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

Clinical Incident Management Policy

Department of Health 2015

(Revised April 2018)

Delivering a **Healthy WA**

Clinical Incident Management Policy 2015 (Revised April 2018)

About this Policy

The Australian Commission on Safety and Quality in Health Care reviewed and updated the Australian sentinel events list to Version 2 which was endorsed by the COAG Health Council in 2018. Revision to the sentinel events content within this policy was made in April 2018 as WA sentinel event notifications fall under this mandatory CIM policy.

For the latest version of this document, please visit:
http://ww2.health.wa.gov.au/Corporate/Articles/A_E/Clinical-incident-management-system

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Definitions

Absent Without Leave:	Relates to mental health patients detained under the *MHS Act (1996 or MHA 2014)* who leave hospital or place of detention without being granted leave. Please refer to the missing person definition for other patient categories. OD0588/15.
Adverse event:	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.[1] Medical management refers to management under health care services.
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.[1] ▪ **Adverse event** "as above". ▪ **Sentinel event** refers to unexpected occurrences involving death or serious physical or psychological injury, or risk thereof.[1] Please refer to the ten 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.[2]
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.[2]
Escalation:	The organisational level to which an incident must be notified and the timeframe in which this must occur.[2]
Datix CIMS:	Datix CIMS refers to the latest implemented electronic online clinical management system (February 2014), used to capture clinical incidents.
Hazard:	A circumstance, agent or action that can lead to or increase risk.[1]
Health professional:	Includes but not limited to, doctors, nurses, midwives and allied health professionals.
Maternal Death:	Maternal death as "the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes." [3,4]

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.
Missing Person:	Relates to **any** patient at high risk of harm who leaves without the agreement or authorisation of the treating clinicians (e.g. dementia patient wandering off site). For psychiatric patients, missing person relates **only** to voluntary patients. For involuntary patients refer to the Absent Without Leave definition. OD 0588/15.
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.
Patient/consumer:	Refers to any person receiving health care from a WA Health service either as an inpatient /outpatient or community setting.
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*.
Review of Death (ROD: (ROD)	ROD refers to the mandatory mortality review process which provides a standardised approach to the classification and review of all inpatient deaths (including surgical deaths). Mortality review aims to reduce preventable deaths. Recommendations 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. http://ww2.health.wa.gov.au/Corporate/Articles/U_Z/Western-Australian-Review-of-Death-Policy

SAC:	Severity Assessment Code is the assessment of actual or potential 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 ten nationally endorsed sentinel event categories.[5] **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 ten nationally endorsed sentinel event categories[5] (see the ten sentinel event categories listed in Appendix 1).
WA Health:	Refers to the whole of the WA public health system (hospitals and health services).

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 Clinical Incident Management Policy October 2014.

This Policy outlines the process used for the management of Severity Assessment Codes (SAC), which comprise three rating levels used to determine the appropriate level of analysis, action and escalation of a clinical incident according to the harm caused to the patient/consumer (see section 6.3 for further information).[2]

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. Notification of SAC 1 and SAC 2 clinical incidents into Datix CIMS is 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 1-10) 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 (OD):

- WA Open Disclosure Policy Statement: OD -0592/15 available at:
  http://www.health.wa.gov.au/CircularsNew/circular.cfm?Circ_ID=13200
- Western Australian Health Complaint Management Policy (2015) and OD 0589/15 available at:
  http://www.health.wa.gov.au/circularsnew/attachments/1013.pdf
- Western Australian Review of Death Policy (2013) and OD 0448/13 available at:
  http://www.health.wa.gov.au/circularsnew/attachments/767.pdf
- Qualified Privilege information available at:
  http://ww2.health.wa.gov.au/Corporate/Articles/N_R/Qualified-privilege
- Non-Salaried Medical Practitioners: Protocol for Notifying and Managing Medical Treatment Liability Claims/Potential Claims (Non-Teaching Hospitals, Operational Circular OP 1850/04) available at:
  http://www.health.wa.gov.au/CircularsNew/circular.cfm?Circ_ID=11836

  Mandatory Reporting of Notifiable Incidents to the Chief Psychiatrist, Policy and OD 0588/15 available at:
  http://www.health.wa.gov.au/circularsnew/attachments/1012.pdf

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 5.3.

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
- evaluation of recommendations.
- feedback
- learning and sharing lessons

4.2 Responsibilities of Public Hospitals/Health Services

Hospitals and Health Services are required to:

- Take **immediate action** when a clinical incident occurs to ensure the patient receives appropriate treatment and report the clinical incident into Datix CIMS.
- Undertake an initial investigation of the clinical incident within 48 hours to identify critical human error and system failures and implement preliminary actions to prevent harm to further patients.
- Notify the PSSU 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.
- Notify the Office of the Chief Psychiatrist of all applicable SAC 1 clinical incidents, which includes sentinel events, as soon as practicable, ideally within 48 hours.
- 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 28 working days of the event notification. Please contact PSSU if there are any problems with achieving this reporting requirement.
- Refer to section 10 for other statutory reporting requirements.
- Implement and evaluate recommendations from clinical incident investigations within six months of completing the investigation report (see section 6.8).
- Provide reports to the PSSU on the completion and evaluation of SAC 1 clinical incident recommendations.
- Report on hospital/health service trends – analysis of local data to monitor quality improvement of clinical incidents.

Hospitals and Health Services are required to:

- 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 the onsite/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 10).

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 SAC 1 clinical incidents resulting in serious harm or death of a patient/consumer. This includes all sentinel events (categories 1-10) 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 and Accreditation Regulatory Unit of all SAC 1 clinical incidents within seven days of the event's occurrence.
- Initiate appropriate investigations of all SAC 1 clinical incidents (including sentinel event categories 1-10; see Appendix 1).
- Refer to section 10 for other statutory reporting requirements.
- Report SAC 1 investigation findings to the PSSU within 28 working days of the event notification. Please contact PSSU if there are any problems with achieving this reporting requirement.
- Implement and evaluate recommendations from clinical incident investigations within six months of completing the investigation report (see section 6.8).
- Provide a report to the PSSU on the completion and evaluation of SAC 1 clinical incident recommendations, where possible.
- 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, 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 ten nationally endorsed sentinel event categories listed in Appendix 1.[5]

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.** High risk mental health patients include those detained under the *Mental Health Act (1996 or 2014)* and voluntary patients at high risk of causing significant harm to themselves or others, or being harmed by others. The assessment of a mental health patient as high risk is based on the patient's mental health condition and is determined using clinical judgement. For example, if a mental health patient who is deemed at high risk of suicide leaves hospital, this would be notified as a SAC 1 clinical incident. Further information can be found in the *Policy for Mandatory Reporting of Notifiable Incidents to the Chief Psychiatrist* available at: http://www.health.wa.gov.au/CircularsNew/attachments/1012.pdf

Another example of a clinical incident would be if a mental health patient became increasingly agitated during the course of a shift, which resulted in the patient physically, verbally or sexually assaulting a staff member. It would be important to investigate this clinical incident to see if all appropriate health care strategies were in place to prevent the patient from clinically deteriorating, becoming aggressive, and potentially harming themselves and others.

5.2 Clinical Incidents Within the Scope of this Policy

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 or serious self harm, suicidal behaviour
- retained instruments/material after surgery requiring re-operation/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 associated with pregnancy, birth and the puerperium. This includes maternal death while pregnant or within 42 days post delivery (see Appendix 1 for full definition).
- 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 or anaesthetic management
- complications of surgery
- complications of an inpatient fall
- infection control breaches (e.g. IV cannula related bacteraemia infections)
- unexpected death of a mental health patient/consumer

Examples of clinical incidents include but are **NOT LIMITED** to the following:

- missing patients who leave without the agreement or authorisation of the treating clinicians (e.g dementia patient wandering off site or voluntary mental health patients at high risk of harm).
- absent without leave of any high risk mental health patients including those detained under the *Mental Health Act (1996 or 2014)* at high risk of causing significant harm to themselves or others or being harmed by others.
- therapeutic equipment failure/medical device incident
- hospital acquired pressure injuries
- clinical deterioration of a mental health patient resulting in harm (either physical, verbal, or sexual) to staff, other patients, or other persons.

  For further examples see the SAC 1 Clinical Incident Notification List in Appendix 1.

5.3 Clinical Incidents that Should be Managed Outside of this Policy

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 manager so it can be addressed using the appropriate management and governance processes. Cases of suspected misconduct of mental health staff must also be reported to the Chief Psychiatrist using the appropriate form located on the Office of the Chief Psychiatrist website.

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 manager to cease the investigation.

Incidents that should NOT be managed 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
  - 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 Policy (2014) OD 0562/14) available at: http://www.health.wa.gov.au/CircularsNew/circular.cfm?Circ_ID=13150
- WA Health Preventing and Responding to Workplace Bullying Policy (2013) OD 0437/13 available at: http://www.health.wa.gov.au/CircularsNew/circular.cfm?Circ_ID=12968

6. The Clinical Incident Management Process

A key function of clinical incident management is to ensure patients' safety when receiving health care. A strong and rigorous CIM process provides staff with the necessary information and resources required to address, improve and evaluate the safety of health care delivery.

The key steps to effective clinical incident management are:

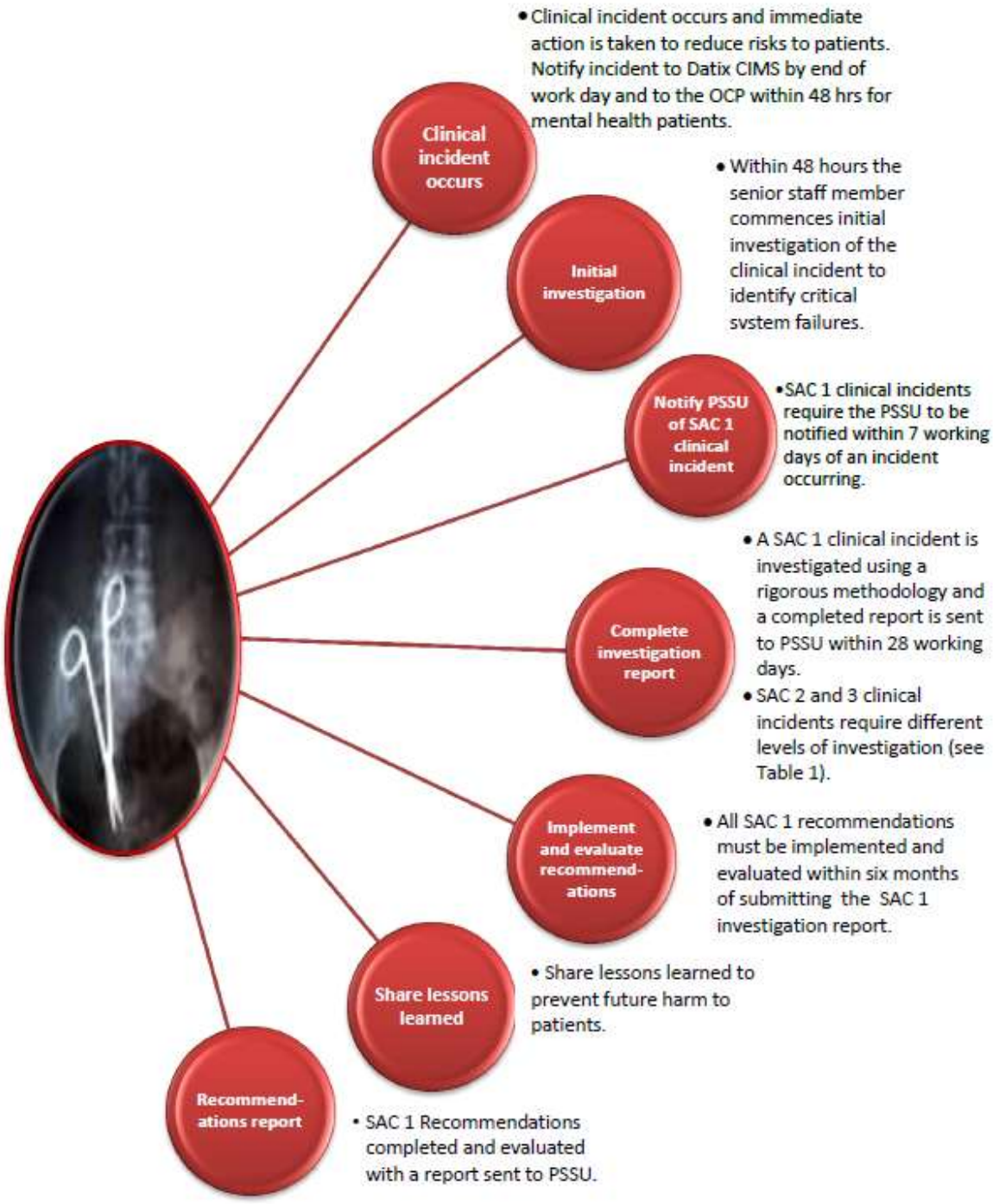
- identification of a clinical incident, take immediate action necessary to reduce risk to the patient/consumer and undertake the open disclosure process (see section 6.2.4)
- notification
- prioritisation of investigation
- analysis and investigation
- development of recommendations
- reporting of investigation outcomes
- feedback
- implementation of recommendations
- monitoring of recommendations
- evaluation of recommendations.

For detailed guidelines on how to manage a clinical incident refer to the Clinical Incident Management Toolkit which is available at:

http://ww2.health.wa.gov.au/Corporate/Articles/A_E/Clinical-incident-management-system

Key to the delivery of quality health care is the provision of systematic approaches to patient safety that enable staff to notify, investigate and understand the nature of clinical incidents and the factors that have contributed to their occurrence. Once contributing factors have been identified only then can appropriate recommendations be implemented to prevent future harm to patients. Figure 1 depicts the clinical incident management system process used within WA Health.

Figure 1: Clinical Incident Management Process



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:[6]

- 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 an online clinical incident form (refer to your line manager for more information).

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 Patient Safety Surveillance Unit within seven working days of the clinical incident occurring and to the Chief Psychiatrist (for mental health patients/consumers) with 48 hours.

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. All SAC 1 clinical incidents/ sentinel events must be notified using the Datix CIMS Clinical Incident Form (see Appendix 2 for where to access hard copy forms). Additionally, the WA Health Licensing and Accreditation Regulatory Unit is to be notified of all SAC 1 clinical incidents within seven working days.

For SAC 2 and SAC 3 clinical incidents please notify the incident within 24 hours to your manager/director and complete and submit a notification via Datix CIMS.

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.

Please refer to the WA Open Disclosure Policy available at:
http://www.health.wa.gov.au/circularsnew/attachments/1021.pdf

The Operational Directive OD 0592/15 available at:
http://www.health.wa.gov.au/circularsnew/pdfs/13200.pdf

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.[2]

Table 1: WA Health Severity Assessment Codes (SAC) to be used by Public Hospitals and Health Services

<table>
<tr><th></th><th>SAC 1</th><th>SAC 2</th><th>SAC 3</th></tr>
<tr><td>Actual/potential consequence to patient/consumer</td><td colspan="2">Serious harm or death 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></tr>
<tr><td>Type of event/ incident</td><td colspan="2">SAC 1 clinical incidents include:
National Sentinel Event Categories (see categories 1-10 below)
Any other clinical incident which results in serious harm or death of a patient
Increased length of stay greater than 7 days
Near miss that could have resulted in serious harm or death.
1. Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death.
2. Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death.
3. Wrong surgical or other invasive procedure performed on a patient resulting in serious harm or death.
4. Unintended retention of a foreign object in a patient after surgery or other invasive procedure resulting in serious harm or death.
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility resulting in serious harm or death.
6. Suspected suicide of a patient in an acute psychiatric unit or acute psychiatric ward.
7. Medication error resulting in serious harm or death
8. Use of physical or mechanical restraint resulting in serious harm or death.
9. Discharge or release of an infant or child to an unauthorised person.
10.Use of an incorrectly positioned oro-or naso-gastric tube resulting in serious harm or death.</td><td>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.</td><td>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.</td></tr>
<tr><td>Action required</td><td colspan="2">Notify management and submit a notification via Datix CIMS or equivalent by end of notifier's work day and to the Office of the Chief Psychiatrist (OCP) for mental health patients within 48 hrs.
Within 48 hours commence initial investigation to identify human errors and critical system failures.
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 a SAC 1 notification to PSSU via Datix CIMS within seven working days, and other reporting as required (see section 10).
Undertake SAC 1 investigation by Root Cause Analysis (RCA) or equivalent*.</td><td>Complete and submit a notification via Datix CIMS within 24 hours.
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.</td><td>Complete and submit a notification via Datix CIMS within 24 hours.
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.</td></tr>
<tr><td>Reporting requirements</td><td colspan="2">PSSU, OCP (for mental health related incidents) and HS Safety Quality and Performance team are to be informed about completed investigation reports which are due within 28 working days of notification.
Refer to section 10 of this Policy for other reporting requirements.</td><td>Complete investigation and actions taken within 60 working days of incident notification.</td><td>Complete investigation and actions taken within 60 working days of incident notification.</td></tr>
<tr><td colspan="4">Recommendations: All SAC 1 recommendations need to be both implemented and evaluated within six months of the investigation report submission. A report on evaluated SAC 1 recommendations must also be forwarded to PSSU within six months of the investigation report submission.
* For other equivalent investigation methods which can be used in place of an RCA please see section 6.4.2 or the CIM Toolkit.</td></tr>
</table>

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)*[5] provides a framework to facilitate the investigation of Clinical Incidents. The WA *QI Act* is available at: http://www.slp.wa.gov.au/legislation/statutes.nsf/main_mrtitle_416_homepage.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 at:

http://ww2.health.wa.gov.au/Corporate/Articles/N_R/Qualified-privilege

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 or delegated authority (e.g. 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://ww2.health.wa.gov.au/Corporate/Articles/A_E/Clinical-incident-management-system

To ensure that lessons are learnt especially from SAC 1 clinical incidents, every SAC 1 investigation will include recommendation/s.

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 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 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.

Guidelines for undertaking cross boundary investigations are available at: http://ww2.health.wa.gov.au/Corporate/Articles/F_I/Guidelines-for-the-investigation-of-clinical-incidents-across-health-service-boundaries

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:

http://ww2.health.wa.gov.au/Corporate/Articles/A_E/Business-rules-for-accessing-a-confidential-post-mortem-report-via-the-Coronial-Liaison-Unit 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 and evaluation (within six 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.

6.6 Reporting of Investigation Outcomes

6.6.1 SAC 1 clinical incident investigation report

Following endorsement of the final investigation report (including recommendations) by the Chief Executive (or delegate), please inform the HS Safety Quality and Performance team, the PSSU and the OCP (for incidents concerning mental health patients/consumers) within 28 working days of the incident notification date (For organisations without access to Datix CIMS please see Appendix 2 for reporting template details).

6.6.2 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 Datix CIMS clinical incident form (notification and investigation sections) constitutes a final report.

After a preliminary investigation if it is necessary to reclassify a SAC 2 or SAC 3 incident, do this by simply updating your initial notification and completing all the requirements for that SAC level.

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.[8]

For suggested models of feedback refer to the CIM Toolkit.

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 and evaluated within six months of the finalised investigation report. For all SAC 1 clinical incidents, public hospitals/ health services, private licensed health care facilities and non-government organisations are required to notify their Health Service Safety Quality and Performance team and the PSSU when recommendations have been completed.

6.9 Monitoring of Recommendations

Hospitals/health services must provide to PSSU evaluation results of quality improvement projects undertaken to assess SAC 1 clinical incident recommendations.

Private licensed health care facilities and non-government organisations need to submit a completed "Evaluation of Recommendation Actions Following Investigation of SAC 1 Incidents" template/s directly to PSSU, where possible.

The PSSU will conduct audits of closed recommendation actions to ensure recommendations are being implemented, monitored and evaluated. For SAC 2 and SAC 3 clinical incidents the responsibility for monitoring the implementation and evaluation of recommendations is managed at a hospital/health service level.

6.10 Evaluated Recommendations

When all recommendations have been implemented and given time to embed (e.g. three months post implementation) the hospital/health service should evaluate the effectiveness of the strategies in order to validate that improvements have been made.[9] 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.[9]

For suggested evaluation methods refer to the CIM Toolkit.

Please note: A SAC 1 recommendations evaluation report must be forwarded to PSSU within six months of the investigation report submission.

6.11 Disposal of Clinical Incident Forms

There may be circumstances where hard copy clinical incident forms are used to capture analysis of a clinical incident. It is expected that these will be entered into the Datix CIMS as soon as possible. Hard copy clinical incident forms must be kept for seven years.

It is permissible to retain scanned copies of the clinical incident, analysis and investigation, 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/sites/default/files/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.[9]

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.[9]

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

8. 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).

9. Declassification/Inactivation of Clinical Incidents

9.1 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 clinical incident was not preventable.

Any hospitals/health service providers reaching these conclusions may request declassification of the incident by completing the declassification request section located on the Clinical Incident 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 a SAC 1 clinical incident , hospitals/health services are still required to implement any recommendations developed from the investigation to improve patient/consumer care and monitor and evaluate these at a local level.

Declassification of a SAC 1 incident means that it has been determined that the incident is **not** a clinical incident resulting from health care delivery. SAC 1 incidents that have been approved for declassification need to be made **inactive** within Datix CIMS via the steps described in the *WA Health Datix Clinical Incident Management System SAC 1 Management Guide* available at: http://ww2.health.wa.gov.au/~/media/Files/Corporate/general%20documents/patient%20safety/PDF/SAC_1_Management_Guide.ashx

9.2 Inactivation of a Severity Assessment Code Clinical Incident

After appropriate investigation of a 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 clinical incident was not preventable. Managers can inactivate these types of SAC 2 or 3 clinical incidents within Datix CIMS but for SAC 1 clinical incidents please contact your Risk Manager or HS Safety Quality and Performance team.

10. Statutory Reporting Requirements

Statutory reporting requirements include:

- assessment of the Extinction of Life and Certification of Death (see Operational Directive OD 0462/13 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
- abnormal or unplanned radiation exposure must be reported to the Radiological Council.

For further information on reporting requirements please refer to the Death in Hospital Form and Guidelines information circular (IC 0083/11) is available from:
http://www.health.wa.gov.au/CircularsNew/circular.cfm?Circ_ID=13097

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

http://www.public.health.wa.gov.au/3/287/3/statutory_notifications_and_authorisation.pm

Information regarding coronial reporting requirements is available at:
http://www.public.health.wa.gov.au/3/502/2/notifications_of_deaths.pm

Information regarding reporting requirements as per Radiation Safety Act 1975/Regulations 1983 is available from:

http://www.public.health.wa.gov.au/3/1199/2/radiation_standards_and_codes_of_practice.pm

11. 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 1-10** referring to **sentinel events** now included as SAC 1 clinical incidents.

Table 2: SAC 1 Clinical Incident Notification List[1]

Category	Clinical incidents (category 1-10 sentinel events that must be reported)
1	**Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death.**
2	**Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death.**
3	**Wrong surgical or other invasive procedure performed on a patient resulting in serious harm or death.**
4	**Unintended retention of a foreign object in a patient after surgery or other invasive procedure resulting in serious harm or death.**
5	**Haemolytic blood transfusion reaction resulting from ABO incompatibility resulting in serious harm or death.**
6	**Suspected suicide of a patient in an acute psychiatric unit or acute psychiatric ward.** Note: Mental Health Services are required to report to the Chief Psychiatrist and to the State Coroner (for involuntary patients) episodes of unexpected death.
7	**Medication error resulting in serious harm or death**
8	**Use of physical or mechanical restraint resulting in serious harm or death.**
9	**Discharge or release of an infant or child to an unauthorised person.**
10	**Use of an incorrectly positioned oro-or naso-gastric tube resulting in serious harm or death.**

To ensure that a comprehensive understanding of SAC 1 notifications is obtained please read this Clinical Incident Management Policy in its entirety.

[1] As per the COAG Health Council, Australian sentinel events list (version 2), March 2018

Appendix 1: SAC 1 Clinical Incident Notification List Continued

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:
Medication error (not resulting in death) includes: ▪ The inappropriate administration of daily oral methotrexate* ▪ The intravenous administration of epidural medication* ▪ Wrong gas being administered.*
Fetal complications associated with health care delivery: ▪ Unrelated to congenital abnormality in an infant having a birth weight greater than 2500 grams causing death, or serious and/or ongoing perinatal morbidity. ▪ Complications not anticipated yet arose and were not managed in an appropriate/timely manner resulting in death, serious and/or ongoing morbidity. ▪ 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.
Misdiagnosis and subsequent management (refers to physical and mental health) ▪ Failure to monitor and respond to oxygen saturation*
Delay in recognising/responding to physical clinical deterioration
Complications of resuscitation: ▪ Events in which staff experienced problems in managing an emergency situation or resuscitation resulting in death, or serious and/or ongoing morbidity. ▪ Failed resuscitation where resuscitation guidelines could not be followed due to a deficiency of equipment, communication, or staffing resulting in death, or serious and/or ongoing morbidity.
Complications of anaesthetic management: ▪ Unintended intra-operative awareness. ▪ Anaesthetic events resulting in death, or serious and/or ongoing morbidity.
Complications of surgery: ▪ Wrong site surgery **not** resulting in death or major permanent loss of function* ▪ Pulmonary embolism ▪ Injury to major blood vessels.
Complications of an inpatient fall.
Hospital process issues: ▪ 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. ▪ Transport or transfer – Events in which delays in transport or transfer contributed to death, or serious and/or ongoing morbidity. ▪ Misidentification of patients.*
Infection control breach (e.g. IV cannula related bacteraemia infections).
The unexpected death of a mental health client (e.g. suspected suicide, unnatural or violent death).
Missing or Absent Without Leave of any high risk mental health patient/consumer.♦
Patient missing or Absent Without Leave with adverse outcome
Wrong route administration of oral/enteral treatment*
Clinical deterioration of a mental health patient resulting in serious harm (either physical, verbal, or sexual) to staff, other patients, or other persons.

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/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.[10] ♦High risk mental health patients include those detained under the *Mental Health Act (1996 or 2014)* and voluntary patients at high risk of causing significant harm to themselves or others, or being harmed by others. The assessment of a mental health patient as high risk is based on the patient's medical condition and is determined using clinical judgement. For example, if a mental health patient who is deemed at high risk of suicide leaves hospital, this would be notified as a SAC 1 clinical incident. Further information can be found in the *Policy for Mandatory Reporting of Notifiable Incidents to the Chief Psychiatrist* available at:

http://www.health.wa.gov.au/CircularsNew/attachments/1012.pdf

Appendix 2: SAC 1 Clinical Incident Reporting Templates

The notification of SAC 1 clinical incidents is mandatory for all Public Hospitals/Health Services and Private Licensed Health Care Facilities/Non-Government Organisations.

1. For Public Hospitals/Health Services please notify incidents via the Datix Clinical Incident Management System (Datix CIMS).

Please refer to the next page for the **Evaluation of Recommendation Actions template or see the CIM Toolkit for examples**.

2. For Private Licensed Health Care Facilities/ Non-Government organisations please notify incidents by completing the **SAC 1 Clinical Incident Notification Form** which is available at:
http://ww2.health.wa.gov.au/Corporate/Articles/S_T/Severity-assessment-codes

Private Licensed Health Care Facility/Non-Government notification of SAC 1 clinical incidents and submission of incident investigation reports can be made by:

- Email: SAC1.events@health.wa.gov.au
- Fax: (08) 9222 4014

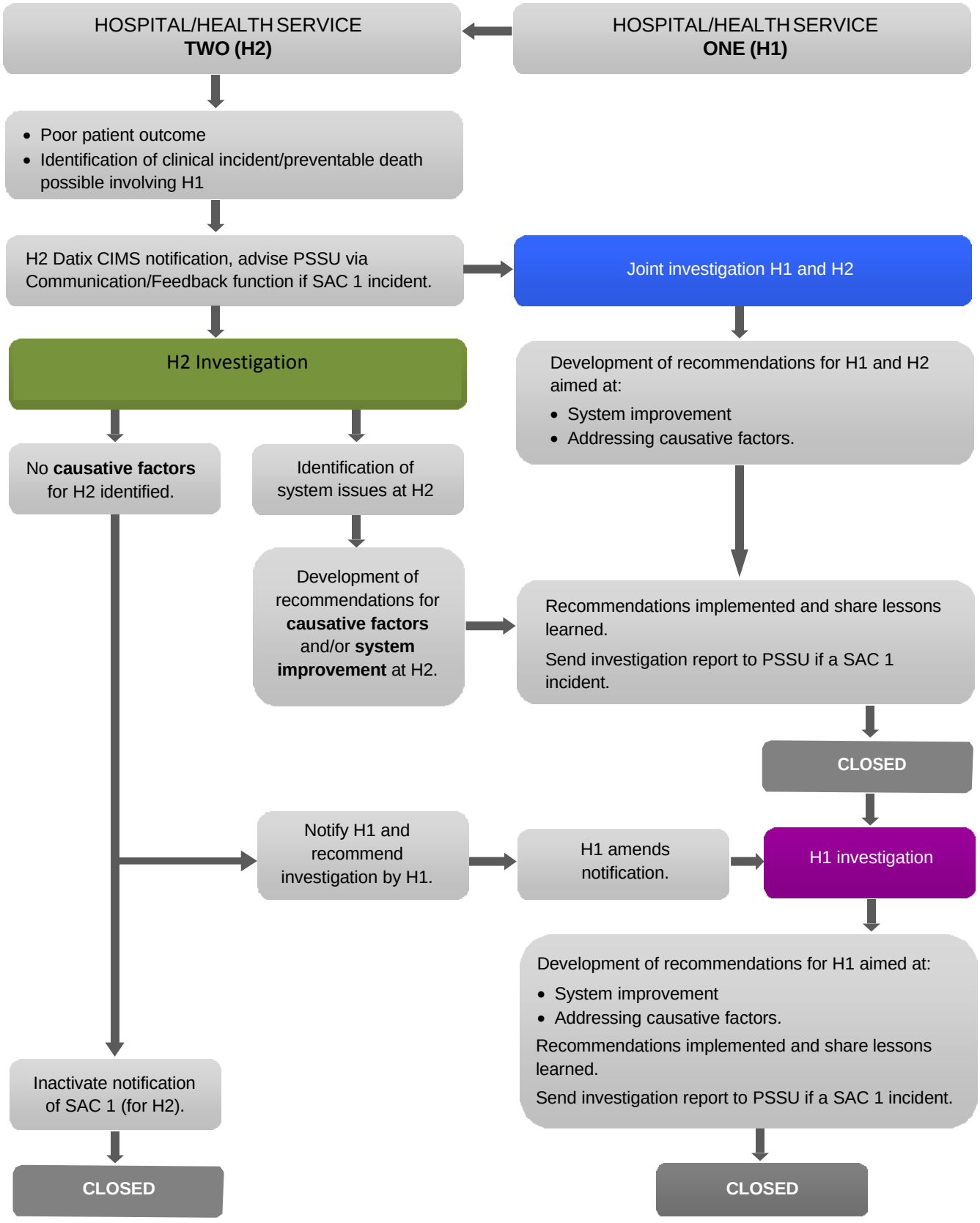
EVALUATION OF RECOMMENDATION ACTIONS FOLLOWING SAC 1 INVESTIGATION TEMPLATE

Datix CIMS no: **Hospital/Site**: **Date Submitted to PSSU**:

Issue	Description of Aims and Actions addressing Contributing Factors	Evaluation Methodology Used Name of staff responsible	Outcome Measure date	Latest Results (state date)	Has QI been achieved Yes/No If No state why not (state date)	Sign Off that Achievements Completed (state date)
1.						
2.						
3.						

Photocopy template as required.

Appendix 3: Figure 2 – Clinical Incident Management across Health Service Provider Boundaries



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Website: http://ww2.health.wa.gov.au/Corporate/Articles/A_E/Clinical-incident-management-system

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