Clinical Incident Management Policy

Department of Health 2012

This policy integrates the:

Clinical Incident Management Policy 2012

The Clinical Incident Management Policy was originally released in September 2011. A 12 month follow up evaluation was conducted and this document was updated in October 2012. For the latest version of this document, please visit: http://www.safetyandquality.health.wa.gov.au

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Suggested Citation:

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Foreword

Western Australians deserve the highest quality of health care available and WA Health is committed to ensuring that clinical excellence in patient/consumer care is delivered.

The basic tenet of quality health care is to “do no harm”, however sometimes human error does occur and it is only by acknowledging and learning from these errors that WA Health can strive to achieve clinical excellence.

Incident notification and audit is a fundamental element in clinical incident management and vital to achieving improvements in patient/consumer care and safety. By critically evaluating our service we are able to identify, treat, and respond to hazards appropriately in order to protect our patients/consumers and prevent further incidents.

In an effort to streamline WA Health policy and procedures, this policy now integrates the:


The integration of these policies provides staff with the necessary information needed to safely and effectively manage clinical incidents and drive improvements in patient/consumer care.

System-wide improvements can only be achieved through the dedication and professionalism of staff and so I take this opportunity to thank them for their ongoing commitment to safe, high quality care for patients/consumers in Western Australia.

Kim Snowball
Director General
WA Health
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## Definitions

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<td><strong>Absconding</strong></td>
<td>Refers to inpatients (voluntary and involuntary) and involuntary patients living in the community who refuse further treatment despite significant risk to health and safety and who leave without discussion with the treating clinicians.</td>
</tr>
<tr>
<td><strong>Adverse event</strong></td>
<td>An adverse event is a clinical incident where an injury/harm is caused by medical management or complication thereof, instead of the underlying disease. It results in an increase in the level of care and/or prolonged hospitalisation and/or disability at the time of discharge. Medical management refers to management under health care services.</td>
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<tr>
<td><strong>AIMS</strong></td>
<td>AIMS refers to the Advanced Incident Management System which is a software product used as part of clinical incident management to capture clinical incidents.</td>
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| **Clinical incident** | A clinical incident is an event or circumstance resulting from health care which could have, or did lead to unintended and/or unnecessary harm to a patient/consumer. Clinical incidents include:  
  - **Near miss** is an incident that may have, but did not cause harm, either by chance or through timely intervention.  
  - **Adverse event** as above.  
  - **Sentinel event** refers to unexpected occurrences involving death or serious physical or psychological injury, or risk thereof. Please refer to the eight national sentinel event categories listed in Appendix 1. |
| **Clinical incident management** | Clinical incident management is the process of effectively managing clinical incidents with a view to minimising preventable harm. |
| **Clinician**    | For the purpose of this document, clinician refers to all health professionals providing clinical care, including medical officers, nurses, midwives, and allied health professionals. |
| **Corrective actions** | Those direct actions taken in the immediate, short, medium, or long term to rectify or minimise the risk of harm to patients/consumers. |
| **Escalation**   | The organisational level to which an incident must be notified and the timeframe in which this must occur. |
| **Hazard**       | A circumstance, agent or action that can lead to or increase risk. |
| **Health professional** | Includes but not limited to, doctors, nurses, midwives and allied health professionals. |
Misconduct: Occurs where a WA public officer:
- Behaves corruptly in their role as a public officer.
- While acting in their official capacity, commits an offence punishable by imprisonment for two years or more.
- Is involved in a breach of trust, or acts with some element of dishonesty or lack of integrity and is involved in conduct that could reasonably result in their dismissal.

The abovementioned acts are to be reported to the (Crime and Corruption Commission (CCC). A second category of misconduct not reported to the CCC includes:
- Disobeys or disregards a lawful order.
- Contravenes any provision of the Public Sector Management Act 1994 or other relevant legislation applicable to that staff member.
- Contravenes a public sector standard, code of ethics or WA Health policy.
- Is negligent or careless in the performance of his or her functions.

Near miss: Incidents that may have, but did not cause harm, either by chance or through timely intervention.¹

Open disclosure: Open disclosure is the open discussion of an incident that results in harm (or might result in future harm) to a patient/consumer while receiving health care.

Qualified privilege: The legal prohibition which may restrict the disclosure of information and documentation created for the purpose of investigations into clinical incidents in accordance with the provisions of the Health Services (Quality Improvement) Act 1994.

Patient/consumer: Refers to any person receiving health care from a WA Health service either as an inpatient /outpatient or community setting.
SAC:

Severity Assessment Code is the assessment of consequences associated with a clinical incident. The SAC rating (1, 2 or 3) is used to determine the appropriate level of analysis, action and escalation.²

**SAC 1** includes all clinical incidents/near misses where serious harm or death is/could be specifically caused by health care rather than the patient's underlying condition or illness.² In WA, SAC 1 also includes the eight nationally endorsed sentinel event categories.³

**SAC 2** includes all clinical incidents/near misses where moderate harm is/could be specifically caused by health care rather than the patient's underlying condition or illness.²

**SAC 3** includes all clinical incidents/near misses where minimal or no harm is/could be specifically caused by health care rather than the patient's underlying condition or illness.²

Sentinel event:

Refers to unexpected occurrences involving death or serious physical or psychological injury/harm or risk thereof.¹

There are eight nationally endorsed sentinel event categories (see the eight sentinel event categories listed in Appendix 1).

WA Health:

Refers to the whole of the WA public health system (hospitals and health services).

WARM:

Western Australian Review of Mortality. Mandatory mortality review processes establish a consistent approach to the classification and review of all inpatient deaths (including surgical deaths). Mortality review aims to reduce preventable deaths by ensuring all inpatient deaths are systematically reviewed to identify preventable deaths/clinical incidents and that recommendations for improvement arising out of mortality reviews are implemented to improve patient/consumer care. Preventable deaths identified via mortality review processes are to be notified as a SAC 1 clinical incident.

1. Purpose

The purpose of the Clinical Incident Management (CIM) Policy (the Policy) is to ensure appropriate management of clinical incidents to prevent or reduce future harm to patients/consumers by:

- identifying and treating hazards before they cause harm
- identifying when patients/consumers are harmed and intervening promptly to minimise the harm
- taking preventative actions and sharing lessons learned.

2. Scope of Policy

The Policy is an integration of all clinical incident management processes within WA Health. This Policy supersedes the following policies:


This Policy also introduces Severity Assessment Codes (SAC) comprising three rating levels used to determine the appropriate level of analysis, action and escalation of a clinical incident according to harm caused to the patient/consumer (see section 6.3 for further information).

It is a WA Health requirement to notify all clinical incidents. As such all clinical incidents within public hospitals/health services (HS) are to be notified via the Clinical Incident Management System (AIMS or equivalent database). Notification of SAC 1 clinical incidents are mandatory for all health service staff and contract staff, including both salaried and non-salaried visiting medical officers (see section 6.2).

Private licensed health care facilities, in accordance with their license with WA Health, are required to report all incidents resulting in serious harm or death of a patient/consumer and conduct an inpatient mortality review. This includes all sentinel events (categories 1-8) which will now be reported as a Severity Assessment Code (SAC) 1 incident to the Patient Safety Surveillance Unit (PSSU).

Other health service providers are to comply with this Policy as per their contract arrangements with WA Health (see section 4.3).

Hospitals/health services are to maintain systems and processes that comply with this Policy in order to provide a consistent approach to identification, notification, investigation, analysis, reporting and monitoring of clinical incidents.
This Policy is to be read in conjunction with the following WA Health policies, guidelines and related Operational Directives (available via: http://www.health.wa.gov.au/circularsnew/index.cfm):

- Clinical Risk Management Guidelines for the Western Australian Health System Policy and Operational Circular OP 1989/05.
- Non-Salaried Medical Officers: Protocol for Notifying and Managing Medical Treatment Liability Claims/Potential Claims (Non-Teaching Hospitals, Operational Circular OP 1850/04).
- Matters to be reported to the Chief Psychiatrist, (Operational Directive OD 0242/09).

3. Principles

WA Health’s CIM Policy is based on the following principles of clinical governance:2

**Transparency** – full and open communication shall occur as part of clinical incident management. As appropriate, patients/consumers, staff and visitors notifying clinical incidents should receive feedback on results of any investigation and preventative actions carried out.

**Accountability** – WA hospitals/health services have a duty to take reasonable care to avoid harm to patients/consumers, staff and visitors. Individuals understand they may be held accountable for their actions.

**Probity/Fairness** – staff, patients/consumers and visitors involved in clinical incidents will be entitled to fair treatment by WA hospitals/health services.

**Patient/consumer centred care** – analysis of incidents should focus on ‘what happened?’ ‘why did it happen?’ and ‘how could it be prevented from occurring again?’ Appropriate patients/consumers and/or their nominated relatives/carers should be asked to contribute to the investigative process. Implementation and evaluation of corrective actions is essential.

**Open 'just' culture** – analysis and investigation of clinical incidents should focus on identifying and correcting underlying system problems rather than focusing on an individual. If misconduct by an individual is suspected refer to section 5.2.

**Obligation to act** – the responsibility to take action to correct problems is clearly accepted.

**Prioritisation** – resources are directed to areas where the greatest improvements are possible.
4. Roles and Responsibilities

To be effective, clinical incident management requires a ‘whole of organisation’ approach that fosters a ‘no blame’ reporting culture and incorporates the following roles and responsibilities.

4.1 Responsibilities of All Staff

To notify clinical incidents and participate in:

- investigations
- implementing recommendations
- evaluating recommendations
- feedback
- learning and sharing lessons

4.2 Responsibilities of Public Hospitals/Health Services

Hospitals and Health Services are required to:

- Notify the PSSU and where applicable the Office of the Chief Psychiatrist of all SAC 1 clinical incidents, which includes sentinel events, within seven working days of the event. Severity Assessment Codes are discussed further in section 6.3.
- Undertake the Open Disclosure Process with patients/consumers and their nominated relatives/carers.
- Support staff following a clinical incident – by debriefing and/or counselling (both internal and external).
- Provide staff training in clinical incident management and investigation methods.
- Initiate appropriate investigations of clinical incidents.
- Report investigation findings – SAC 1 de-identified clinical incident investigation reports to PSSU within 45 working days of the event notification. Please contact PSSU if there are any problems with achieving this reporting requirement.
- Refer to section 11 for other statutory reporting requirements.
- Implement and evaluate recommendations from clinical incident investigations.
- Provide updates to the PSSU on a six monthly basis on the status of the implementation of SAC 1 clinical incident recommendations. Complete the implementation of recommendations within 12 months of completion of the investigation.
- Work collaboratively to investigate clinical incidents with other hospital/health service providers/organisations when incidents occur across health service boundaries (see section 6.4.3).
- For clinical incidents that are, or who have the potential to result in legal proceedings, contact with on site/HS medico-legal staff and the Safety, Quality and Performance Team is required. Hospitals and health services are also required to notify/report incidents in accordance with other statutory, medico-legal and insurance requirements (see section 11).
4.3 Responsibilities of Private Licensed Health Care Facilities and Non Government Organisations

Private licensed health care facilities and non government organisations in accordance with their license or contractual agreements with WA Health, are required to report ALL incidents resulting in serious harm or death of a patient/consumer. This includes all sentinel events (categories 1-8) which will now be reported as a SAC 1 clinical incident to the PSSU. Private licensed health care facilities and non government organisations are required to:

- Notify the PSSU of all SAC 1 clinical incidents (including sentinel events) within seven working days of the event’s occurrence.
- Notify the WA Health Licensing Standards Review Unit of all SAC 1 clinical incidents within 48 hours.
- Initiate appropriate investigations of all SAC 1 clinical incidents (including sentinel event categories 1-8) (see Appendix 1).
- Refer to section 11 for other statutory reporting requirements.
- Report investigation findings to the PSSU within 45 working days of the event notification. Please contact PSSU if there are any problems with achieving this reporting requirement.
- Provide updates to the PSSU on a six monthly basis on the status of the implementation of recommendations and complete the implementation of recommendations within 12 months of completion of the investigation.
- Work collaboratively to investigate clinical incidents with other hospital/health service providers/organisations when incidents occur across health service boundaries (see section 6.4.3).

Other health service providers including those contracted and licensed health services who deliver clinical care are to comply with this Policy as per their contract arrangements with WA Health.

4.4 Responsibilities of the Patient Safety Surveillance Unit

The PSSU is required to:

- monitor and maintain executive oversight of the clinical incident management process
- share lessons learned at a system level
- develop clinical incident management policy
- analyse and report de-identified aggregate data at a system level
- produce clinical incident management annual reports
- maintain support of the CIM database in association with the Health Information Network.

4.5 Responsibilities of the Office of the Chief Psychiatrist (OCP)

The OCP requires the investigation and reporting of both serious incidents and unexpected deaths of patients/consumers/residents in any mental health service/facility including those events that occur to WA Health patients/consumers receiving health care services in the community.
5. Clinical Incidents, Adverse Events, Sentinel Events, and Severity Assessment Codes

A clinical incident is an event or circumstance resulting from health care which could have, or did lead to unintended and/or unnecessary harm to a patient/consumer. Clinical incidents include:

- **Near miss** – an incident that may have, but did not cause harm, either by chance or through timely intervention.¹
- **Adverse event** – is a clinical incident where an injury/harm is caused by medical management or complication thereof, instead of the underlying disease. It results in an increase in the level of care and/or prolonged hospitalisation and/or disability at the time of discharge.¹ Medical management refers to management under health care services.¹
- **Sentinel event** – refers to unexpected occurrences involving death or serious physical or psychological injury, or risk thereof.¹ See the eight nationally endorsed sentinel event categories listed in Appendix 1.³

The above-mentioned incidents are further categorised using the following SAC ratings, to determine the appropriate level of analysis, action and escalation:

- **SAC 1** includes all clinical incidents/near misses where serious harm or death is/could be specifically caused by health care rather than the patient’s underlying condition or illness.²
- **SAC 2** includes all clinical incidents/near misses where moderate harm is/could be specifically caused by health care rather than the patient’s underlying condition or illness.²
- **SAC 3** includes all clinical incidents/near misses where minimal or no harm is/could be specifically caused by health care rather than the patient’s underlying condition or illness.²

5.1 Mental Health Patients

With regard to clinical incidents involving mental health patients, the focus should be on how did health care delivery or the lack of health care delivery contribute to the clinical incident occurring.

For example a mental health patient who is deemed a ‘suicide risk’ absconds from hospital and commits suicide. From a clinical incident perspective an investigation would be required to ascertain if all appropriate health care strategies were in place to prevent the patient from absconding and self harming.
5.2 Clinical Incidents within the Scope of this Policy

For the purposes of notification to the Clinical Incident Management System, staff are to notify clinical incidents that meet the definitions listed on the previous page. Examples of clinical incidents include but are not limited to the following:

- procedures involving the wrong patient or body part resulting in death or major permanent loss of function
- suicide of an inpatient
- retained instruments or other material after surgery requiring re-operation or further surgical procedures
- intravascular gas embolism resulting in death or neurological damage
- haemolytic blood transfusion reaction resulting from ABO incompatibility
- medication error resulting in death of a patient
- maternal death or serious morbidity associated with labour or delivery
- infant discharged to wrong family or infant abduction
- adverse events resulting in serious patient harm or death
- fetal complications associated with health care delivery
- delay in recognising or responding to clinical deterioration
- complications of resuscitation
- complications of anaesthetic management
- complications of surgery
- complications of an inpatient fall
- infection control breaches
- unexpected death of a mental health patient/consumer
- absconding of any mental health patient/consumer
- therapeutic equipment failure/medical device incident
- self harm, suicidal behaviour
- hospital acquired pressure injuries.

See the SAC 1 Clinical Incident Notification List of incidents in Appendix 1 for further examples.

Note: The line manager or local Risk Manager or HS Safety Quality and Performance team can provide guidance where staff are unsure whether to notify an incident.
5.3 Incidents Outside the Scope of this Policy

Incidents that should not be reported through the CIM process include (but are not limited to):

- Occupational Safety and Health incidents that involve staff only e.g. tripping on carpet.
- Incidents involving visitors unrelated to the provision of a health care service to a patient e.g. visitor spilling hot drink on themselves.
- Allegations or suspicions of:
  - misconduct (see definition section)
  - workplace aggression between staff e.g. rudeness, bullying
  - physical or verbal aggression from non-mental health patients or visitors toward staff where the patient is not harmed
  - physical altercation or sexual misconduct by staff involving a patient/consumer
  - suspected or alleged alcohol/substance use by a staff member/health care provider.

For further information refer to the following WA Health policy and Operational Directive:

- Amendment to WA Health Misconduct and Discipline Policy and Guidelines (2011) (Operational Directive OD 0323/11)
- Code of Practice: Violence, Aggression and Bullying at Work (2006)

6.0 The Clinical Incident Management Process

The key steps to effective clinical incident management are:

1. identification of a clinical incident, take immediate action necessary to reduce risk to the patient/consumer and undertake the open disclosure process (see section 6.2.4)
2. notification
3. prioritisation of investigation
4. analysis and investigation
5. development of recommendations
6. reporting of investigation outcomes
7. feedback
8. implementation of recommendations
9. monitoring of recommendations
10. evaluation of recommendations.

For detailed guidelines on how to manage a clinical incident refer to the Clinical Incident Management Toolkit which is available at [www.safetyandquality.health.wa.gov.au](http://www.safetyandquality.health.wa.gov.au)
Figure 1 depicts the clinical incident management system process used within WA Health and shows how this process is integrated within a framework for safety, quality and risk management.

**Figure 1: Clinical Incident Management Framework**

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6.1 Identification of a Clinical Incident and Immediate Action

A clinical incident may be identified by a patient/consumer, visitor or any staff member. It is important for all staff to recognise when a clinical incident has occurred. When a clinical incident is identified, **immediate action** should be taken to reduce risk to the patient/consumer. This action may include:

- providing immediate care to the patient/consumer involved in the incident
- 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 as a result of a clinical incident.

6.2 Notification of Clinical Incidents

6.2.1 Who Can Notify?

Any staff member can identify that a clinical incident has occurred (including both salaried and non-salaried visiting medical officers). Please note that the Department of Health’s medical indemnity cover will not be jeopardised by statements made by a doctor in the course of reporting activities to their employer, nor where the doctor has in good faith, acted in accordance with open disclosure principles.

 Patients/consumers or visitors to hospitals/health services can also notify clinical incidents. This may be via the Nurse Manager, Patient/Customer Liaison Unit or other appropriate avenues for the hospital/health service.

6.2.2 How to Notify

Notification of a clinical incident is made via a hard copy clinical incident form (refer to your line manager for this form). However, WA Health is currently working toward implementing an electronic notification system.

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/consumer's medical record.

6.2.3 Notification Requirements and Timeframes

Clinical incidents must be notified immediately to management and documented in the patient’s medical notes by the end of the notifier’s work day. All SAC 1 clinical incidents (including Sentinel Events) require mandatory notification to the hospital/health service executive as per hospital/health service guidelines and to the Director of Performance and the Chief Psychiatrist (for mental health patients/consumers) within seven days of the clinical incident occurring (see Appendix 2 for where to access SAC notification templates).
Private licensed health care facilities and non government organisations in Western Australia are also required to report SAC 1 clinical incidents (including Sentinel Events) in accordance with their licensing requirements/contractual agreements to the PSSU. Sentinel Events must be notified using the SAC 1 clinical incident notification form (see Appendix 2 for where to access notification templates). Additionally, the WA Health Licensing Standards Review Unit is to be notified of all SAC 1 clinical incidents within 48 hours.

6.2.4 Open Disclosure Process

All clinical incidents require the initiation of an open discussion when a clinical incident occurs. The Open Disclosure Process (in accordance with the WA Open Disclosure Policy), ideally should take place within 24 hours of the clinical incident occurring. Note: The Department of Health’s medical indemnity cover will not be jeopardised by statements made by a doctor in the course of reporting activities to their employer, nor where the doctor has in good faith, acted in accordance with open disclosure principles.


6.3 Prioritisation of investigation

Before an investigation of the clinical incident can take place, a severity assessment rating must be decided which will determine the prioritisation of the clinical incident investigation (see Table 1 for further details). There are three Severity Assessment Codes (SAC):

- **SAC 1** includes all clinical incidents/near misses where serious harm or death is/could be specifically caused by health care rather than the patient’s underlying condition or illness.
- **SAC 2** includes all clinical incidents/near misses where moderate harm is/could be specifically caused by health care rather than the patient’s underlying condition or illness.
- **SAC 3** includes all clinical incidents/near misses where minimal or no harm is/could be specifically caused by health care rather than the patient’s underlying condition or illness.
Table 1: WA Health Severity Assessment Codes (SAC) to be used by Public Hospitals and Health Services

<table>
<thead>
<tr>
<th>Actual/potential consequence to patient/consumer</th>
<th>SAC 1</th>
<th>SAC 2</th>
<th>SAC 3</th>
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<tbody>
<tr>
<td>Serious harm or death that is/could be specifically caused by health care rather than the patient’s underlying condition or illness.</td>
<td>Moderate harm that is/could be specifically caused by health care rather than the patient’s underlying condition or illness.</td>
<td>Minor or no harm that is/could be specifically caused by health care rather than the patient’s underlying condition or illness.</td>
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Type of event/incident

**SAC 1 clinical incidents include:**
- National Sentinel Event Categories (see categories 1-8 below)
- Any other clinical incident which results in serious harm or death of a patient/consumer
- Increased length of stay greater than 7 days
- Near miss that could have resulted in serious harm or death.

1. Procedure involving the wrong patient or body part resulting in death or major permanent loss of function.
2. Suicide of a patient in an inpatient unit (or whilst on leave).
3. Retained instruments or other material after surgery requiring reoperation or further surgical procedures.
4. Intravascular gas embolism resulting in death or neurological damage.
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility.
7. Maternal death or serious morbidity associated with labour or delivery.
8. Infant discharged to wrong family or infant abduction.

**SAC 2 clinical incidents include,** but are not limited to, the following:
- Increased length of stay (More than 72 hours to 7 days)
- Additional investigations performed
- Referral to another clinician
- Surgical intervention
- Medical intervention
- Near miss that could have resulted in moderate harm.

**SAC 3 clinical incidents include,** but are not limited to, the following:
- No harm
- Only first aid treatment required
- Minor harm resulting in increased length of stay of up to 72 hours
- Near miss that could have resulted in minor harm.

Action required

- Notify management and submit a notification via CIMS or equivalent by end of notifier’s work day.
- Document the clinical incident in the patient’s medical notes.
- Notify executives as per hospital/health service guidelines and Health Service Safety Quality and Performance team.
- Undertake a formal Open Disclosure Process.
- Complete and submit an SAC 1 notification form to PSSU (and the Office of the Chief Psychiatrist (OCP) for mental health patients/consumer) within seven working days and other reporting as required (see section 11 of this Policy).
- Undertake SAC 1 investigation by Root Cause Analysis (RCA) or equivalent*.

**SAC 2 clinical incidents include,** but are not limited to, the following:
- Complete and submit a notification via CIMS.
- Document the clinical incident in the patient’s medical notes.
- Notify Unit Manager/Director within 24 hours.
- Investigate at a local level an incident using clinical review as a minimum requirement.

**SAC 3 clinical incidents include,** but are not limited to, the following:
- Complete and submit a notification via CIMS.
- Document the clinical incident in the patient’s medical notes.
- Notify Unit Manager within 24 hours.
- Investigate at a local level an incident using aggregated analysis or similar tools.

Reporting requirements

- Completed investigation report is to be sent to the PSSU, OCP (incidents concerning mental health patients/consumers) and Health Service Safety Quality and Performance team within 45 working days of notification.
- Refer to section 11 of this Policy for other reporting requirements.

**SAC 2 clinical incidents include,** but are not limited to, the following:
- Complete investigation and actions taken within 60 working days of incident notification.

**SAC 3 clinical incidents include,** but are not limited to, the following:
- Complete investigation and actions taken within 60 working days of incident notification.

* For other equivalent investigation methods which can be used in place of an RCA please see section 6.4.2 or section 3 of the CIM Toolkit.
6.4 Analysis and Investigation

6.4.1 Investigation of Clinical Incidents with or without Qualified Privilege

The Health Services (Quality Improvement) Act 1994 (QI Act) provides a framework to facilitate the investigation of Clinical Incidents. The WA QI Act is available at: http://www.slp.wa.gov.au/Index.html

Investigations are conducted through an approved quality improvement committee established under the QI Act.

The QI Act encourages health professionals to participate in quality improvement processes and aims to improve the quality of clinical care. In some circumstances, documents and information created for the purpose of the committee’s functions may be prohibited from disclosure.

Alternatively, hospitals/health services may decide to conduct an investigation outside of the framework established by the QI Act.

Further information on the State Qualified Privilege scheme, including disclosure of information, can be found in the Qualified Privilege Guidelines, available at: http://www.safetyandquality.health.wa.gov.au

For additional advice on the matter of patient confidentiality and the release of patient information for the purposes of clinical incident investigations or Freedom of Information requests etc, staff should consult with their Risk Manager/Safety, Quality and Performance team and/or the Department of Health’s Legal and Legislative Services or the State Solicitor’s Office, as appropriate.

6.4.2 Analysis and Investigation of Clinical Incidents

All notified clinical incidents require review by the line manager/delegated authority (i.e. Risk Manager or Safety Quality and Performance team) to determine the level of investigation and escalation required.

The analysis and investigation phase is used to establish the course of events and to identify the contributing factors.

A SAC 1 clinical incident requires a RCA investigation or similar methodology identified by the notifying organisation for the appropriate investigation of the incident. Examples of methodologies include the London Protocol, Failure Modes and Effects Analysis (FMEA), Human Error and Patient Safety (HEAPS) or Health Record Review. See the CIM Toolkit, for more details, which is available at: http://www.safetyandquality.health.wa.gov.au

A SAC 2 clinical incident requires a clinical review or investigation using an appropriate methodology. SAC 3 clinical incidents require investigation using aggregated analysis or a similar tool.

Consideration should be given to providing patients/consumers 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.
If during the course of the investigation it is suspected that the clinical incident may contain elements of misconduct, the investigation team should refer the matter to the hospital/health service Risk Manager/Director of Safety, Quality and Performance, or other relevant senior manager so it can be addressed using the appropriate management and governance processes.

The clinical investigation should continue separately to the misconduct processes unless advised by the hospital/health service Risk Manager/Director of Safety, Quality and Performance, or other relevant senior manager to cease the investigation.

6.4.3 Investigation of Clinical Incidents Across Health Service Provider Boundaries

For complex clinical incidents involving a number of hospitals and health service providers, all organisations are to be consulted and are expected to participate in a collaborative investigation plan, including but not limited to non-government care providers such as St John Ambulance, Royal Flying Doctor Service or Health Direct services (see Appendix 3).

This will:

- ensure the development of effective recommendations to address system issues at multiple points across the health system, and
- facilitate the inclusion of transport and non-government health care providers.

The last hospital/health service providing care (e.g. 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/consumer in establishing the investigation.

There are a number of investigation options to be considered where multiple hospitals/health services are involved in the care of the transferred patient/consumer including:

a) Joint investigation involving all hospitals/health services.

b) Investigation by the hospital/health service where the clinical incident occurred.

c) External review to obtain expert opinion.

Note: The last hospital/health service providing care is also required to:

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

When undertaking investigations across health service boundaries, hospitals/health services need to take into consideration the issue of patient confidentiality. For further advice on the matter of patient confidentiality and the release of patient information for the purposes of clinical incident investigations, public hospitals/health services should consult with Legal and Legislative Services or the State Solicitor's Office as appropriate.
6.4.4 Accessing Post-Mortem Reports for the Investigation of Clinical Incidents

The Office of the State Coroner routinely sends hard copies of all forensic Post-Mortem Reports (PMR) by mail to public hospitals for inclusion in the deceased patient’s/consumer’s medical records. Where a recent PMR is required promptly by a public hospital for quality improvement purposes (e.g. completing mortality review or investigation of an SAC 1 clinical incident), medical staff or the Safety and Quality Executive may request a faxed copy of the report via the PSSU Coronial Liaison Unit. Business Rules for accessing a confidential PMR via the PSSU Coronial Liaison Unit are available at: www.safetyandquality.health.wa.gov.au or call 9222 2154.

In the event that post-mortem reports are not available, clinical investigation processes should not be delayed as this would result in lost information and a delay in implementation of outcome measures. The level of initial clinical investigation should be determined locally according to the requirements of the case. This may not require an RCA but other modalities such as a clinical review may be suitable. If the PMR report provides any additional information, this can be addressed subsequently.

6.5 Development of Recommendations

Recommendations must:
- address the causative/contributory factors and lead to system improvements
- be assigned to a particular position responsible for the implementation
- have a specified timeframe for completion (within 12 months for SAC 1 incidents)
- be endorsed by the Chief Executive (or delegate) of the hospital/health service, private licensed health care facility or non government organisation.

For information regarding the development of recommendations refer to the CIM Toolkit available at: www.safetyandquality.health.wa.gov.au

6.6 Reporting of Investigation Outcomes

SAC 1 clinical incident investigation report

Following endorsement of the final investigation report (including recommendations), the signed report is to be forwarded to the Health Service Safety Quality and Performance team and the PSSU within 45 working days of the incident notification date (see Appendix 2 for reporting template details).

SAC 2 and SAC 3 clinical incident investigation outcomes

Health Services should have in place processes for the reporting and follow-up of SAC 2 and SAC 3 clinical incidents. All SAC 2 and SAC 3 clinical incidents require the completion of investigation and actions taken within 60 working days of the clinical incident being notified. The completion of the clinical incident form (CIF) may be submitted as the final report.
6.7 Feedback

Feedback on submission of a notification is to be given by the line manager/delegated authority involved with the incident follow-up. The success of clinical incident management is dependent on feedback to all staff on the recommendations/outcome of investigations in a timely manner. Lack of feedback from incident reporting has been highlighted as inhibiting the willingness of staff to report incidents.5

For suggested models of feedback refer to the CIM toolkit available at: www.safetyandquality.health.wa.gov.au

Feedback to patient/consumer and nominated relative/carer is to occur as part of the Open Disclosure Process.

6.8 Implementation of Recommendations

Recommendations arising from clinical incident investigations are to be implemented within 12 months of the finalised investigation. For all SAC 1 clinical incidents, public hospitals/health services, private licensed health care facilities and non government organisations are required to notify the Health Service Safety Quality and Performance team and the PSSU when recommendations have been completed. Once all recommendations are implemented and evaluated the clinical incident is considered closed.

6.9 Monitoring of Recommendations

The PSSU will request information from hospitals/health services and private licensed health care facilities and non government organisations regarding implementation of SAC 1 clinical incident recommendations on a six monthly basis. For SAC 2 and SAC 3 clinical incidents the responsibility for monitoring the implementation of recommendations is managed at a hospital/health service level.

6.10 Evaluation of Recommendations

When all recommendations have been implemented and given time to embed (e.g. six months post implementation) the hospital/health service should evaluate the effectiveness of the strategies in order to validate that improvements have been made.6 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.6

For suggested evaluation methods refer to the CIM Toolkit available at: www.safetyandquality.health.wa.gov.au
6.11 Disposal of Clinical Incident Forms

For hospitals/health services which utilise the Clinical Incident Management System (AIMS) for capturing their clinical incidents, hard copy of the clinical incident, analysis and investigative recommendation forms must be kept for seven years.

It is permissible to retain scanned copies of the clinical incident analysis and investigative recommendation forms and destroy the hard copy after six months, please refer to the General Disposal Authority for Source Records available at: http://www.sro.wa.gov.au/pdfs/GDA_SourceRecords.pdf

7. Sharing Lessons Learned

“Closing the loop” is the completion of the process where recommendations arising from the investigation into clinical incidents are disseminated at multiple levels of the health system resulting in change to procedure/policy/clinical practice to prevent the recurrence of health care-related errors and ultimately increase patient safety.6

Essentially “closing the loop” involves two key steps:

1. 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.

2. Ensuring that these changes are implemented ‘on the ground’ and evaluating their effectiveness in altering practice and behaviour and preventing the recurrence of clinical incidents.6

Health Services are required to disseminate de-identified information in accordance with their current processes to ensure the sharing of lessons learned.

8. Patient Safety Alert System

The WA Health Patient Safety Alert System includes three different options for the dissemination of patient safety information depending on the priority of the response required by hospitals/health services.

1. Patient Safety Alerts (red)
2. Safer Practice Notice (amber)

In the event of a clinical incident investigation, hospitals/health services should consider if the incident has system wide implications for patient safety. Once a clinical risk has been identified, the Office of Safety and Quality will undertake an assessment of the patient safety issue to determine the level of response and action required by hospitals/health services in accordance with the Patient Safety Alert Policy.

Refer to the Patient Safety Alert Policy found at: www.safetyandquality.health.wa.gov.au
9. Coronial Investigations

In some circumstances, preventable deaths investigated by the hospital/health service as a clinical incident may become subject to examination by the Office of the State Coroner. The hospital/health service should seek advice regarding the release of documents generated from a clinical incident investigation from the Department of Health’s Legal and Legislative Services Directorate (for a non-tertiary hospital) or the State Solicitor’s Office (for a tertiary hospital).

10. Declassification/Inactivation of Clinical Incidents

10.1 Declassification of a Severity Assessment Code 1 Clinical Incident

Following the comprehensive and systematic investigation of a notified SAC 1 clinical incident (including sentinel events), the hospitals/health services’ investigation team may determine that no causative factors contributed to the patient’s/consumer’s outcome and in fact the event was not preventable.

Hospitals/health services reaching these conclusions may request declassification of the incident by completing the declassification request section located on the SAC 1 Clinical Incident Report Form and submitting the request to the PSSU.

Declassification requests received by PSSU are tabled at the Peak Incident Review Committee (PIRC*) meeting where members consider the outcomes of the investigation and determine if the clinical incident is to be declassified as an SAC 1 clinical incident. Following approval to declassify an SAC 1 clinical incident by PIRC, hospitals/health services are required to implement any recommendations developed from the investigation to improve patient/consumer care and monitor and evaluate these at a local level.

For those organisations using the Clinical Incident Management System (via AIMS), once an incident has been declassified it can then be inactivated on the CIMS by contacting your Risk Manager or HS Safety Quality and Performance team.

10.2 Inactivation of a Severity Assessment Code 2 or 3 Clinical Incident

After appropriate investigation of an SAC 2 or 3 clinical incident the investigation team may determine that no causative factors contributed to the patient’s/consumer’s outcome and in fact the event was not preventable. For inactivation of an SAC 2 or 3 clinical incident please contact your Risk Manager or HS Safety Quality and Performance team.

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*b The Peak Incident Review Committee (PIRC) provides executive oversight of SAC I clinical incidents, the WA Sentinel Event Program, Coronial Liaison Unit and mandatory mortality review processes. Membership includes the Executive Director of the Performance Activity and Quality Division, Chief Medical Officer, Director of Performance, Chief Psychiatrist, Chief Nurse and Midwifery Officer, Chief Health Professions Officer, and representatives from the health services and private healthcare sector.
11. Statutory Reporting Requirements

Statutory reporting requirements include:

- assessment of the Extinction of Life and the Certification of Death (See Operational Directive OD 0087/07 for reporting requirements).
- maternal deaths must be reported to the Executive Director, Public Health
- perinatal and infant deaths must be reported to the Executive Director, Public Health
- deaths of persons under anaesthesia must be reported to the Executive Director, Public Health
- reportable deaths must be reported to the Office of the State Coroner
- patient/consumer suicides and serious clinical incidents that occur in mental health services or in the community throughout WA must be reported to the Office of the Chief Psychiatrist.

For further information on reporting requirements please refer to the Death in Hospital Form and Guidelines information circular (IC 0083/11) is available from:

Information regarding statutory notifications and authorisations is available by calling 9222 2295 or go to the Public Health internet site:

Information regarding coronial reporting requirements is available from the Legal and Legislative Services Directorate intranet site: http://intranet.health.wa.gov.au/LLSD/coronial/index.cfm
12. Appendix 1: SAC 1 Clinical Incident Notification List

Public Hospitals/Health Services and Private Licensed Health Care Facilities/Non Government Organisations are to report on all SAC 1 clinical incidents with Categories 1-8 referring to sentinel events now included as SAC 1 clinical incidents.

Table 2: SAC 1 Clinical Incident Notification List

<table>
<thead>
<tr>
<th>Category</th>
<th>Clinical incidents (category 1-8 sentinel events that must be reported)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Procedures involving the wrong patient or body part resulting in death or major permanent loss of function.</td>
</tr>
<tr>
<td>2</td>
<td>Suicide of an inpatient (including patients on leave). Note: Mental Health Services are required to report to the Chief Psychiatrist and to the State Coroner (for involuntary patients) episodes of unexpected death.</td>
</tr>
<tr>
<td>3</td>
<td>Retained instruments or other material after surgery requiring reoperation or further surgical procedures. Retention of a foreign object in a patient after surgery or other procedure including surgical instruments or other material such as gauze packs inadvertently left inside the patient when the surgical incision is closed – excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.</td>
</tr>
<tr>
<td>4</td>
<td>Intravascular gas embolism resulting in death or neurological damage. Death or serious disability associated with intravascular gas embolism that occurs while the patient is being cared for in a facility – excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular gas embolism.</td>
</tr>
<tr>
<td>5</td>
<td>Haemolytic blood transfusion reaction resulting from ABO incompatibility.</td>
</tr>
<tr>
<td>6</td>
<td>Medication error resulting in death of a patient. Death or serious injury associated with a medication error, including, but not limited to errors involving: the wrong drug, a contaminated drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, the wrong route of administration, insufficient surveillance (e.g. blood tests, clinical observation). This category excludes reasonable differences in clinical judgment on drug selection and dose.</td>
</tr>
<tr>
<td>7</td>
<td>Maternal death or serious morbidity associated with labour or delivery. Maternal death or serious disability associated with labour or delivery while the patient is being cared for in a facility or by maternity care providers, including events that occur within 42 days post delivery.</td>
</tr>
<tr>
<td>8</td>
<td>Infant discharged to wrong family or infant abduction.</td>
</tr>
</tbody>
</table>

- To ensure that a comprehensive understanding of SAC 1 notifications is obtained please read this Clinical Incident Management Policy in its entirety.
### Table 2: SAC 1 Clinical Incident Notification List. Note this list is not Exhaustive

**SAC 1** includes all clinical incidents/near misses where **serious harm or death** is/could be specifically caused by health care rather than the patient’s underlying condition and include:

<table>
<thead>
<tr>
<th>Medication error (not resulting in death) includes:</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>The inappropriate administration of daily oral methotrexate</em></td>
</tr>
<tr>
<td><em>The intravenous administration of epidural medication</em></td>
</tr>
<tr>
<td><em>Wrong gas being administered</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fetal complications associated with health care delivery:</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Unrelated to congenital abnormality in an infant having a birth weight greater than 2500 grams causing death, or serious and/or ongoing perinatal morbidity.</em></td>
</tr>
<tr>
<td><em>Complications not anticipated yet arose and were not managed in an appropriate/timely manner resulting in death, serious and/or ongoing morbidity.</em></td>
</tr>
<tr>
<td><em>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.</em></td>
</tr>
</tbody>
</table>

**Misdiagnosis and subsequent management (refers to physical and mental health)**

<table>
<thead>
<tr>
<th>Delay in recognising/responding to physical clinical deterioration</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Failure to monitor and respond to oxygen saturation</em></td>
</tr>
</tbody>
</table>

**Complications of resuscitation:**

<table>
<thead>
<tr>
<th>Increased morbidity or mortality of patients undergoing resuscitation due to events such as:</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Events in which staff experienced problems in managing an emergency situation or resuscitation resulting in death, or serious and/or ongoing morbidity.</em></td>
</tr>
<tr>
<td><em>Failed resuscitation where resuscitation protocols or guidelines could not be followed due to a deficiency of equipment, communication, or staffing resulting in death, or serious and/or ongoing morbidity.</em></td>
</tr>
</tbody>
</table>

**Complications of anaesthetic management:**

<table>
<thead>
<tr>
<th>Increased morbidity or mortality of patients undergoing anaesthesia due to events such as:</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Unintended intra-operative awareness.</em></td>
</tr>
<tr>
<td><em>Anaesthetic events resulting in death, or serious and/or ongoing morbidity.</em></td>
</tr>
</tbody>
</table>

**Complications of surgery:**

<table>
<thead>
<tr>
<th>Increased morbidity or mortality of patients undergoing surgery due to events such as:</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Wrong site surgery not resulting in death or permanent loss of function.</em></td>
</tr>
<tr>
<td><em>Pulmonary embolism.</em></td>
</tr>
<tr>
<td><em>Injury to major blood vessels.</em></td>
</tr>
</tbody>
</table>

**Complications of an inpatient fall**

<table>
<thead>
<tr>
<th>Increased morbidity or mortality of patients who fall while in hospital due to events such as:</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Events in which hospital processes such as triaging, assessment, planning or delivery of care e.g. miscommunication of test results, response to abnormal test results contributed to death, or serious and/or ongoing morbidity.</em></td>
</tr>
<tr>
<td><em>Transport or transfer – Events in which delays in transport or transfer contributed to death, or serious and/or ongoing morbidity.</em></td>
</tr>
<tr>
<td><em>Misidentification of patients.</em></td>
</tr>
</tbody>
</table>

**Infection control breach**

<table>
<thead>
<tr>
<th>The unexpected death of a mental health client</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absconding of any mental health patient/consumer</td>
</tr>
<tr>
<td>Patient absconding with adverse outcome</td>
</tr>
<tr>
<td>Wrong route administration of oral/enteral treatment*</td>
</tr>
</tbody>
</table>
Note: This SAC 1 notification list is not exhaustive and if unsure of whether to notify an incident, please contact your line manager or local risk manager or HS Safety Quality and Performance team or the PSSU for advice.

*Never Events refer to serious, preventable patient safety incidents that should not occur if preventative measures are in place.*
Appendix 2: SAC 1 Clinical Incident Reporting Templates

The notification of SAC 1 clinical incidents are mandatory for all Public Hospitals/Health Services and Private Licensed Health Care Facilities/Non Government Organisations staff using:

1. The Clinical Incident Management System notification process via AIMS (WA Health only).
2. The SAC 1 Clinical Incident Notification Form and SAC 1 Clinical Incident Investigation Report (templates) which are available at:
   http://www.safetyandquality.health.wa.gov.au

On the SAC 1 Clinical Incident Notification form, the hospital identification code, which is the establishment code listed in the Hospital Morbidity Data System Reference Manual (July 2012), is available at: http://www.health.wa.gov.au/healthdata/docs/Hospital_Morbidity_Data_System_Reference_Manual.pdf

Notification of SAC 1 clinical incidents (including sentinel events/preventable deaths) and submission of event investigation reports can be made to the Director, Performance via the Senior Policy Officer by:

- Email: SAC1.events@health.wa.gov.au
- Fax: (08) 9222 4014
Appendix 3: Figure 2 – Clinical Incident Management across Health Service Provider Boundaries

HOSPITAL/HEALTH SERVICE TWO (H2)
- Poor patient outcome
- Identification of clinical incident/preventable death possible involving H1
- H2 AIMS notification and PSD if a SAC 1 incident

H2 investigation
- No causative factors for H2 identified.
- Identification of system issues at H2
- Development of recommendations for causative factors and/or system improvement at H2.
- Notify H1 and recommend investigation by H1
- Inactivate notification of SAC 1 (for H2)
- CLOSED

HOSPITAL/HEALTH SERVICE ONE (H1)
- Joint investigation
  - H1 and H2
- Development of recommendations for H1 and H2 aimed at:
  - system improvement
  - addressing causative factors.
- Recommendations implemented and share lessons learned.
- Send report to PSD if a SAC 1 incident.
- CLOSED

H1 investigation
- H1 Amends notification
- Development of recommendations for H1 aimed at:
  - system improvement
  - addressing causative factors.
- Recommendations implemented and share lessons learned.
- Send report to PSD if a SAC 1 incident.
- CLOSED

Superseded by: OD: 0521/14
13. References


