

Policy Frameworks Mandatory Policy

MP 0122/19

Effective from: 1 November 2019 Amended on: 19 December 2024

Clinical Incident Management Policy

1. Purpose

The purpose of the Clinical Incident Management (CIM) Policy (the policy) is to ensure WA health entities implement consistent and accountable processes and systems for the management of clinical incidents across the WA health system. The policy aims to prevent harm to patients and consumers, improve patient safety and support consumers and staff when a clinical incident occurs.

The policy promotes best practices in CIM to:

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

The National Safety and Quality Health Service Standards (the National Standards) aim to protect the public from harm and improve the quality of health service provision. This policy is underpinned by those requirements of Clinical Governance Standard and Partnering with Consumers Standard of the National Standards that relate to the management of clinical incident.

The policy forms part of the assurance mechanisms that support the System Manager in fulfilling its functions of oversight and monitoring of the safety and quality of services provided by WA health entities.

The policy supports the WA health system to report on sentinel events to the Commonwealth. Further, episodes of care, including sentinel events, must also be reported to the Independent Health and Aged Care Pricing Authority for funding purposes.

This policy is a mandatory requirement for Health Service Providers 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 is also a mandatory requirement for the Department of Health pursuant to section 29 of the *Public Sector Management Act 1994*.

Incidents not within the scope of this policy include suspected staff misconduct, work health and safety incidents involving staff, or incidents involving visitors unrelated to providing healthcare to a patient. The management of clinical incidents, particularly the investigation process, must not be used as a method to investigate staff misconduct.

This policy is to be read in conjunction with MP 0127/20 Discipline Policy, MP 0125/19 Notifiable and Reportable Conduct Policy and MP 0015/16 Information Access, Use and Disclosure Policy

2. Applicability

This policy is applicable to WA health entities, excluding Health Support Services.

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

The requirements contained within this policy apply to the services purchased from contracted health entities where it is explicitly stated in the contract between the contracted health entity and the State of Western Australia or Health Service Provider (HSP). The State of Western Australia or HSP contract manager is responsible for ensuring that any obligation to comply with this policy by the contracted health entity is accurately reflected in the relevant contract and managed accordingly.

3. Policy Requirements

WA health entities must ensure they maintain systems and processes that provide a consistent approach to the management of clinical incidents, including:

- (i) utilising a Clinical Incident Management System (CIMS)
- (ii) preventing further harm by ensuring a robust review of a clinical incident and implementing subsequent recommendations
- (iii) supporting affected consumers
- (iv) supporting affected staff.

All clinical incidents must be managed in accordance with the best practices principles of transparency, accountability, partnering with consumers, probity, fairness and just culture, timely action, prioritisation of action and shared learning as outlined in the <u>Australian</u> Commission on Safety and Quality in Health Care Incident Management Guide.

3.1 Identification of clinical incidents

When a clinical incident (or near miss) is identified, immediate action must be taken. This includes, but is not limited to:

- implementing any preliminary actions to mitigate further risk of harm to the patient, staff, or others (i.e., carers/guardian/enduring guardian)
- ensuring the surrounding environment (physical or psychological) is safe to prevent immediate recurrence of the incident.

Clinical incidents also 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 have 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, as defined by the <u>Australian Commission on Safety and Quality in Health Care</u>. The reporting requirements for SAC 1 sentinel events are broader than the national list of sentinel events, which includes reporting of near-miss sentinel events in the WA health system.

3.2 Notification of clinical incidents

When a clinical incident has occurred, staff must:

- inform relevant management within 24 hours and follow any other local notification processes.
- notify the incident in the WA health entity's CIMS as soon as practicable (within 48 hours) of the identification of the incident.
- document a summary, any essential information, and any action(s) taken in the patient's healthcare record.
- notify the local work, health, and safety (WHS) team if a WHS hazard is suspected.
 The WHS team will determine if the incident is notifiable under the Work, Health and Safety Act 2020 and will notify WorkSafe where required.
- assign a WA health Severity Assessment Code (SAC) rating (section 3.2.1).

Where an event has not been identified at the time as a clinical incident, these initial identification and notification steps must be undertaken as soon as the WA health entity or staff becomes aware of the clinical incident. This may include an incident identified via the consumer feedback process.

The WA health entity must commence and document an appropriate level of open disclosure to the patient, their family, and carers/guardians/enduring guardians as per the <u>Australian Open Disclosure Framework</u>. They must also have processes in place to ensure support for the teams or individual staff involved in a clinical incident is provided.

3.2.1 WA Health System Severity Assessment Codes

There are three WA health system SACs which must be used:

SAC 1	A clinical incident that has or could have resulted in serious harm or death (including near miss incidents); and which is attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness.
	When the patient outcome of a clinical incident is 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	A clinical incident that has or could have resulted in moderate harm (including near miss incidents); and which is attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness.
SAC 3	A clinical incident that has or could have resulted in minor or no harm (including near miss incidents); and which is attributed to health care provision (or lack thereof) rather than the patient's underlying condition or illness.

3.3 Confirmation requirements

Relevant staff involved in CIM are to review, confirm and allocate a WA Health SAC rating within 3 working days of the incident being notified into the CIMS. The following actions must be undertaken in accordance with each confirmed SAC rating:

3.3.1 SAC 1 requirements:

Timeframes	Action		
As soon as practicable	 Commence and document in patient healthcare records and CIMS, an appropriate level of open disclosure for all SAC 1 incidents to the patient, their family, and carers/guardians/enduring guardians. 		
Within 3 working days following the confirmation of a SAC 1 clinical incident (or near miss)	Undertake and provide a serious clinical incident notification (SCIN) for SAC 1 clinical incident (or near miss) to WA health entity's executive team. The purpose of the SCIN is to: identify remaining risks to other patients and staff identify immediate actions for people to be safe and supported appoint a dedicated family contact to liaise with the family/carer/guardian make any immediate notifications to external parties such as the coroner guide the next steps to be taken.		
Within seven working days of a confirmed SAC 1 clinical incident (or near miss) or seven working days of the site becoming aware of the clinical incident	 Notify the incident to the Department of Health Patient Safety and Surveillance Unit (PSSU). Where a risk is identified through a clinical incident that is likely to impact the wider WA health system, alert Department of Health PSSU. 		

3.3.2 SAC 2 and SAC 3 requirements:

During the first 48 hours of notification, SAC 2 and 3 clinical incidents must be reviewed by the relevant staff involved in the management of clinical incidents. Relevant WA health entity staff must follow local processes to manage confirmed SAC 2 and SAC 3 clinical incidents. This includes but is not limited to:

- commence an initial investigation to identify human errors and system failures that may have led to the clinical incident occurring.
- implement preliminary actions to mitigate further risk of harm to the patient and/or staff.
- initiate an appropriate level of open disclosure processes.

3.4 Analysis and Investigation Requirements

Following the notification of a clinical incident, the relevant WA health entity must investigate to:

- establish and analyse the course of events that led to the clinical incident (or near miss).
- identify and acknowledge contributing factors that may have contributed to the incident.
- develop recommendations to address identified contributing factors to avert future harm.

The level of investigation and reporting required is determined by the SAC rating allocated to the clinical incident.

Where the clinical incident investigation identifies a WHS hazard as a causal or contributing factor, the clinical incident investigation is to continue separately to the review of the WHS incident. For more information, refer to the local WHS policies and procedures or contact the relevant WHS team.

3.4.1 Investigation requirements

WA health entities must ensure that a methodology appropriate for the circumstances of the clinical incident is employed. This includes but is not limited to considering if there is a predominance of patient factors contributing to the clinical incident in relation to the system factors. For more information, refer to the <u>Clinical Incident Management Guideline</u> section 6.4

Investigations must be undertaken in accordance with the SAC rating as per the following:

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

WA health entities must ensure that relevant staff are appropriately trained in the chosen methodology. For further information, refer to <u>section 3.7.2</u>.

If, during an investigation, it appears that notifiable and reportable conduct or a suspected breach of discipline may have occurred, then the appropriate member of the investigation team must advise the relevant Integrity/Human Resources Officer for appropriate consideration and action in accordance with MP 0125/19 Notifiable and Reportable Conduct Policy and MP 0127/20 Discipline Policy (applicable to HSPs) or the relevant Department of Health Discipline Policy. For private health entities, refer to relevant policies related to notifiable and reportable conduct and discipline.

For more information, refer to section 6.4.2 of the Clinical Incident Management Guideline.

3.5 Reporting of final investigation outcomes

WA health entities must ensure that investigation reports or equivalent meet minimum standards of quality, which include but are not limited to:

- following appropriate methodologies for clinical incident investigations.
- ensuring that there has been an appropriate level of investigation conducted and any areas for system improvement have been addressed in the recommendations and evaluations.

All clinical incidents require reporting of final investigation outcomes in CIMS. WA health entities must ensure that analysis and findings of clinical incident investigations are reported as outlined in <u>section 3.5.1</u>.

3.5.1 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 WA health entity's Chief Executive or equivalent (or as per the approved delegation schedule)					
	 be submitted to the PSSU within 45 working days of the date of 					
	notification.					
SAC 2 and 3	SAC 2 and 3 investigations must					
	• include the completion of the relevant clinical incident forms within the approved CIMS. This can constitute a final investigation report.					
	be completed within 60 working days of the clinical incident's date of notification.					

3.5.2 Feedback to staff and consumer

WA health entities are subject to a statutory duty of confidence not to disclose personal information about a person without the consent of the individual or each individual to whom the personal information relates.

WA health entities must provide feedback to staff involved in a clinical incident (or near miss) on the investigation's findings and recommendations.

Consumers who are the subject of an investigation report may request a copy of the report and may be provided with a copy of the investigation report in a form that complies with WA health entities privacy obligations.

Access to the investigation report by any other person will be subject to the Freedom of Information Act 1992.

3.5.3 Declassification and inactivation requirements

Following a clinical incident investigation, the investigation team may determine that there were no healthcare contributing factors and that the event did not meet the definition of a clinical incident. In these circumstances, a request for declassification from the PSSU and other local processes, such as inactivation in the CIMS, must be initiated.

The following must be undertaken in accordance with the confirmed SAC rating:

SAC 1	 Submit a request for declassification of the clinical incident to the PSSU for review. Following approval to declassify a SAC 1 clinical incident by PSSU, any recommendations related to incidental findings from the investigation are to be implemented, monitored, and evaluated at a local level. Approved declassification requests require the incident to be made inactive in the CIMS. 		
SAC 2 and 3	Manage inactivation as per local processes.		

If a declassification request of a SAC 1 clinical incident is rejected by the PSSU, WA health entities must review the clinical incident and develop recommendation(s) to address the contributing factor(s).

3.6 Closing the Loop

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

3.6.1 Recommendation development, implementation, and evaluation

Recommendations that address the contributing factors leading to a clinical incident must be developed.

WA health entities must ensure each recommendation:

- follows recognised methodologies in goal setting
- includes action strengths to ensure the effectiveness of altered practices in preventing the clinical incident (or near miss) from reoccurring
- is allocated to a recommendation owner responsible for its implementation
- has specified timeframes for implementation
- is evaluated for effectiveness.

WA health entities must monitor the implementation of recommendations and have escalation processes for recommendations that cannot be progressed. WA health entities must also have processes to ensure that implemented changes are communicated with staff and sustained.

3.6.2 Recommendation requirements

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

SAC 1	Following the submission of SAC 1 investigation report:			
	a progress report must be submitted to the PSSU within 6 months (182 calendar days) to advise the status of each endorsed recommendation.			
	 an evaluation report must be submitted to the PSSU within 12 months (365 calendar days) with evidence of implemented recommendation actions. 			
SAC 2 and 3	Recommendations must be evaluated within 12 months of the investigation being completed. Monitoring of these processes must occur at the WA health entity level.			

3.6.3 Sharing lessons learned

Sharing lessons learned is key to preventing future harm and making care safer. WA health entities must disseminate de-identified information on learnings from clinical incidents, including the actions taken in response to the event, in accordance with their local processes at various system levels.

Where the PSSU identifies relevant lessons for other providers, PSSU may request the WA health entity develop a synopsis of the incident and lessons learned for wider dissemination. For further guidance on the format of a synopsis report, see section 6.6.2.1 of the Clinical Incident Management Guideline.

3.7 Key considerations during analysis and investigation

WA health entities must ensure the following when managing a clinical incident:

3.7.1 Investigation of clinical incidents across WA health system boundaries

When a clinical incident occurs in the patient journey that involves multiple organisations, all WA health entities involved in the patient journey must participate in a collaborative investigation, recommendation, and evaluation plan.

For further information, refer to the <u>Guideline for the Investigation of Multi-Site Clinical</u> Incidents.

3.7.2 Education and training

WA health entities must 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 and monitor and assess the effectiveness of recommendations.

WA health entities must ensure the processes implemented for education and training are frequently evaluated to ensure the training is effective and meets the requirements to develop staff to participate in CIM.

3.7.3 Staff support and engagement

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

WA health entities must implement local processes that:

- support the wellbeing of staff involved in a clinical incident (or near miss).
- ensure staff are provided with professional development opportunities to develop skills in CIM.
- uphold the principles of just culture.
- support open sharing of lessons learned to support the delivery of safe care.

For more information, refer to section 7.3 of the Clinical Incident Management Guideline.

3.7.4 Data Quality

WA health entities must have operational procedures and guidelines to manage data quality for clinical incidents (or near misses) effectively. This includes ongoing, regular review of the data and quality improvement efforts with relevant stakeholders such as the custodians of the CIMS. This is in accordance with MP 0152/21 Information Management Governance Policy.

4. Compliance Monitoring

The PSSU on behalf of the System Manager, will monitor compliance with this policy by reviewing data reported within the clinical incident management system. System Manager compliance monitoring includes but is 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 CIMS. Action taken in response to these trends and issues will be commensurate with the associated level of system risk.
- comparing CIM information from the CIMS 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.

- case-level management of SAC 1 clinical incidents across the WA health system.
- activities such as clinical and data governance audits reporting on adherence by WA health entity to the requirements outlined in section 3 of the policy.
- aggregating clinical incident data extracted from the CIMS at a system level and producing clinical incident management reports.

The System Manager may also request additional information on local policies, processes, and systems for managing clinical incidents and implementing and evaluating recommendations and quality improvement initiatives in response to clinical incidents (or near misses) to ensure alignment with policy requirements.

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
- Closing the Loop Program Resources
- SAC 1 Clinical Incident Investigations Roles and Responsibilities
- Guideline for the Investigation of Multi-Site Clinical Incidents
- Reporting of healthcare-associated Staphylococcus aureus bloodstream infections as a SAC 1 incident
- SAC 1 Clinical Incident Investigations Consumer-Friendly Document
- SAC 1 Clinical Incident Investigations Consumer Friendly Document (e-form)
- Clinical Risk Management Guideline

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 Centre 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 (or near miss)	An event or circumstance resulting from health care provision (or lack thereof) which could have or did lead to unintended or unnecessary physical or psychological harm to a patient. This includes patients who are participating in a clinical trial.		

Clinical Incident Management (CIM)	The process of effectively managing clinical incidents with a view to minimising preventable harm.		
Clinical Incident Management System (CIMS)	An organisation's approved nominated information system used to notify, report, and investigate clinical incidents. It may also include functions to record the implementation and evaluation of recommendations.		
Closing the Loop	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 systemic lessons learned.		
Comprehensive Analysis	Used for complicated and complex incidents that resulted in serious harm, or the significant risk thereof.		
Concise Incident Analysis	A succinct, yet systematic way to analyse incidents with no, low or moderate severity of harm.		
Contributing factors	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increasing the risk of an incident.		
Consumer	A person who uses (or may use) a health service, or someone who provides support for a person using a health service. Consumers can be patients, carers, family members or other support people.		
Data Custodian	Implements MP 0152/21 Information Management Governance Policy on behalf of the steward and has the delegation authority for granting access, use and disclosure of information from Information Assets in line with legislation and policy.		
Date of notification	For SAC 1 incidents, there is the date of notification to PSSU, which is the date PSSU is notified of the SAC 1 incident. Within the 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 the CIMS. This is the CIMS date of notification field.		
Declassification	Declassification is in relation to a SAC 1 incident and means that it has been determined that the incident is not a clinical incident resulting from health care delivery.		
Hazard	Any source of potential harm or situation that may cause loss or injury to a person.		
Inactivation	A process used for events which are deemed as not within the definition of a SAC 1,2,3 clinical incident and are not used within PSSU for reporting purposes (unless specified).		
douvduoi1	Note that a SAC 1 undergoes declassification and then inactivation. A SAC 2 or 3 is deemed not a clinical incident and then inactivated.		

A culture that identifies opportunities for systemic learning from systemic failures. This is a culture that focuses on patient safety, trust, fairness, learning and accountability. Within this culture, staff, patients, carers, and families feel encouraged to speak up and report when a clinical incident occurs.			
An incident that may have, but did not result in harm, either by chance or through timely intervention.			
Notifiable and reportable conduct means conduct by a staff member that:			
 may be suspected on reasonable grounds to constitute or may constitute Professional Misconduct or Unsatisfactory Professional Performance as defined in accordance with section 5 of the Health Practitioner Regulation National Law (WA) Act 2010 (National Law) (reportable to the Department CEO pursuant to section 146(1) of the Health Services Act 2016 and/or 			
 relates to a charge for a Serious Offence (reportable to the Department CEO pursuant to Health Services Act 2016: Section 146(2): or 			
may concern a suspected breach of discipline sections 160, 161 & 162 of the <i>Health Services Act 2016</i> and/or			
 may concern Suspected Minor or Serious Misconduct as defined in accordance with section 4 of the Corruption, Crime and Misconduct Act 2003 (notifiable to the Corruption and Crime Commission or the Public Sector Commission pursuant to section 28 or 45D of the Corruption, Crime and Misconduct Act 2003). 			
An 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.			
Any person receiving health care in a health service organisation.			
A unit within 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.			
Within a WA health entity, 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. 		
Risk	The effect of uncertainty on objectives (either positive or negative).		
Severity Assessment Code (SAC) rating	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.		
Sentinel events	A subset of serious clinical incidents that has resulted in or could have resulted in serious harm or death of a patient. It refers to preventable occurrences involving physical or psychological injury, or risk thereof.		
Synopsis report	A brief summary which provides readers an overview of the main points.		
WA health entities	 WA health entities include: (i) Health Service Providers as established by an order made under section 32 (1)(b) of the Health Services Act 2016. (ii) Department of Health as an administrative division of the State of Western Australia pursuant to section 35 of the Public Sector Management Act 1994. 		
WA health system	The WA health system is comprised of: (i) the Department. (ii) Health Service Providers (North Metropolitan Health Service, South Metropolitan Health Service, Child and Adolescent Health Service, WA Country Health Service, East Metropolitan Health Service, PathWest Laboratory Medicine WA, Quadriplegic Centre, and Health Support Services); and (iii) contracted health entities, to the extent they provide health services to the State.		

8. Policy Contact

Enquiries relating to this policy may be directed to:

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9. Document Control

Version	Published date	Review date	Amendment(s)
MP 0122/19	1 November 2019	November 2022	Original version
MP 0122/19 v.1.0	19 July 2023	November 2022	Amendments as listed below.

Broken hyperlinks amended throughout the supporting information documents: Clinical Incident Management Guideline and Clinical Incident Management Toolkit.

MP 0122/19	19	Effective from	December	Policy review and amendment,
v.2.0	December	date	2027	as detailed below.
	2024	23 January		
		2025		

- Purpose section refined.
- Applicability section contracted health entities statement updated. Removal of requirements applicable to HSS.
- Policy requirement sections strengthened, refined, and updated.
- Policy requirement timeframes updated to support WA health entities in conducting thorough clinical incident investigations.
- Compliance monitoring section updated to reflect PSSU as the policy owner and responsibility for policy compliance on behalf of System Manager.
- Definitions section: Inclusion of 'Closing the loop', 'Comprehensive analysis', 'Concise Incident analysis', 'Contributing factors', 'Consumer', 'Data custodian', 'Hazard', 'Just culture', 'Risk and Notifiable' and 'Reportable conduct', 'Synopsis report' and 'WA health entities' definitions. Removal of 'Notifier' definition.
- Supporting information documents: Clinical Incident Management Guideline and Clinical Incident Management Toolkit refined and updated. Inclusion of Clinical Incident Management Toolkit within the Clinical Incident Management Guideline.

Note: Mandatory policies that exceed the scheduled review date will continue to remain in effect.

10. Approval

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

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