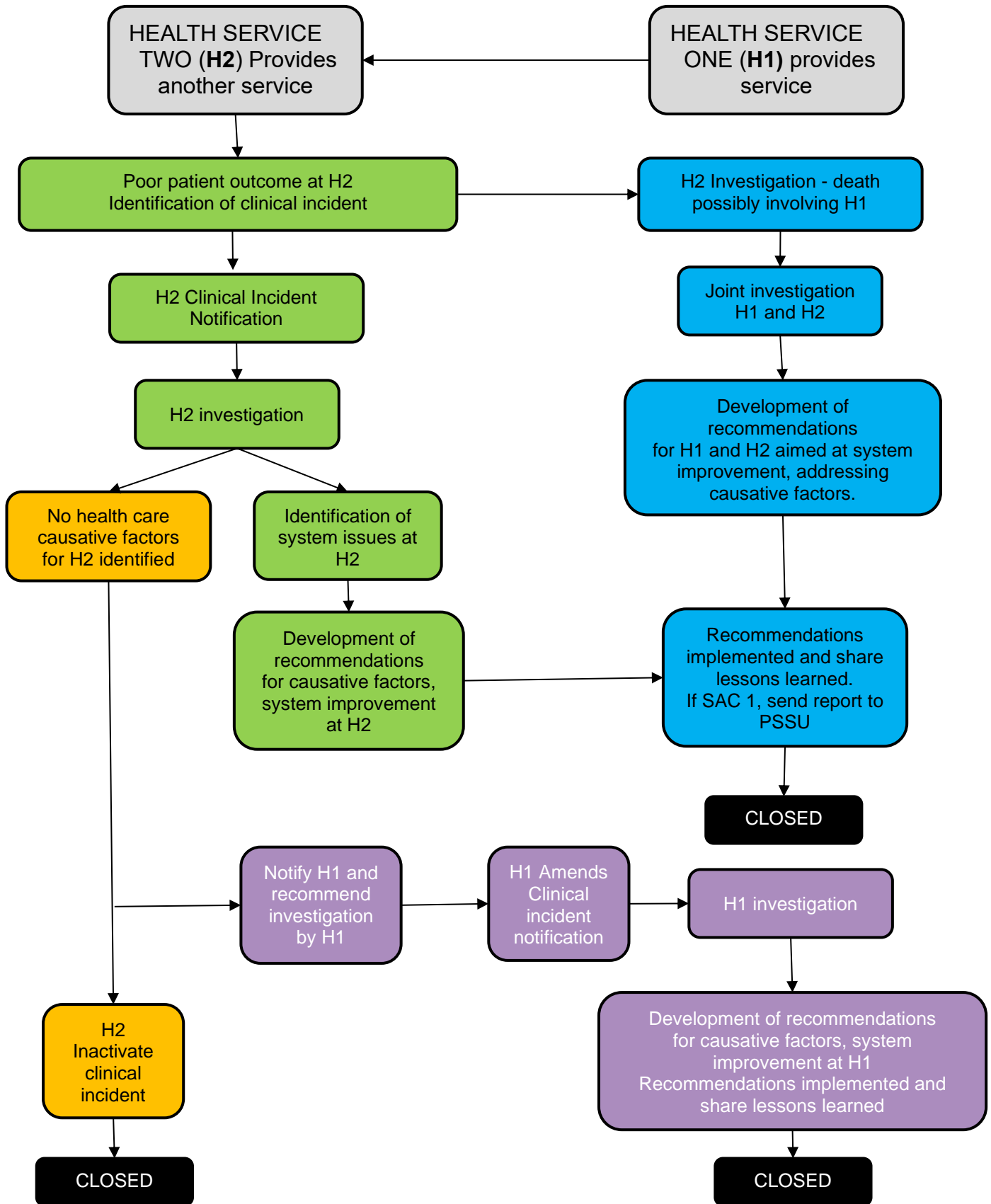
## Appendix 2: SAC 1 Clinical Incident Notification List (Other)

SAC 1 includes 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. Note this list is NOT EXHAUSTIVE. If unsure of whether to notify an incident, contact relevant staff involved in the management of clinical incidents

<p><b>SAC 1 Clinical Incident Notification List (Other)</b></p> <p><b>Medication error (not resulting in death, serious harm or a near miss sentinel event) may include:</b></p> <ul style="list-style-type: none"> <li>• The inappropriate administration of daily oral methotrexate</li> <li>• The intravenous administration of epidural medication</li> <li>• Wrong gas being administered.</li> </ul> <p><b>Fetal complications associated with health care delivery:</b></p> <ul style="list-style-type: none"> <li>• Unrelated to congenital abnormality in an infant causing death, or serious and/or ongoing perinatal morbidity.</li> <li>• Complications not anticipated yet arose and were not managed in an appropriate/timely manner resulting in death, serious and/or ongoing morbidity.</li> <li>• 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.</li> </ul> <p><i>Note that for clinical incident reporting a fetus is from conception to birth. Please note this may differ to clinical service definitions</i></p> <p><b>Misdiagnosis and subsequent management (refers to physical and mental health)</b></p> <p><b>Clinical deterioration of a mental health patient resulting in serious harm (physical, verbal, or sexual) or death to staff, other patients, or other persons.</b></p> <p><i>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.</i></p> <p><b>Complications of resuscitation:</b></p> <ul style="list-style-type: none"> <li>• Events in which staff experienced problems in managing an emergency situation or resuscitation resulting in death, or serious and/or ongoing morbidity.</li> <li>• 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.</li> </ul> <p><b>Complications of anaesthetic management:</b></p> <ul style="list-style-type: none"> <li>• Unintended intra-operative awareness.</li> <li>• Anaesthetic events resulting in death, or serious and/or ongoing morbidity.</li> </ul> <p><b>Complications of surgery:</b></p> <ul style="list-style-type: none"> <li>• Intentional retention of foreign material for treatment which is found to have resulted in harm</li> <li>• Pulmonary embolism</li> <li>• Injury to major blood vessels.</li> </ul> <p><b>Complications of a fall within a health service.</b></p> <p><b>Delay in recognising/responding to physical clinical deterioration</b></p> <p><b>Hospital Acquired Pressure Injuries</b></p> <p><b>Hospital/Service process issues:</b></p> <ul style="list-style-type: none"> <li>• Events in which hospital or other health service processes such as triaging, assessment, planning or delivery of care</li> <li>• e.g. miscommunication of test results, response to abnormal test results contributed to death, or serious and/or ongoing morbidity.</li> <li>• Transport or transfer – Events in which delays in transport or transfer contributed to death, or serious and/or ongoing morbidity.</li> <li>• Misidentification of patients.</li> </ul> <p><b>Intravascular gas embolism resulting in death or neurological damage.</b></p> <p><b>Infection control breach (e.g. IV cannula related bacteraemia infections).</b></p> <p><b>The unexpected death of a mental health client:</b></p> <ul style="list-style-type: none"> <li>• suspected suicide which occurs in a location other than an acute psychiatric unit or acute psychiatric ward</li> <li>• unnatural or violent death</li> </ul> <p><i>Note an unnatural or violent death involving mechanical or physical restraint in a health service, should be categorised as a sentinel event.</i></p> <p><b>Maternal death</b> - 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.<sup>43,44</sup></p> <p><b>Missing or Absent Without Leave of any high-risk mental health patient/consumer.</b></p> <p><i>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.</i></p> <p><b>Patient missing or Absent Without Leave with adverse outcome</b></p>
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## Appendix 3: Clinical Incident Management across Health Service Boundaries

Please note this process map provides a general process on engaging with another site. For more specific guidance with other entities please contact the PSSU at [PSSU@health.wa.gov.au](mailto:PSSU@health.wa.gov.au)



In December 2018, it was communicated by DOHWA to each Health Service Provider's Chief Executive that investigations of clinical incidents across health service boundaries between public Health Service Providers, private entities and other contracted health entities are still under review and discussion. However Health Service Providers (PUBLIC) can still engage via service agreements in an investigation across health service boundaries. It is recommended that other services (private or contracted) seek advice either from your General Counsel or from Legal and Legislative Services before performing multi-site clinical incident investigations involving private entities.



## Appendix 4: Suggested Reading Guidance

Below are suggested sections to refer to for further information when reading the CIM Policy. Please note this is not an exhaustive mapping, it is recommended that services read the Policy and Guideline in full for a comprehensive understanding of CIM.

CIM Policy Title	CIM Guideline Title	CIM Toolkit Title
<b>1. Purpose</b>	Introduction 1. Principles	1. CIM in WA: Introduction and Background
<b>2. Applicability</b>	2. Applicability 3. Roles and Responsibilities	
<b>3. Policy Requirements</b>	Note: how to use the suite of CIM documents 1. Principles 3. Roles and Responsibilities 8.3 Roles and Responsibilities (private facilities)	1.2 Key steps: The CIM Process 2. A Safety Culture 2.1 CIM Principles and Key Concepts
<b>3.1 Identification of CI</b>	5.1 Identification of a CI and immediate action	3. Identification
<b>3.2 Notification of a CI</b> <b>3.2.1 WA health system SAC</b> <b>3.2.2 Notification Requirements</b>	5.2 Notification of CI 4.1 Definitions 4.2 Determination of SAC	
<b>3.3 Analysis and Investigation</b> <b>3.3.1 Initial investigation</b> <b>3.3.2 Investigation Requirements</b>	5.3 Prioritisation of investigation 5.4 Analysis of CI	4. Analysis
<b>3.4 Reporting of final investigation outcomes</b> <b>3.4.1 Reporting requirements</b>	5.5 Reporting of final investigation outcomes	4.1 Investigation
<b>3.4.2 Declassification Inactivation requirements</b>	5.5.4 Declassification of CI	
<b>3.5 Closing the Loop (CLP)</b>	5.6 Closing the Loop (CLP)	5. Closing the Loop Section
<b>3.5.1 Recommendations: Development, Implementation and Evaluation</b> <b>3.5.2 Recommendation Requirements</b>	5.6 Closing the Loop 5.6.1 Development of recommendations	4.2 Recommendations
<b>3.5.3 Sharing Lessons Learned</b>	5.6.4 Sharing Lessons Learned	5.3 Sharing lessons learned
<b>3.6 Key Considerations during Analysis and Investigation</b>	6. Key Considerations during Analysis and Investigation	
<b>3.6.1 Investigation of CI across Health Service Provider boundaries</b>	6.1 Investigation of CI across Health Service Provider boundaries <i>*Note this has separate guidance material available from PSSU not in this CIM Guideline</i>	
<b>3.6.2 Education and Training</b>	6.2 Education and Training	
<b>3.6.3 Staff Support and engagement</b>	6.3 Staff Support and engagement	
<b>3.6.4 Data Quality</b>	7.2 Data Quality	

## Definitions

<b>Absent Without Leave</b>	<p>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:</p> <ol style="list-style-type: none"> <li>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);</li> <li>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);</li> <li>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);</li> <li>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);</li> <li>v. any involuntary community patient who leaves the place where they are detained under MHA 2014 s 130(2)(b).</li> </ol>
<b>Carer</b>	<p>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.</p>
<b>Clinical incident</b>	<p><b>Clinical Incident-</b> an event or circumstance resulting from health care provision which could have, or did lead to unintended or unnecessary harm to a patient. Clinical incidents include:</p> <ul style="list-style-type: none"> <li>• <b>Near miss:</b> an incident that may have, but did not cause harm, either by chance or through timely intervention.</li> <li>• <b>Sentinel events:</b> 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.</li> </ul> <p>Please note there is a list of nationally endorsed sentinel event categories which can be reviewed in the CIM Guideline. The WA CIM Policy for reporting SAC 1 events is broader than the national list - near misses are also to be reported in the WA health system.</p>
<b>Clinical incident management</b>	<p>Clinical incident management is the process of effectively managing clinical incidents with a view to minimising preventable harm.</p>
<b>Clinical Incident Management System (CIMS)</b>	<p>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 evaluate identified recommendations.</p> <p>Datix CIMS is the approved WA health statewide enterprise electronic online clinical incident management system which has been used since February 2014, to capture and manage clinical incidents that occur within the WA health system. Refer to the <i>CIM Guideline</i> for further guidance on other incident management system.</p>

<b>Clinical Risk</b>	Refers to risks associated with delivering clinical functions.
<b>Contracted Health Entity (CHE)<sup>47</sup></b>	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.
<b>Escalation</b>	The organisational level to which an incident must be notified and the timeframe in which this must occur.
<b>Datix CIMS</b>	Datix CIMS refers to the current electronic online clinical management system (implemented February 2014), used to capture and manage clinical incidents that occur within the WA health system.
<b>Hazard</b>	A circumstance, agent or action that can lead to or increase risk.
<b>Clinician</b>	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.
<b>Date of Notification</b>	For SAC1 incidents, there is the Date of notification to PSSU, which is the date PSSU is notified of the SAC1 incident. Within the current approved clinical incident management system (Datix CIMS) this is currently the date within step 1 of the SAC 1 action chain.  For SAC 2/3/4 incidents, the date of notification is the date the incident was entered (notified) into Datix CIMS. This is the Datix CIMS date of notification field.
<b>Health Service<sup>47</sup></b>	A health service is a service for maintaining, improving, restoring or managing people's physical and mental health and wellbeing.
<b>Health Service Provider<sup>47</sup></b>	Health Service Providers (HSP) are governed by Health Service Boards and/or a Chief Executive. Each Health Service Provider 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: <ol style="list-style-type: none"> <li>1. Child and Adolescent Health Service</li> <li>2. North Metropolitan Health Service</li> <li>3. South Metropolitan Health Service</li> <li>4. East Metropolitan Health Service</li> <li>5. WA Country Health Service</li> <li>6. PathWest</li> <li>7. Quadriplegic Centre</li> </ol>
<b>Maternal death</b>	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." <sup>43,44</sup>
<b>Misconduct<sup>45</sup></b>	<b>Serious Misconduct</b> is when a public officer: <ul style="list-style-type: none"> <li>- acts corruptly or corruptly fails to act in the course of their duties; OR</li> <li>- corruptly takes advantage of their position for the benefit or detriment of any person; OR</li> <li>- commits an offence which carries a penalty of two or more years imprisonment.</li> </ul> <b>Minor misconduct</b> occurs if a <u>public officer</u> engages in conduct that:

	<ul style="list-style-type: none"> <li>- adversely affects the honest or impartial performance of the functions of a public authority or public officer, whether or not the public officer was acting in their public officer capacity at the time of engaging in the conduct;</li> <li>- involves the performance of functions in a manner that is not honest or impartial;</li> <li>- involves a breach of the trust placed in the public officer; or</li> <li>- involves the misuse of information or material that is in connection with their functions as a public officer, whether the misuse is for the benefit of the public officer or the benefit or detriment of another person;</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>- <u>constitutes, or could constitute, a disciplinary offence providing reasonable grounds for termination</u> of a person's office or employment.</li> </ul> <p>The abovementioned acts are to be reported to the Public Sector Commission (PSC) or (Crime and Corruption Commission (CCC).</p> <p>Another category of misconduct included in the Discipline Policy<sup>18</sup> which references the Health Services Act is:</p> <p>"a breach of discipline is committed by an employee when the employee:</p> <ul style="list-style-type: none"> <li>(a) disobeys or contravenes a lawful order; or</li> <li>(b) contravenes: <ul style="list-style-type: none"> <li>(i) any provision of the HSA applicable to the employee; or</li> <li>(ii) any public sector standard or code of ethics; or</li> <li>(iii) a policy framework; or</li> </ul> </li> <li>(c) commits an act of misconduct; or</li> <li>(d) is negligent or careless in the performance of the employee's functions; or</li> <li>(e) commits an act of victimisation within the meaning of the Public Disclosure Act 2003 section 15." </li></ul>
<b>Missing Person</b>	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.
<b>Near miss</b>	Incidents that may have, but did not cause harm, either by chance or through timely intervention.
<b>Open disclosure</b>	<p>Open disclosure is the open discussion of an incident that results in harm (or might have resulted in future harm) to a patient while receiving health care.</p> <p>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.</p>
<b>Patient</b>	<p>Refers to any person receiving health care in a health service.</p> <p>The term 'consumer' refers to a person who has used, or may potentially use, health services and in the current CIM Policy and Guideline the term patient refers to the patient or consumer.</p>
<b>Patient Safety<sup>46</sup></b>	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.

<b>Qualified Privilege</b>	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 <i>Health Services (Quality Improvement) Act 1994</i> .
<b>Review of Death (ROD)</b>	<p>ROD refers to the mandatory mortality review process to ensure that Health Service Providers (HSPs) implement consistent policies, processes and systems for the recording and review of patient deaths. This is in order to identify:</p> <ul style="list-style-type: none"> <li>- Potentially preventable deaths</li> <li>- Opportunities for improvement in the delivery of health services, including the quality of end-of-life care.</li> </ul> <p>Preventable deaths identified via mortality review processes are to be notified as a SAC 1 clinical incident as per the Review of Death Policy<sup>11</sup>.</p>
<b>Relevant staff involved in the management of clinical incidents</b>	<p>Within a health service, the delegated team and structures which govern clinical incident management. This may be (but not limited to)</p> <ul style="list-style-type: none"> <li>- A line manager</li> <li>- Delegated authority such as a Risk Manager or Safety, Quality and Performance teams</li> <li>- Staff who oversee quality improvement activities.</li> </ul>
<b>Root Cause Analysis</b>	RCA is a comprehensive and systematic methodology to identify the gaps in hospital systems and the processes of health care that may not be immediately apparent and which may have contributed to the occurrence of an event.
<b>Severity Assessment Code (SAC)</b>	The SAC rating is the way clinical incidents are rated in WA's health system. Clinical Incidents are categorised using the SAC rating to determine the appropriate level of analysis, action and escalation.
<b>WA health system<sup>47</sup></b>	The WA health system is comprised of <ul style="list-style-type: none"> <li>(a) the Department; and</li> <li>(b) health service providers; and</li> <li>(c) to the extent that contracted health entities provide health services to the State, the contracted health entities.</li> </ul>

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## Further Resources

### Psychological Harm/Homicide information

#### NHS Clinical Incident Management Guide

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### Clinical Incident Management Guides and other frameworks

#### Queensland

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#### Canada

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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.*

#### USA - Institute for Healthcare Improvement (IHI)

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