Government of Western Australia
Department of Health

Policy Frameworks
MP 0122/19
Effective from: 1 November 2019

Clinical Incident Management Policy 2019

1. Purpose

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.

The CIM Policy is also part of the assurance mechanisms supporting the Department CEO in fulfilling their functions of overseeing and monitoring the safety and quality of services provided by Health Service Providers in Western Australia.

The Policy supports the WA health system to report on sentinel events[1] to the Commonwealth. On behalf of the WA health system, the Department reports this clinical incident data. Further, episodes of care which include sentinel events are also required to be reported to the Independent Hospital Pricing Authority (IHPA) for funding purposes.

This Policy is a mandatory requirement under the *Clinical Governance, Safety and Quality Policy Framework* pursuant to section 26(2) (a), (c) and (d) of the *Health Services Act 2016*. This Policy supersedes Operational Directive 0611/15 *Clinical Incident Management Policy* (Revised April 2018).

Incidents not within the scope of this Policy include suspected staff misconduct, occupational safety and health incidents that involve staff or incidents involving visitors unrelated to the provision of a health care service to a patient. The management of clinical incidents, particularly the investigation process must not be used as a method to investigate staff misconduct.[2]

[1] Refer to Appendix 1 SAC 1 Clinical Incident Notification List (Sentinel Events) for the list
[2] Refer to CIM Guideline 2019, Section 4.3 on Incidents out of scope for further guidance.

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.

3. Policy requirements

For key terms used throughout this Policy, please refer to the definitions provided at section 7.

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 (CIMS)[3,4]. Further, clinical incidents must be managed in accordance with the principles of Transparency, Accountability, Probity/Fairness, Patient Centred Care, Open Just Culture, Obligation to Act and Prioritisation of resources[5].

3.1 Identification of clinical incidents

When a clinical incident is identified, immediate action must be taken by appropriate staff to ensure 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.

3.2 Notification of clinical incidents

When a clinical incident has occurred (or near miss) staff must:

- Inform relevant management involved with clinical incidents within 24 hours and follow any other local notification processes.
- Document a summary and any essential information and any action(s) taken in the patient's medical record.
- Notify the incident in the approved clinical incident management system (CIMS) by the end of the notifier's workday.
- Review, confirm and allocate a WA Health Severity Assessment Code (SAC) rating (section 3.2.1) within 48 hours of the incident being notified into the approved CIMS. This is to be done by the relevant staff involved in the management of clinical incidents within each Health Service Provider.
- Complete any additional requirements for each individual SAC rating (section 3.2.2)

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. A notification may be lodged anonymously.

Health Service Providers must facilitate an appropriate level of open disclosure[6] 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.

[3] Refer to CIM Guideline 2019, Section 3, 8.3 on Roles and Responsibilities for further detail and Table 1 for a summary.
[4] Refer to CIM Guideline 2019, section 2.1 and 8 on approved clinical incident management systems for further guidance.
[5] Refer to CIM Guideline 2019, section 1 on Principles for further detail.
[6] In accordance with the Australian Open Disclosure Framework.

3.2.1 WA health system Severity Assessment Codes

There are three WA health system Severity Assessment Codes (SAC), which must be used:

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

3.2.2 Notification requirements

In addition, the following actions must be also be undertaken in accordance with each confirmed SAC rating[7]:

SAC 1	SAC 1 confirmed clinical incidents must 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. When an event results in death and during review it is determined that there is any possibility that it was preventable, it must be notified as a SAC 1 and investigated as such.
SAC 2 and 3	SAC 2 and 3 confirmed clinical incidents must be informed to the relevant staff involved in the management of clinical incidents as per local processes.

3.3 Analysis and investigation

Following the notification of a clinical incident, the relevant Health Service Provider must conduct an investigation to establish and analyse the course of events that led to the clinical incident, and to identify the contributing factors. The level of investigation (section 3.3.2) and reporting (section 3.4.1) required is determined by the SAC allocated to the clinical incident (section 3.2.1).

3.3.1 Initial investigation

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 of 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.

[7] Refer to the CIM Guideline 2019 Section 4.2.1 for other processes which can assist such as Review of Death.

3.3.2 Investigation requirements

Investigations[8] must be undertaken in accordance with the SAC rating, as per the following:

SAC 1	SAC 1 incidents require a Root Cause Analysis (RCA) or other analysis of similar rigorous methodology to be undertaken.
SAC 2	SAC 2 incidents require a clinical review or investigation using an appropriate methodology.
SAC 3	SAC 3 incidents require an investigation using an aggregated analysis or other appropriate investigation methodology.

3.4 Reporting of final investigation outcomes

Health Service Providers must ensure that analysis and findings of clinical incident investigations are reported as outlined in section 3.4.1. Health Service Providers must ensure that investigation reports or equivalent meet minimum standards of quality which includes following recognised methodologies for investigations[9], 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. All clinical incidents require reporting of final investigation outcomes in the approved CIMS.

3.4.1 Reporting requirements

The following reporting must be undertaken in accordance with each SAC rating:

SAC 1	Final SAC 1 investigation reports must: • be endorsed by the Health Service Provider Chief Executive or by their delegate(s) as per the approved delegation schedule. • include recommendation(s) for each contributing factor (section 3.5.1). • be submitted to the PSSU within 28 working days of the date of notification to PSSU.
SAC 2 and 3	SAC 2 and 3 investigations must: • be completed within 60 working days of the clinical incident's date of notification. • include the completion of the relevant clinical incident forms within the approved clinical incident management system. This can constitute a final investigation report

3.4.2 Declassification inactivation requirements

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 and other local processes such as inactivation must be initiated.

The following must be undertaken in accordance with each SAC rating:

SAC 1	Submit requests of declassification of the incident to the PSSU for review. If approved, following declassification of a SAC 1 clinical incident any recommendations presented in the report must be implemented, monitored and evaluated at a local level.

[8] Refer to the CIM Toolkit 2019 section 4.2 Investigation methods for more detail
[9] Refer to the CIM Toolkit 2019 section 4.2 Investigation methods for more guidance.

SAC 2 and 3	Manage inactivation as appropriate at a local level.

3.5 Closing the Loop

Closing the Loop is a term used to describe a focus on enhancing the components of CIM during the development, implementation and evaluation of recommendations, with an objective to share the lessons learned.

3.5.1 Recommendation development, implementation and evaluation

Recommendations that address the contributing factors of a clinical incident must be developed. The Health Service Provider must also implement, monitor and then evaluate the effectiveness of recommendations made. Processes for developing and evaluating recommendations must follow recognised methodologies[10] in goal setting and must include action strengths to ensure the effectiveness of altered practices in preventing the clinical incident from reoccurring. Recommendations must be endorsed by the Chief Executive or as per the approved delegation schedule. Recommendations must be assigned to a particular position to be responsible for their implementation and have a specified timeframe for completion and evaluation. Recommendations arising from clinical incident investigations must be implemented and evaluated within 6 months (182 calendar days) of the investigation report submission.

3.5.2 Recommendation Requirements

The following must be undertaken in accordance with each SAC rating:

SAC 1	Evaluation results from recommendations must be • submitted to the PSSU within 6 months (182 calendar days) of the investigation report submission. • included in the final report submitted to PSSU.
SAC 2 and 3	Recommendations must be implemented and evaluated within 6 months (182 calendar days) of the investigation being completed. Monitoring of these processes must occur at the Health Service Provider level.

3.5.3 Sharing lessons learned

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.

3.6 Key considerations during analysis and investigation

Health Service Providers must ensure the following when managing a clinical incident.

3.6.1 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 who have been involved with the care of the patient. All Health Service Providers identified as being involved with a clinical incident must participate in a

[10] 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.

collaborative investigation, recommendation and evaluation plan unless directed otherwise by their executives.[11]

3.6.2 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 relevant staff have the required skills to participate, facilitate or chair clinical incident investigations. Relevant staff must also be proficient in monitoring and 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 and further developing staff to participate in CIM.

3.6.3 Staff support and engagement

It is recognised that clinical incidents can have a significant impact not only on the patient but also the clinician(s) involved.

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.
- Review and investigate if a CIM investigation was used with the wrong intent (breach in CIM Principles).

3.6.4 Data Quality

The Health Service Provider must have operational procedures and guidelines in place to ensure data quality for clinical incidents is managed effectively. This includes ongoing, regular review of the data and data quality improvement efforts with relevant stakeholders such as Data Custodians of the approved clinical incident management system.

4. Compliance monitoring

Health Service Providers are required to monitor their compliance with this mandatory policy.

The PSSU also undertakes activities to assure the System Manager that Health Service Providers are complying with this Policy and managing the responsibilities of the Data Custodian. These compliance monitoring activities include, but are not limited to:

- Monitoring and responding to clinical incident trends and issues, identified through the review and analysis of clinical incident data extracted from the approved clinical incident management system. Action taken in response to these trends and issues will be commensurate to the associated level of system risk.

[11] For further information please see CIM Guideline.

- Comparing CIM information from the approved clinical incident management system with other data sets to review certain subsets of incidents such as (but not limited to) surgical deaths reviewed under the Western Australian Audit of Surgical Mortality (WAASM), and deaths being investigated by the WA State Coroner.
- Activities such as clinical and data governance audits reporting on adherence by Health Service Providers to the requirements outlined in section 3 of the Policy.
- Aggregating clinical incident data, extracted from the approved clinical incident management system, at a system level and producing clinical incident management reports. These reports may include (but are not limited to) the PSSU annual report and focus reports.
- Monitoring via other internal departmental divisions such as the Purchasing and System Performance Division who utilise SAC data for the Health Service Performance Report (HSPR).

5. Related documents

The following documents are mandatory pursuant to this Policy:

- N/A

6. Supporting information

The following information is not mandatory but informs and/or supports the implementation of this Policy:

- Clinical Incident Management Guideline 2019
- Clinical Incident Management Toolkit 2019

7. Definitions

The following definition(s) are relevant to this Policy.

Term	Definition
Action Strength	A Recommendation Hierarchy was developed by the Veterans Affairs National Center for Patient Safety (USA) and adopted for use in the WA health system. This hierarchy assists in the development of actions/recommendations to ensure effective system change.
Clinical Incident	An event or circumstance resulting from health care provision (or lack thereof) which could have or did lead to unintended or unnecessary physical or psychological harm to a patient. 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.

	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.
Clinical Incident Management (CIM)	The process of effectively managing clinical incidents with a view to minimising preventable harm.
Date of Notification	For SAC1 incidents, there is the Date of notification to PSSU, which is the date PSSU is notified of the SAC1 incident. Within the 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 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.
Data Custodian	The person(s) responsible for the day-to-day management of a data collection, as nominated by the Data Steward. Data Custodians assist the Data Steward to protect the privacy, security and confidentiality of information within data collections. Data Custodians also aim to improve the accuracy, usability and accessibility of data within the data collection. This has been further clarified under the Department CEO Instrument of Delegation signed 2 January 2019.
Declassification	Declassification is in relation to a SAC 1 incident and means that it has been determined that the incident is not a clinical incident resulting from health care delivery.
Inactivation	Inactivation is a process 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, as they are an event that meets the definition of a clinical incident they are not used within PSSU reporting of clinical incidents (unless specified). Note that a SAC 1 undergoes declassification and then inactivation. A SAC 2 or 3 is deemed not a clinical incident and then inactivated.
Clinical Incident Management System (CIMS)	The CIMS refers to an organisation's approved nominated information system used to notify report and investigate clinical incidents. It may also include functions to evaluate identified recommendations. 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 *CIM Guideline* for further guidance on other clinical incident management systems.
Notifier	Profiles are used within Datix CIMS to allow different types of access to CIMS data. A Notifier is any person within the WA health system who will utilise Datix CIMS to report a clinical incident.

Open Disclosure	Open Disclosure is the open discussion of incidents that result in harm to a patient while receiving health care with the patient, their family, carers and other support persons. The elements of open disclosure are an apology or expression of regret (including the word 'sorry'), a factual explanation of what happened, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.
Patient	Refers to any person receiving health care in a health service. 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.
Patient Safety Surveillance Unit (PSSU)	The PSSU is part of the Patient Safety and Clinical Quality Directorate, Department of Health, WA. It is responsible for state-wide patient safety policy and reporting on consumer complaints, clinical incidents, clinical risk management and mortality review.
Relevant staff involved in the management of clinical incidents	Within a health service, the delegated team and structures which govern clinical incident management. This may be (but not limited to) • A line manager • Delegated authority such as a Risk Manager or Safety, Quality and Performance teams • Staff who oversee quality improvement activities.
Root Cause Analysis (RCA)	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.
Severity Assessment Code (SAC)	The SAC rating is the way clinical incidents are rated in the WA health system. Clinical incidents are categorised using the SAC rating to determine the appropriate level of analysis, action and escalation.
Western Australian Audit of Surgical Mortality (WAASM)	The WAASM follows a peer review methodology for surgically-related deaths. The audit includes deaths where no procedure was undertaken if the patient was under the care of a surgeon. Where a decision for terminal care had been made at the point of admission, only the deaths where a procedure was undertaken are audited.

8. Policy contact

Enquiries relating to this policy may be directed to:

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9. Document control

Version	Published date	Effective from	Review date	Effective to	Amendment (s)
MP 0122/19	1 November 2019	1 November 2019	1 November 2022	Current	Original version

10. Approval

Approval by	Dr David Russell-Weisz, Director General, Department of Health
Approval date	25 September 2019

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