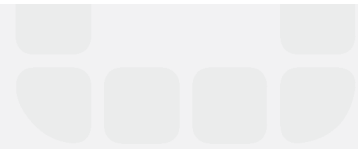


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Foreword

Since 2003, Western Australia has released three public reports on Sentinel Events. Although the first report initially raised some concerns, its release was overwhelmingly supported by many as it marked the beginning of a more open reporting culture in hospitals. The second and third report were well received. Health care is entering an era in which it is time to share information on adverse events both to patients through a formal disclosure process, and to the community through publishing of adverse event data. It is important we continue to improve the complex systems and processes inherent in the delivery of health care.

This revision of the Sentinel Event Policy for WA Health incorporates strategic developments in the quality culture, such as the need to formally disclose very serious adverse events to patients, and with their approval to their families and carers. This document reflects updates to qualified privilege schemes and also incorporates information generated from an extensive evaluation of the Clinical Incident Reporting and Management Program carried out by the Office of Safety and Quality in Healthcare in 2005.

As safety and quality in health care is an area that is changing rapidly, updates of this policy will be available on the Office of Safety and Quality in Healthcare website (www.safetyandquality.health.wa.gov.au).

One sentinel event can give rise to multiple reporting requirements so it is important that this document is read in conjunction with other relevant policies and guidelines, including:

- Clinical Incident Management Policy for WA Health Services using the Advanced Incident Management System (AIMS);
- Western Australian Review of Mortality (WARM) Policy;
- Communicating in Times of Stress Policy: procedural guidelines for practicing open disclosure in WA Health Services; and
- Qualified Privilege Guidelines.

All of the above policies are available on the Office of Safety and Quality in Healthcare website: www.safetyandquality.health.wa.gov.au

We encourage all health service staff to read these policies and embrace the culture of change as we strive for an improved, open and accountable health care system.



Dr Neale Fong
Director General
Department of Health

1. Purpose

The purpose of the Sentinel Event Policy is to define the process for identification, reporting, investigation and management of sentinel events that occur in both public and licensed private health care facilities across Western Australia.

2. Reportable sentinel events

Sentinel events are rare events that lead to catastrophic patient outcomes. Health Ministers throughout Australia mandated reporting of sentinel events in 2003. The Australian Council on Safety and Quality endorsed a national list of sentinel events (see below).

Reporting of sentinel events is mandatory for all public hospital and health service staff (Operational Directive OD0002/06). This includes both salaried and non-salaried visiting medical practitioners as outlined in the Safety and Quality requirements set out in the terms and conditions of the salaried and non-salaried medical practitioners contracting arrangements since 2003/04. Please see Operational Circular 1861/04 and Terms and Conditions of Indemnity for Salaried Medical Officers and Terms and Conditions of Indemnity for Non-Salaried Medical Officers available at:

<http://www.health.wa.gov.au/indemnity>

Licensed private health care facilities in Western Australia are also required to report sentinel events as part of their licensing requirements.

For Western Australia, the list of reportable sentinel events is based on nationally endorsed categories and includes:

1. Procedures involving the wrong patient or body part.
2. Suicide of a patient in an inpatient unit.
3. Retained instruments or other material after surgery requiring re-operation or further surgical procedure.
4. Intravascular gas embolism resulting in death or neurological damage.
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility.
6. Medication error resulting in major permanent loss of function or death of a patient reasonably believed to be due to incorrect administration of drugs.
7. Maternal death or serious morbidity associated with labour or delivery.
8. Infant discharged to wrong family or infant abduction.
9. Other adverse event resulting in serious patient harm or death.

Please see Attachment 1 for greater detail on the sentinel events outlined above. The list of sentinel events should be widely distributed throughout hospitals and health services.

3. Reporting requirements

All hospitals and health services, including community groups and primary care units, are required to report sentinel events to the Director, Office of Safety and Quality in Healthcare via the Senior Policy Officer at the Office of Safety and Quality in Healthcare within seven (7) working days of the event occurring.

Sentinel events must be reported using the Sentinel Event Notification Form (Attachment 2) and include the hospital identification code, the date on which the event occurred, a brief description of the sentinel event and whether the investigation will be conducted under qualified privilege or is a coroner's case. The name of a contact person must be included. Electronic copies of the Sentinel Event Notification Form are available at: <http://www.safetyandquality.health.wa.gov.au>

Notifications can be submitted via secure fax, email, post or courier (Attachment 3).

In cases where a sentinel event has occurred and the patient has been transferred to another hospital or health service, only one Sentinel Event Notification Form should be raised. The reporting hospital or health service should be the one in which the sentinel event occurred. Where one or more organisations are involved, all organisations need to be consulted and represented during the investigation.

4. Additional reporting requirements

One sentinel event can give rise to several reporting requirements. Hospital and health service staff should note that in addition to reporting the sentinel event to the Director, Office of Safety and Quality in Healthcare there may be statutory reporting requirements, mandated reporting requirements as per Department of Health (WA) policy as well as professional reporting obligations, some of which are outlined below.

(i) Statutory requirements

- Maternal deaths must be reported to the Executive Director, Public Health (Section 336 A of *Health Act 1911*, please see Operational Circular 1453/01).
- Perinatal and infant deaths must be reported to the Executive Director, Public Health (Section 336 A of *Health Act 1911*, please see Operational Circular 1454/01).
- Deaths of persons under anaesthesia must be reported to the Executive Director, Public Health (Section 336 B of *Health Act 1911*, please see Operational Circular 1197/99).
- Reportable deaths which require notification to the Coroner (*Coroner's Act 1996*, please see Information Circular 0008/07).
- Certification of death (*Births, Deaths and Marriages Registration Act 1998*, please see Operational Circular 1652/03).

(ii) Mandated requirements as per Department of Health policy

- Sentinel events should also be reported to the Advanced Incident Management System (AIMS). See the Clinical Incident Management Policy for WA Health Services using the Advanced Incident Management System for further information. This policy is available at:
<http://www.safetyandquality.health.wa.gov.au>
- Serious adverse events (including deaths) that result in a medico-legal claim or have the potential to result in a medico-legal claim (please see Operational Circular 1850/04) are to be reported to the appropriate bodies.
- Patient suicides and serious incidents that occur in mental health services throughout WA must be reported to the Chief Psychiatrist (*Mental Health Act 1996*, please see Operational Circular 2061/06).

(iii) Professional obligations

- Deaths should be reported to the hospital or health service Mortality Review Team, Clinical Governance Committee or similar.
- Communication with the patient and/or their family/carer. Where relevant this may include disclosure of the incident.
- Deaths that occur while under the care of a surgeon are automatically reported to the WA Audit of Surgical Mortality (please see Terms and Conditions of Indemnity for Salaried Medical Officers and Terms and Conditions of Indemnity for Non-Salaried Medical Officers available at: <http://www.health.wa.gov.au/indemnity/nonsalaried>).

5. Investigation of sentinel events

Sentinel events often signal serious breakdowns in health care systems and require thorough investigation and response. The investigation of a sentinel event should involve a comprehensive and systematic analysis of the facts to identify contributing factors. Recommendations and strategies should be developed and implemented to minimise the occurrence of similar events in the future. Hospitals and health services are encouraged to follow the standard for investigating high and extreme risk clinical incidents which can be found at the Office of Safety and Quality in Healthcare website:

<http://www.safetyandquality.health.wa.gov.au>

The principles of natural justice must be followed in every sentinel event investigation. Natural justice encompasses various rules of procedural fairness to achieve two basic principles:

- i) persons involved in an incident must be given adequate opportunity to present their case, and
- ii) decision-makers hearing the case must be unbiased.

There are a number of methodologies that can be used for investigating sentinel events. Root Cause Analysis (RCA) is one investigation methodology recommended by the Department of Health for investigating sentinel events. Guidelines for RCA investigation can be found at the Office of Safety and Quality in Healthcare website:

<http://www.safetyandquality.health.wa.gov.au>

Following an investigation, the Sentinel Event Final Report is to be forwarded to the Senior Policy Officer at the Office of Safety and Quality in Healthcare within 45 working days of initial notification. The report can be submitted by secure fax, email, post or courier (see Attachment 3). An electronic copy of the report template is available from the Office of Safety and Quality in Healthcare website at:

<http://www.safetyandquality.health.wa.gov.au>

If an extension is required, a request must be forwarded to the Senior Policy Officer stating the reason and the estimated extra time required.

The Office of Safety and Quality in Healthcare acts as a central repository of deidentified recommendations arising from the investigations of sentinel events and where appropriate will disseminate lessons learned to hospitals and health services across the State. If hospitals and health services consider there is an urgent need to alert the whole health sector in WA of a potential risk, they are invited to highlight this when submitting the completed report. A special State-wide alert may then be issued.

6. Qualified privilege

A hospital or health service may decide to conduct an investigation without qualified privilege, in which case all documents generated via the investigation process are not necessarily protected and may be accessible under the *Freedom of Information Act 1992 (WA)* or by discovery in legal proceedings. Hospitals and health services undertaking investigations without privilege should ensure that any documentation regarding the investigation that is released to the patient is accompanied by a general disclaimer. Public hospitals and health services are advised to refer any draft correspondence and disclaimers to patients for legal review.

If a public hospital or health service wishes to conduct the investigation under qualified privilege it may:

- (i) conduct the investigation under the State qualified privilege scheme via a registered committee; or
- (ii) conduct the investigation under the Commonwealth qualified privilege scheme via the AIMS process.

If a private hospital wishes to conduct the investigation under qualified privilege it can utilise the State qualified privilege scheme via a registered committee.

Privately licensed health care facilities can utilise the Commonwealth scheme via the Advanced Incident Management System (AIMS) process only if AIMS is in place.

6.1 Conducting sentinel event investigations under the State Qualified Privilege scheme

The *Health Services (Quality Improvement) Act 1994* (the 'Act') provides for the approval and protection of Quality Improvement Committees. The Act encourages health professionals to participate in quality improvement processes aimed at improving

the quality of clinical care by protecting information generated solely for the purpose of an approved quality improvement process from disclosure or use in court and other proceedings. Standards have been gazetted in order to define the type of information that can be made available to health services (the 'health section of the public') for the purposes of making changes to health care processes. The Standard is available at: <http://www.safetyandquality.health.wa.gov.au>

A registered committee that investigates sentinel events under the State qualified privilege scheme must ensure that this function is clearly outlined in the committee's terms of reference. If the hospital or health service wishes to disclose the recommendations to the patient, they must seek the written consent of the patient prior to the disclosure of the information to the patient. The signing of the consent form should be witnessed and kept in a separate file dealing with the open disclosure process. If the patient consents to release of this information it is important that a general disclaimer accompanies recommendations. Public hospitals and health services are advised to refer any draft correspondence and disclaimers to patients for legal review.

It is important to note that if the disclosure of recommendations to the patient would also directly or indirectly identify another individual (such as a health professional) then the consent of that other individual will also have to be obtained in addition to the consent of the patient. Please refer to the Clinical Incident Management Policy using the Advanced Incident Management System for further information.

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>

6.2 Conducting sentinel event investigations under the Commonwealth qualified privilege scheme by concurrent reporting to the Advanced Incident Management System (AIMS)

The *Commonwealth Health Insurance Act 1973*, Part VC (the 'HI Act') was established to provide approval and protection for those seeking to assess or evaluate the quality of health care services in Australia. The object of the *HI Act* is to encourage efficient quality assurance activities in the provision of health services. The Advanced Incident Management System (AIMS) is a declared quality assurance activity under the *HI Act*. AIMS is in place at all public hospitals and health services across Western Australia.

For further information on AIMS, including its statutory protection, please refer to the Clinical Incident Management Policy for WA Health Services

using the Advanced Incident Management System available at:
<http://www.safetyandquality.health.wa.gov.au>

Public hospital and health services can investigate a sentinel event under qualified privilege via the AIMS process. In such cases the hospital should notify the Senior Policy Officer at the Office of Safety and Quality in Healthcare in the required way and then investigate and analyse the incident using the Commonwealth qualified privilege scheme. Recommendations that are de-identified and do not infer the identity of any individual (either expressly or by implication) are to be forwarded to the Senior Policy Officer at the Office of Safety and Quality in Healthcare.

7. Suspected or alleged blameworthy behaviour and purposeful unsafe acts

If during the course of the investigation of a sentinel event it is suspected that the event may contain elements of blameworthy behaviour or a purposeful unsafe act, the investigation team should immediately cease the investigation and refer it to the Risk Manager, Clinical Director, senior management or other relevant staff member so that it can be managed using the appropriate management and governance processes.

Such behaviour or acts include:

- physical altercation or sexual misconduct by staff or other individuals involving a patient;
- non-compliance with a hospital or health service policy or practice concerning work safety.

In some cases it is possible that an event will be a sentinel event and involve some incidental blameworthy behaviour or purposeful unsafe act that is perhaps secondary to the adverse outcome pertaining to the patient. In such cases, the investigation of the sentinel event can continue alongside parallel processes of performance management into the alleged or suspected behaviour or acts of staff members involved.

Any incidents of the nature contemplated in this section should be reported to Legal and Legislative Services or other relevant bodies in order to deal with potential liability claims.

8. Management of sentinel events

As a result of a sentinel event there are a number of actions that need to be taken. Hospitals and health services are encouraged to develop management pathways for the immediate care and management of patients involved in sentinel events and consider staff and families who may be distressed by these events.

Local Area Health Service policies will largely define the internal management of sentinel events. It is important that key recommendations of investigations are forwarded to the Chief Executive of the Area Health Service for sign off and the relevant Clinical Governance Committee or similar for action. It is also envisaged that recommendations with high risk consequences for patients are entered onto the health service risk register or other such registers so that completion of the recommendations can be monitored. These are then accessible to external auditors.

Attachment 1

Examples of healthcare incidents that must be reported as Sentinel Events

Please note, incidents that could be defined as a near miss, (i.e., no harm occurred) may also be investigated as Sentinel Events.

1. Procedures involving the wrong patient or body part.
 - Surgery performed on a wrong body part or the wrong surgical procedure performed that is not consistent with the documented informed consent of that patient.
2. Suicide of a patient in an inpatient unit.
 - Mental Health services are required to report to the Chief Psychiatrist episodes of unexpected death. See Operational Circular OP 2061/06 for further information.
3. Retained instruments or other material after surgery requiring re-operation or further surgical procedure.
 - Retention of a foreign object in a patient after surgery or other procedure including surgical instruments or other material such as gauze packs are 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.
4. 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.
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility.
6. Medication error resulting in major permanent loss of function or death reasonably believed to be due to incorrect administration of drugs. Includes:
 - 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 and insufficient surveillance (e.g. blood tests, clinical observation). This category excludes reasonable differences in clinical judgment on drug selection and dose.
7. Maternal death or serious morbidity associated with labour or delivery.
 - Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while the patient is being cared for in a facility, including events that occur within 42 days post delivery and excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.
8. Infant discharged to wrong family or infant abduction.
9. Unexpected death or serious disability reasonably believed to be preventable. Assessment should be based on clinical judgement, circumstances and context of the incident.

Attachment 2



Sentinel Event Notification Form

For initial notification to the Director, Office of Safety and Quality in Healthcare, within 7 working days

Hospital ID: _____ Date of event: ____/____/____

Event Description:

Please tick [✓] the Sentinel Event that has occurred in the right hand column

Procedures involving the wrong patient or body part	
Suicide of a patient in an inpatient unit (*Episodes of unexpected deaths, including suicide, should continue to be reported to the Chief Psychiatrist. See Operational Circular OP 2061/06 for further information.)	
Retained instruments or other material after surgery requiring re-operation or further surgical procedure	
Intravascular gas embolism resulting in death or neurological damage	
Haemolytic blood transfusion reaction resulting from ABO incompatibility	
Medication error resulting in major permanent loss of function or death of a patient reasonably believed to be due to incorrect administration of drugs	
Maternal death or serious morbidity associated with labour or delivery	
Infant discharged to wrong family or infant abduction	
Other adverse event resulting in serious patient harm or death	

Please indicate whether the Coroner has been notified of the event:

Yes No

Please indicate how the event will be investigated:

No qualified privilege State qualified privilege via registered committee Commonwealth qualified privilege via AIMS

Please indicate whether the hospital will undertake the open disclosure process with the patient and with their permission, their family and/or carer regarding this sentinel event:

Yes No

An investigation of root causes is required for all reported sentinel events. Consultants from the Department of Health are available at no cost to guide and train staff in the investigative process. See the policy for further information.

Health service contact regarding Sentinel Events: _____

Please forward the completed form via mail, e-mail or fax:

Mail: Office of Safety and Quality in Healthcare
Locked Bag 200
Perth Business Centre 6849

E-mail: sentinel.events@health.wa.gov.au

Fax: (08) 9222 4014

On receipt of initial notification the Department will provide the hospital with a Sentinel Event Reference Number, to be indicated on correspondence regarding this episode. This form is available electronically at: <http://www.safetyandquality.health.wa.gov.au> Please contact the Office of Safety and Quality in Healthcare on (08) 9222 4080 if you have questions regarding this process or visit the website as referenced above.

Attachment 3

The Sentinel Event Notification Form is available from the Office of Safety and Quality in Healthcare website at

<http://www.safetyandquality.health.wa.gov.au>

The hospital identification three digit code is the establishment code listed in the Hospital Morbidity Data System (HMDS) Reference Manual July 2002, which can be found on the Department of Health intranet

http://www.health.wa.gov.au/Publications/HMDS/HMDS_Ref_Manual_July_2005

Notification of sentinel events can be made to the Director, Office of Safety and Quality in Healthcare via the Senior Policy Officer via fax/phone, email or by courier if in the metropolitan area.

The Office of Safety and Quality in Healthcare can be contacted between 8:30am and 4:30pm, Monday to Friday (excluding public holidays) on (08) 9222 4080.

By Fax

(08) 9222 4014

A secure facsimile machine has been isolated within the Office of Safety and Quality in Healthcare to receive sentinel event notifications.

By Email

sentinel.events@health.wa.gov.au

By Post

Senior Policy Officer - Sentinel Event Program
Office of Safety and Quality in Healthcare
Locked Bag 200
Perth Business Centre 6849

By courier (in metropolitan areas)

Senior Policy Officer - Sentinel Event Program
Department of Health (WA)
Office of Safety and Quality in Healthcare
3rd Floor, C Block
189 Royal St
East Perth WA 6005