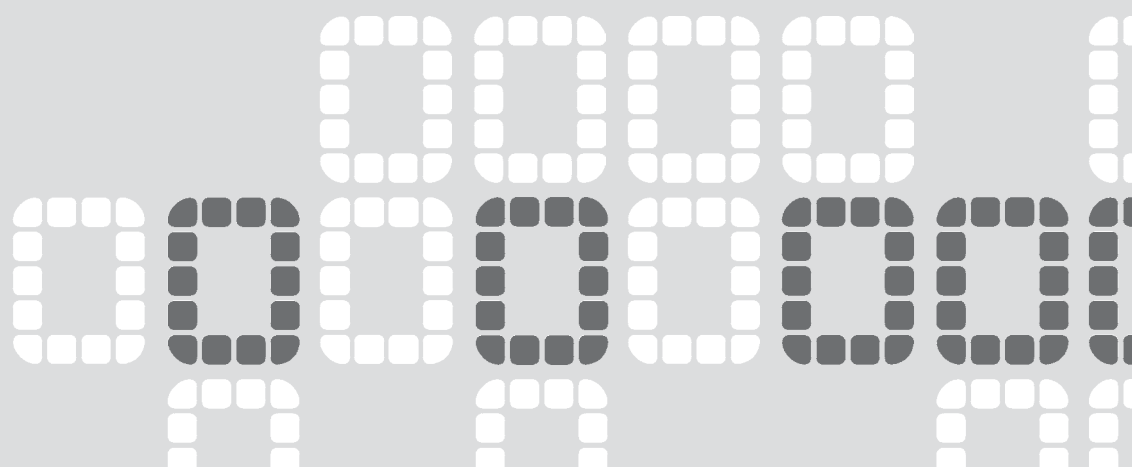




WA Open Disclosure Policy:

Communication and Disclosure Requirements for Health Professionals Working in Western Australia

May 2009



WA Open Disclosure Policy Information Series No. 10 (2009)

The *WA Open Disclosure Policy* may be updated at regular intervals. For the latest version of this document, please visit the Office of Safety and Quality in Healthcare website at:
<http://www.safetyandquality.health.wa.gov.au>

The *WA Open Disclosure Policy* is protected by copyright. Copyright resides with the State of Western Australia. Apart from any use permitted by the *Copyright Act 1968* (Cth), no part of this document may be published, or reproduced in any material form whatsoever, without the permission of the Office of Safety and Quality in Healthcare, Innovation and Health System Reform, Department of Health.

For further details please contact:

Office of Safety and Quality in Healthcare
Innovation and Health System Reform
Western Australian Department of Health
189 Royal Street, East Perth Western Australia 6004
Tel: (08) 9222 4080 Fax: (08) 9222 4324
E-mail: safetyandquality@health.wa.gov.au
Web: www.safetyandquality.health.wa.gov.au

Foreword

Open disclosure is the “open discussion of an incident that results in harm (or might result in future harm) to a patient while receiving health care”.¹

WA Health is dedicated and committed to providing safe and high quality health care to all patients, however, despite the best intentions of our highly skilled and committed health professionals occasionally things go wrong. When a patient is harmed in a WA hospital, there is a professional and ethical responsibility on the part of health practitioners to communicate with the patient about the clinical incident that has occurred.

Effectively communicating with patients and their nominated relatives/carers is a vital part of the process of dealing with clinical incidents and has been routinely occurring within WA Health by health professionals for many years.

The *WA Open Disclosure Policy: Communication and Disclosure Requirements for Health Professionals Working in Western Australia* (the Policy) has been developed in good faith for health professionals working in WA to assist in the management of clinical incidents. For all public hospitals/health services, compliance with the procedures outlined in the Policy is mandatory.

The Policy establishes the process of open disclosure in WA based on the National Open Disclosure Standard (2003) and the specific statutory provisions that apply in WA as at May 2009.

The objectives of the Policy are to:

1. Establish a standardised approach for health practitioners working in WA hospitals/health services, to communicate with the patient and/or their nominated relatives/carers after a clinical incident.
2. Ensure that communication with, and support for all affected patients and staff, occurs in a supportive and timely manner.

The Open Disclosure Process, as outlined in the Policy, will guide health practitioners in WA to continue to deliver best practice clinical care for patients by informing them in an open and timely manner if an adverse event or clinical incident occurs.

Through this process of honest and open discussion with patients and their nominated relatives/carers following a clinical incident, WA Health will continue to promote a patient centred culture that encourages learning from errors and continuous improvement in the delivery of safe and high quality health care.

Please contact your local Director of Safety, Quality and Performance or the Office of Safety and Quality in Healthcare if you have any queries regarding the Policy.



Dr Peter Flett
Director General, Department of Health
May 2009

Contents page

1. The WA Open Disclosure Policy Objectives	5
1.1 Implementation at the local level	5
1.2 Private hospitals	5
2. Background	6
3. Key Open Disclosure Principles	8
4. Pathway Algorithm for the Open Disclosure Process	10
5. The Open Disclosure Process	11
5.1 Reporting of a clinical incident to a relevant authority, in accordance with Department of Health policy	11
5.2 Initial disclosure to the patient	13
5.3 Investigation of a clinical incident	16
5.4 Provision of feedback to the patient and/or their nominated relatives/carers	18
5.5 Developing an agreed plan for the ongoing care of the patient	19
6. Completing the Open Disclosure Process	20
6.1 Record keeping and management of documentation	20
7. Roles and Responsibilities for Open Disclosure	22
7.1 Ensuring the safety and wellbeing of patients and staff	22
7.2 Ensuring compliance with insurance and legal/legislative policies	22
7.3 Ensuring compliance with registration and indemnity conditions for hospital/health service staff and non-salaried medical practitioners	23
Appendix A – Definitions	24
Appendix B – Open Disclosure Legal Information	26
A RiskCover and insurers	26
B Disclosure of information arising from investigations	27
C Apologies	32
D Patient confidentiality	33
E Defamation	33
F Guidelines for good medical record keeping	33
References	36

1. The WA Open Disclosure Policy Objectives

The Department of Health Western Australia (WA) recognises that doctors, nurses, allied health and health science professionals and other staff in WA hospitals/health services have, for many years, routinely reported and disclosed clinical incidents that may or may not have resulted in harm to a patient. The Department of Health encourages all health service staff to continue with this open and honest approach towards the management of clinical incidents.

The objectives of this Policy are to:

1. Establish a standardised approach for health practitioners working in WA hospitals/health services, to communicate with the patient and/or their nominated relatives/carers after a clinical incident.
2. Ensure that communication with, and support for all affected patients and staff, occurs in a supportive and timely manner.

1.1 Implementation at the local level

The Policy outlines the processes that health practitioners and hospitals/health services in WA are to follow when informing a patient and/or their nominated relatives/carers about a clinical incident that has occurred in a WA public hospital/health service.

Compliance with the procedures outlined in the Policy is mandatory. All public hospitals/health services in WA will either adopt the Policy *in toto*, or utilise it as a framework for developing their own Open Disclosure Policy that meets their clinical and operational needs, and available resources.

Before implementing any local variations of this Policy, public hospitals/health services, must consult with RiskCover (the Government of Western Australia's self-insurance fund), their private insurer (where relevant), the Legal and Legislative Services Directorate of the Department of Health or the State Solicitor's Office, to ensure:

- that their Open Disclosure procedure meets the needs of the hospital/health service
- compliance with the requirements of any relevant legislation, insurance policy and/or self-insurance cover document.

Mental Health Services in WA should also consult with the Office of the Chief Psychiatrist at the Department of Health in regard to implementing procedures for investigating and disclosing clinical incidents and deaths that occur in mental health facilities throughout WA.²

1.2 Private hospitals

Private hospitals may wish to use the Policy as a basis for developing their own Open Disclosure Policy/Procedure.

2. Background

There is strong worldwide evidence suggesting that clinical incidents are a significant cost to patients and health systems. The Harvard Medical Practice (HMP) Study^{3,4} and the Quality in Australian Health Care (QAHC) Study⁵ into medical error, remain the benchmarks in providing population level data on the rates of injuries or clinical incidents to patients in hospitals. Both studies identified a substantial amount of unnecessary human suffering as a result of medical error. For example, the HMP Study estimated that medical error in the United States resulted in 44,000 to 98,000 unnecessary deaths and 1,000,000 excess injuries each year. The consequences for patients also included prolonged admission or residual disability at the time of discharge in 3.7% of acute care admissions.⁵

In the QAHC Study an extrapolation to all acute hospitals within Australia (from the 1992 data) suggested that 50,000 patients in Australia would have suffered permanent disability and 18,000 would have died annually.⁶

Evidence suggests that patients affected by a clinical incident spend longer in hospital and have higher hospital costs. In the HMP Study, the incremental cost associated with each adverse drug event was US\$2,595 and the length of stay was increased by 2.2 days. Among adverse drug events deemed by the authors as being preventable, the excess cost was US\$4,685 and the length of stay was increased by 4.6 days.⁷ The cost of adverse drug events alone for a 700 bed teaching hospital was estimated to be US\$5.6 million per year.⁸

An extrapolation of the 1995 QAHC Study methodology to all acute hospitals within Australia, suggests that clinical incidents 'cost' the Australian health care system up to \$4.7 billion per annum⁹, of which approximately \$2 billion is preventable.^{5, 6, 10}

The modelled impact for Western Australia (at 10% of national population) is that in 2003/2004 over 40,000 inpatients sustained a clinical incident. If each clinical incident results in an extra 7.1 bed days⁵ (costing between \$700 per day and \$1,000 per bed day), it is estimated that the additional bed day cost of clinical incidents to the WA public health system in 2003/2004 was between \$198 million and \$284 million.

In addition, studies show that the most important factor in people's decisions to file lawsuits is not negligence, but ineffective communication between patients and providers. Malpractice suits often result when an unexpected adverse outcome is met with a lack of empathy from physicians and a perceived or actual withholding of essential information. Stemming the causes of medical errors requires disclosure and analysis, which creates tension in the current litigious environment.¹¹

A number of hospital systems and liability insurance providers around the world have adopted a policy of robust disclosure of medical errors.

In 2002, the University of Michigan Health System launched a program with three components:¹²

1. Acknowledge cases in which a patient was hurt because of medical error, and compensate these patients quickly and fairly.
2. Aggressively defend cases that the hospital considers to be without merit.
3. Study all clinical incidents to determine how procedures could be improved.

Before August 2001, the organisation had approximately 260 claims and lawsuits pending at any given time. As of August 2005 the number had dropped to 114. The average time from the filing of a claim to its resolution was reduced from approximately 21 months to less than 10 months. Annual litigation costs reduced from about US\$3 million to US\$1 million. The University of Michigan Health System has begun to reinvest these savings in the automation of its patient-safety reporting systems.¹²

In 1987, after two malpractice cases that together cost it more than US\$1.5 million, the Veterans Affairs (VA) Hospital in Lexington, Kentucky adopted a policy of disclosure of medical errors to its injured patients. Over 19 years the hospital has reduced its liability costs below those of comparable VA hospitals. Data indicates that average settlements were approximately US\$15,000 per claim, as compared with more than US\$98,000 at other VA institutions. The policy has also decreased the average duration of cases, from two to four years, to, two to four months, and has reduced costs for legal defence.¹²

These are just two examples of such programs, but their results are consistent with those of other organisations that have adopted a similar model.

In 2002, the Australian Council for Safety and Quality in Health Care commissioned Standards Australia to develop a National Open Disclosure Standard.¹ Endorsed by Australian Health Ministers in July 2003, the National Open Disclosure Standard promotes a clear and consistent approach by hospitals (and other organisations, where appropriate) to openly communicate with patients and their nominated relatives/carers following a clinical incident.

A national pilot of the National Open Disclosure Standard was conducted in 40 sites across Australia, including four sites in Western Australia's South Metropolitan Area Health Service (Fremantle Hospital and Health Service, Armadale Health Service, Bentley Health Service and Peel and Rockingham Kwinana Health Service). The evaluation of the National Open Disclosure Pilot was reported to the Australian Health Ministers, who in April 2008 agreed to work towards the implementation of the National Open Disclosure Standard in all health care facilities.

Concurrent with the pilot of the National Open Disclosure Standard, the Western Australian Council for Safety and Quality in Health Care has worked in partnership with the Department of Health to develop the *WA Open Disclosure Policy: Communication and Disclosure Requirements for Health Professionals Working in Western Australia* (the Policy). The Policy is a key element of the WA Clinical Governance Framework.¹³

3. Key Open Disclosure Principles

All WA public hospitals/health services practicing open disclosure will do so in accordance with the following key principles:^{1, 14}

- Expression of regret
- Disclosure of a clinical incident to a patient
- Staff support and training
- Incompetent adults and minors support
- Patient support
- Clinical governance
- Confidentiality
- Fairness

A. Expression of regret

A patient should receive an expression of regret for any harm that they have suffered as a result of a clinical incident. An apology or expression of regret **must not** include any admission of liability or fault.

B. Disclosure of a clinical incident to a patient

When a clinical incident has occurred, a patient, and with the patient's consent, their nominated relative/ carer may reasonably expect to be fully informed of the facts surrounding the clinical incident and its consequence.

C. Staff support and training

Members of the clinical team should receive appropriate support from the hospital/health service when a clinical incident occurs. The clinical team should also receive appropriate training in communication and the principles of open disclosure.

D. Incompetent adults and minors support

If a patient involved in a clinical incident is deemed to be incompetent, the patient's legal guardian should be fully informed of the facts surrounding the clinical incident and its consequences for the patient. If a guardian has not been appointed, efforts should be made to involve the patient's spouse/ defacto partner, nearest living relative, or person with a close relationship to the patient in the Open Disclosure Process if the matter is related to consent. Otherwise, legal advice should be sought.

If the patient involved in a clinical incident is a minor, the patient's parents should be involved in the Open Disclosure Process. If the patient was deemed to be a mature minor^a during the consent to treatment process, the patient should also be deemed to be a mature minor during the Open Disclosure Process. A mature minor is entitled to be fully informed of the facts surrounding the clinical incident and its consequences, and consent is required before the clinical incident is disclosed to their parents.

^a Mature minor – Refer to Appendix A: Definitions.

E. Patient support

When a clinical incident has occurred, the patient is entitled to be treated with respect and compassion and to receive appropriate, ongoing support. All patients in WA hospitals/health services have the right to seek a second medical opinion. Where possible, hospital/health service staff will assist a patient to obtain a second medical opinion, subject to the availability of an alternative medical practitioner.

The patient has a right to complain or comment about the quality of their care. The hospital/health service should provide appropriate information and assistance in relation to the complaint process. Where possible, a designated hospital/health service staff member should be assigned to assist and coordinate the provision of any ongoing support to the patient and his/her nominated relatives/carers.

F. Clinical governance

Open disclosure is a key element of the WA Clinical Governance Framework.¹³ Hospitals/health services are required to establish appropriate accountability systems that integrate the Open Disclosure Process with other clinical governance processes, including clinical incident management and reporting processes and clinical risk management procedures.

G. Confidentiality

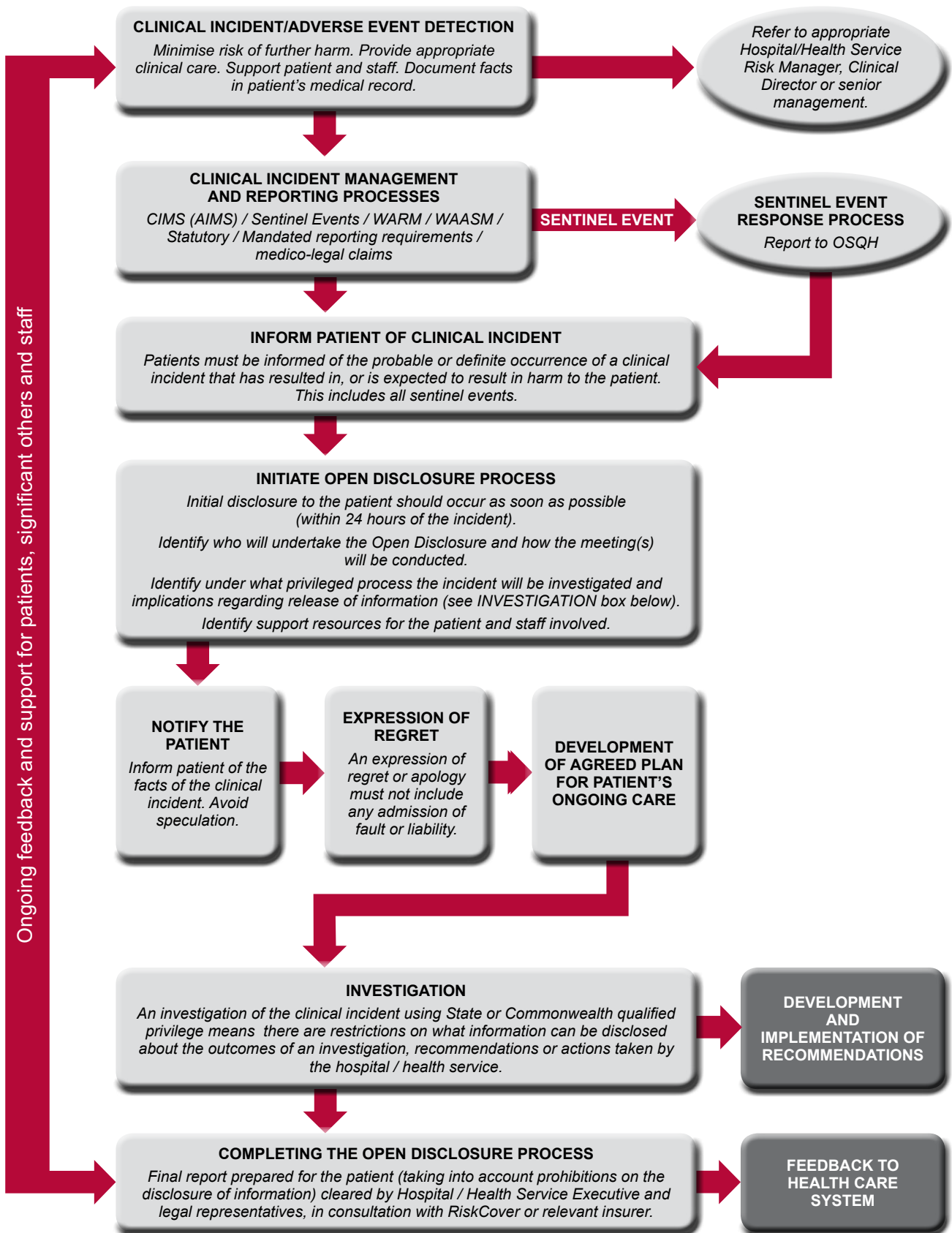
Due to the sensitive nature of the information collected during the investigation and analysis of a clinical incident, hospitals/health services and their staff are obligated to maintain the confidentiality of patient information.¹⁵ Hospitals/health services are to develop policies and procedures that take into account privacy and confidentiality for patients and staff, in compliance with relevant law.¹

Where an investigation (e.g. a Root Cause Analysis) was conducted under Qualified Privilege, there are restrictions on the information that can be disclosed (see Appendix B, Part B).

H. Fairness

When a clinical incident occurs and the Open Disclosure Process is initiated, patients and health practitioners have the right to be treated fairly. Hospitals/health services will establish a process to communicate and support patients and health practitioners when a clinical incident occurs. Additionally, clinical incidents will be investigated in accordance with relevant Department of Health policies, and system failures corrected to improve patient safety. Health practitioners are entitled to procedural fairness (the right to a fair and unbiased hearing including the right to be informed of all relevant information and the right to respond to the information) in the investigation of a clinical incident.

4. Pathway Algorithm for the Open Disclosure Process



This algorithm is intended as a summary of steps only and should not be relied upon on its own. Clinicians must ensure they are familiar with, and act in accordance with, the whole policy.

5. The Open Disclosure Process

Open disclosure is the open discussion of an incident that results in harm (or might result in future harm) to a patient* while receiving health care.¹

The Open Disclosure Process will commence after the detection of a clinical incident by:¹

- a member of staff at the time of the incident
- a member of staff, when an unexpected outcome is first detected at some time after the incident
- a patient who expresses concern or dissatisfaction with their health care either at the time of the incident or at some time after the incident
- an incident detection system such as incident reporting or medical records review.

Following the detection of a clinical incident, members of the clinical team and the hospital/health service must ensure that steps are taken to immediately prevent or reduce the occurrence of further suffering and harm to the patient. After any such steps have been initiated, the following measures should be implemented by the hospital/health service:

1. Report the clinical incident to a relevant authority, in accordance with Department of Health policy – refer to 5.1.
2. Notify the patient of the clinical incident and the facts that are known up to that point in time – refer to 5.2.
3. Undertake an investigation of the clinical incident – refer to 5.3.
4. Provide feedback to the patient – refer to 5.4.
5. Develop an agreed plan for the ongoing care of the patient – refer to 5.5.

5.1 Reporting of a clinical incident to a relevant authority, in accordance with Department of Health policy

The WA Department of Health requires all hospital/health service staff to identify, report, investigate and manage clinical incidents that occur in public hospitals (and private hospitals providing health care services to public patients) across Western Australia. This includes serious clinical incidents and deaths that occur in mental health services throughout Western Australia.

Please refer to the following policies for further guidance:

- Department of Health (2007): *Clinical Incident Management Policy for WA Health Services using the Advanced Incident Management System (AIMS)* (2nd Edition).¹⁶
- Department of Health (2008): *Sentinel Event Policy* (3rd Edition).¹⁴
- Department of Health (2006): *Matters to be reported to the Chief Psychiatrist*.²

Clinical incidents may give rise to a number of different reporting requirements, which are outlined below.

* Throughout this document, for all references to 'patient' refer to Section 3, Principal D 'Incompetent adults and minors support'.

5.1.1 Reporting of potential/actual medico-legal claims

Under the RiskCover Fund Guidelines, hospitals/health services must report all actual or potential medico-legal claims to RiskCover. Teaching hospitals report directly to RiskCover, and non-teaching hospitals/health services report through a senior manager who is responsible for medico-legal matters. Health services that are not covered with RiskCover must follow their usual reporting procedures.

5.1.2 Statutory and mandated reporting requirements

Hospital/health service staff should note that there are a number of statutory and mandated reporting requirements that need to be fulfilled, in accordance with Department of Health policy, as well as professional reporting obligations, **some of which** are outlined below:

(i) Statutory requirements

- Maternal deaths^b, perinatal and infant deaths^c and deaths under anaesthesia^d are required to be reported under sections 336, 336A and 336B respectively of Part XIII of the *Health Act 1911* (the Health Act).
- Deaths that are or may be reportable to the Coroner pursuant to section 17 of the *Coroners Act 1996*.¹⁹
- Deaths that are not reportable to the Coroner are required to be certified under section 44 of the *Births, Deaths and Marriages Registration Act 1998*.²⁰

(ii) Mandated requirements as per Department of Health (WA) policy

- Serious incidents and deaths that occur in mental health services throughout Western Australia must be reported to the Chief Psychiatrist.²
- Sentinel events must be reported to the Director, Office of Safety and Quality in Healthcare (OSQH) within seven (7) working days of the incident occurring, and the sentinel event final report submitted to the OSQH within forty five (45) working days of initial notification.²¹
- Sentinel events should also be reported via the Advanced Incident Management System (AIMS).²²
- Clinical incidents (including deaths) that result in a medico-legal claim or have the potential to result in a medico-legal claim must be reported (refer to 5.1.1 above). Any non-salaried medical practitioner (VMO/VMP) who becomes aware of an actual or potential medico-legal claim is required to forward a completed Medical Treatment Liability Notification Form to the Medical Treatment Liability Claims Manager or equivalent.²³
- Deaths should be reported to the relevant local hospital/health service body (e.g. Mortality Review Team, Clinical Governance Committee) as directed by the *Western Australian Review of Mortality: Policy and Guidelines for Reviewing Inpatient Deaths*.²⁴

^b Under section 336(1) of the *Health Act 1911*: (1) Whenever any woman shall die as the result of pregnancy or of childbirth, or as the result of any complications arising from or following upon pregnancy or childbirth, the facts of such death shall be reported forthwith to the Executive Director, Public Health by the medical practitioner and any nurse who were at the time of the death attending such woman.¹⁷

^c Under section 336A(1) of the *Health Act 1911*: (1) Whenever any child of more than 20 weeks gestation is stillborn or any child under the age of one year shall die from any cause whatsoever, the fact shall be reported forthwith to the Executive Director, Public Health by the medical practitioner who was at the time of such stillbirth or death attending that child or who certified that the death of the child had occurred.¹⁷

^d Under section 336B of the *Health Act 1911*: (1) Whenever any person shall die within the period of 48 hours following the administration of an anaesthetic agent or as the result of any complications arising from the administration of an anaesthetic, the fact of such death shall be reported forthwith to the Executive Director, Public Health by the person who administered the anaesthetic to the deceased.¹⁸

(iii) Professional obligations

- Deaths that occur while under the care of a surgeon are automatically flagged and forwarded to the WA Audit of Surgical Mortality (please see Terms and Conditions of Indemnity for Salaried Medical Practitioners and Terms and Conditions of Indemnity for Non-Salaried Medical Practitioners available at: <http://www.health.wa.gov.au/indemnity/indemnity/index.cfm>).
- Health professionals have an obligation to maintain the confidentiality of all information that comes to them in the course of providing medical treatment and care to a patient, subject to limited exceptions e.g. reporting of certain infectious diseases. The duty of confidentiality applies even where a patient has died.¹⁵

5.2 Initial disclosure to the patient

The Open Disclosure Process is part of ongoing communication between the hospital/health service and the patient. Consultation with the nominated relatives/carers of the patient may only take place with the consent of the patient.

The initial disclosure to the patient should occur as soon as possible, ideally within 24 hours of the clinical incident occurring. However, the length of time required to conduct the Open Disclosure Process will be dependent on a number of factors, including:

- the clinical condition, emotional and psychological state of the patient
- the availability of reliable clinical information
- the availability of key staff and of the patient's relatives/carers
- patient preference and privacy.

When preparing for the initial meeting, hospital/health service staff should take into account the following issues:

- Identify whether the clinical incident needs to be disclosed (refer to 5.2.1).
- Identify who will be responsible for leading the Open Disclosure Process with the patient.
- Ensure that all team members maintain a consistent approach in any discussions with the patient and or their nominated relatives/carers.

5.2.1 Identify whether the clinical incident needs to be disclosed

As a matter of policy, patients must be informed of the probable or definite occurrence of a clinical incident that has resulted in, or is expected to result in, harm to the patient, including the following:²⁵

1. A defined Sentinel Event that is reportable to the Director, Office of Safety and Quality in Healthcare (refer to *Sentinel Event Policy* for WA Health).
2. A clinical incident that has or is expected to have a significant clinical effect on the patient and that is perceptible to either the patient or the health care team. For example, if a patient is mistakenly given a dose of frusemide (a diuretic that noticeably increases urine output), disclosure is required because a perceptible effect is expected to occur.
3. A clinical incident that necessitates a change in the patient's care. For example, a medication error that necessitates close observation, extra blood tests, extra hospital days, or follow-up visits that would otherwise not be required, or an error in a surgical procedure that necessitates additional/extra (corrective) surgery.

4. A clinical incident with a known risk of serious future health consequences, even if the likelihood of that risk is extremely small. For example, accidental exposure of a patient to an infection or toxin associated with a rare, but recognised serious long-term effect (e.g. HIV infection or increased incidence of cancer).
5. A clinical incident that requires hospital/health service staff to provide treatment or undertake a procedure without the patient's consent. For example, if a clinical incident occurs while a patient is under anaesthesia, necessitating a deviation from the procedure the patient expected, the clinical incident needs to be disclosed. Patients have a fundamental right to be informed about all aspects of their treatment.

5.2.2 Identify who will undertake the disclosure

When a clinical incident occurs and requires disclosure, members of the treating team should determine who is the most appropriate person to speak to the patient. The person undertaking the Open Disclosure Process should:²⁶

- ideally be known to the patient (however it may not always be practical for a health care practitioner, who is involved in a clinical incident, to lead the Open Disclosure Process)
- be familiar with the facts of the clinical incident and the care of the patient
- be familiar with the *WA Open Disclosure Policy* and have received appropriate training in the Open Disclosure Process
- possess sound interpersonal communication skills
- be empathetic and able to offer reassurance and support to the patient
- be willing to maintain a medium to long-term relationship with the patient, as required.

Ideally, the responsible Consultant/Non-Salaried Medical Practitioner as the most senior member of the team will undertake the Open Disclosure Process. However, each hospital/health service may delegate this responsibility to an appropriate hospital/health service manager or another member of the treating team.

A junior medical practitioner or a nurse may only perform the Open Disclosure Process if he or she meets the criteria set out in the above points and has the support of other members of the treating team, particularly the Consultant/Non-Salaried Medical Practitioner. If a hospital/health service staff member has not previously participated in open disclosure, he/she should liaise with the relevant Head of Department or hospital/health service manager prior to speaking to the patient.

The hospital/health service staff member must refuse to undertake the delegated task if they do not consider they have sufficient skill or experience. Decisions made by a hospital/health service staff member, including a junior medical practitioner or a nurse in this regard, must be respected by the hospital/health service management.

5.2.3 Determine how the Open Disclosure Process will be conducted

The Open Disclosure Process is part of an ongoing communication process between the hospital/health service and the patient. At the first face-to-face discussion with the patient, the nominated leader of the open disclosure team should:

1. Introduce all people attending the meeting, including their role.
2. Acknowledge that a clinical incident has occurred.
3. Disclose any facts known at the time, as documented in the patient's medical record, outlining the chronology of clinical and other events.
4. Provide information of likely short-term and long-term effects if known (however this information may need to be deferred to a second or subsequent meeting).
5. Provide an expression of regret for the event that has occurred (when making an expression of regret avoid admitting liability for what has happened).
6. Listen to the patient's understanding of what happened and address any questions or concerns they may have.
7. Review the care plan, outlining what will happen next (e.g. return to operating theatre, need for more investigations, referral to another specialist).
8. Offer support to the patient, as required.
9. Provide the patient with contact details for the relevant health care practitioner (or an agreed substitute) to discuss further issues.
10. Provide information to the patient about how to take the matter further, including any complaint processes available to them.²⁶

Due to the length of time that may be required to undertake a thorough investigation of the clinical incident, not all of the facts may be known or available to hospital/health service staff at the time of the first meeting. If necessary, the nominated hospital/health service staff member should arrange further meetings with the patient. Hospital/health service staff must ensure that they only disclose the facts known at the time of each meeting.

(i) Admissions of liability

When undertaking the Open Disclosure Process, hospital/health service staff must not make an admission of liability. An admission of liability may occur where a hospital/health service staff member states or agrees that:

- they are liable for the harm caused to the patient or that they were negligent
- another health care practitioner is liable for the harm caused to the patient or was negligent
- the hospital/health service is liable for the harm caused to the patient or was negligent.

EXAMPLE: 1

The following example illustrates the difference between a statement of fact and an admission of liability:

- **Statement of fact:** "You were told that you had breast cancer and a mastectomy was performed. Test results of the breast tissue show that there was no cancer in the breast that was removed".
- **Admission of liability:** "I made a terrible mistake. I removed your breast but now we know that you didn't have breast cancer. It is all my fault".

(ii) Expressing regret for what has happened

During the Open Disclosure Process, a hospital/health service may provide an apology for what has happened. *The Civil Liability Act 2002 (Civil Liability Act)* defines an apology as:

*“an expression of sorrow, regret or sympathy by a person that does not contain an acknowledgement of fault by that person”.*²⁷

When expressing regret, the hospital/health service must ensure that it does not make any acknowledgement of fault/liability, otherwise the protection conferred by the *Civil Liability Act* will be lost.

Where an explanation involves the making of admissions of liability, no such explanation should be given to the patient without the prior written consent of RiskCover (as required by the RiskCover Fund Guidelines) or any other relevant insurer.

Further information is available in Appendix B: Open Disclosure Legal Information.

EXAMPLE 2:

The following example illustrates the difference between an apology and an acknowledgement of fault/admission of liability:

- **Apology:** “I am sorry that a mastectomy was performed when you didn’t have breast cancer”.
- **Acknowledgement of fault/admission of liability:** “I am sorry that I removed your breast when you didn’t have breast cancer. I feel terrible. It’s all my fault. We really messed things up”.

5.3 Investigation of a clinical incident

A clinical incident may signal a serious breakdown in health care systems and require thorough investigation and response. Any clinical incidents identified by the hospital/health service must be appropriately investigated to determine what happened and, where possible, to reduce the risk of a similar clinical incident happening again. Members of the clinical team are required to participate in any investigation that may arise from a clinical incident.

The investigation of a clinical incident should involve a comprehensive and systematic analysis of the facts to identify contributing factors. There are a number of methodologies that can be used for investigating a serious clinical incident. Root Cause Analysis (RCA) is one investigation methodology recommended by the Department of Health for investigating clinical incidents.

Hospitals/health services should refer to the following Guidelines and Standards when investigating a clinical incident:

- Department of Health (2007): *Clinical Incident Management Policy for WA Health Services using the Advanced Incident Management System (AIMS)*(2nd Edition).¹⁶
- Department of Health (2008): *Sentinel Event Policy* (3rd Edition).¹⁴
- Department of Health (2006): *Clinical Incident Investigation Standard*.²⁸
- Department of Health (2006): *Root Cause Analysis Guidelines*.²⁹

These documents can be found at the Office of Safety and Quality in Healthcare website:

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

Hospitals/health services should use an appropriate risk management process, such as the process outlined in the Department of Health's *Clinical Risk Management Guidelines*³⁰, to analyse and address any risks that the investigation has identified as being a potential or actual threat to the WA health system, hospital/health service and/or the patient, thereby minimising the chance of similar events occurring in the future.

5.3.1 Undertaking the investigation process under qualified privilege

A hospital/health service may opt to investigate a clinical incident without the protection of a qualified privilege scheme. Alternatively, a public hospital/health service may opt to conduct an investigation into a clinical incident under the:

1. State qualified privilege scheme via a declared quality improvement committee³¹
2. Commonwealth qualified privilege scheme via the Advanced Incident Management System (AIMS) process.¹⁶

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

Private hospitals and licensed health care facilities can utilise the Commonwealth scheme via the AIMS process only if AIMS is in place.

Depending on circumstances existing at the local level, each hospital/health service must decide whether to conduct the investigation with or without qualified privilege. Each of the above pathways places its own inherent restrictions on what information can be disclosed to the patient.

Further information on the qualified privilege process is available in Appendix B: Open Disclosure Legal Information.

If a hospital elects to undertake an investigation of a clinical incident using State qualified privilege, or under Commonwealth qualified privilege (i.e. AIMS), then **no information pertaining to the investigation should be released to the patient until legal advice has been obtained.**

5.3.2 Undertaking the investigation process under legal privilege

If an investigation into a clinical incident is carried out at the request of a hospital/health service's legal advisers, the communications generated during the investigation, including the investigation report, may be subject to legal professional privilege.²⁸ If a document or record is subject to legal professional privilege, that document or record is protected from disclosure unless legal professional privilege is waived. Waiver of legal professional privilege should only be made following appropriate consultation with the legal advisor, RiskCover or relevant insurer.

Hospitals/health services should consult with the Legal and Legislative Services Directorate of the Department of Health (or the State Solicitor's Office in the case of teaching hospitals), who will liaise with RiskCover or other relevant insurer, to determine whether or not to conduct the investigation with the protection of legal professional privilege.

Further information is available in Appendix B: Open Disclosure Legal Information.

5.3.3 Suspected or alleged blameworthy behaviour and purposeful unsafe acts

The principles of natural justice must be followed for every investigation into a clinical incident. Natural justice requires that:

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

If, during the course of the investigation of a clinical incident, it is suspected that the clinical incident contains elements of blameworthy behaviour or a purposeful unsafe act, the investigation team should immediately cease the investigation and refer it to the relevant hospital/health service Risk Manager, Clinical Director or senior management, allowing it to 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
- deliberate non-compliance with a hospital or health service policy or practice relating to work safety.

In some cases, it is possible that a clinical incident will involve staff performing blameworthy behaviour or committing purposeful unsafe acts (such as that described above) that is secondary to the adverse outcome pertaining to the patient. In such cases the investigation of the clinical incident 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 (5.3.3) should be reported to the Legal and Legislative Services Directorate of the Department of Health or other relevant bodies in order to deal with medico-legal claims.

5.4 Provision of feedback to the patient and/or their nominated relatives/carers

Throughout the Open Disclosure Process the hospital/health service should provide regular feedback to the patient, where legally possible, via the designated contact person. Feedback can only be given to the patient's nominated relatives/carers with the patient's consent.

Regardless of whether an investigation was undertaken with or without legal professional privilege or qualified privilege, there are restrictions on what information can be disclosed to the patient about the outcomes of an investigation, recommendations or actions taken by the hospital/health service.

Further information is available in Appendix B: Open Disclosure Legal Information.

If access to documents generated during the investigation process is sought by means of an application under the *Freedom of Information Act 1992 (FOI Act)*,³² a summons, a subpoena or any other process, please contact the Legal and Legislative Services Directorate of the Department of Health (or the State Solicitor's Office in the case of teaching hospitals) for advice as to whether or not the documents are required to be disclosed or produced.

No information should be released about the investigation until legal advice and clearance has been obtained.

5.5 Developing an agreed plan for the ongoing care of the patient

When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, they should be involved, in a practicable way, in the development of their ongoing clinical management plan.

These discussions, together with the clinical management plan, should be documented and filed in the patient's medical record. Where a patient requires ongoing medical treatment and support that cannot be provided by the hospital/health service, appropriate arrangements and advice should be given to the patient and their nominated relatives/carers^e on how to gain access to these services (e.g. counselling).

Before the patient is discharged from hospital, the hospital/health service, with the patient's consent should send a brief communication to the patient's doctor, providing summary details of:

1. The nature of the clinical incident (based on facts only and no admissions of liability).
2. The continuing care and treatment.
3. The current condition of the patient.
4. Key investigations that have been carried out to establish the patient's clinical condition.
5. Recent results.
6. Expected prognosis.

When the patient is discharged from the hospital, a discharge letter should also be forwarded to the patient's doctor or appropriate community care service, advising them of the clinical management plan that has been developed for the ongoing care and/or treatment of the patient.

^e Consultation with the nominated relatives/carers of the patient may only take place with the consent of the patient.

6. Completing the Open Disclosure Process

At the end of the Open Disclosure Process, it is recommended that the leader of the Open Disclosure Process coordinates the preparation of a final report for the patient. The final report must take into account any prohibitions on the disclosure of information, and must be cleared by the legal representatives of the hospital/health service in consultation with RiskCover or the relevant insurer.

The team leader should also provide information to the patient on how they can take the matter further, including any complaint processes available to them.

6.1 Record keeping and management of documentation

When a clinical incident occurs during treatment, it is possible that the clinical incident could be the subject of a future medical treatment liability claim. Therefore, all hospitals/health services and health practitioners must ensure that proper records are kept for any clinical incident.

Any records generated during the Open Disclosure Process are to be retained for a **minimum of seven years** by the hospital/health service in a central location, with restricted access for reasons of confidentiality. Refer to the *State Records Act 2000*, *State Records Principles and Standards (2002)* and the *Patient Information Retention and Disposal Schedule, Version 3*, (Operational Directive OD 0133/08) for further information.

(i) Documentation to be included in the patient's medical record

A clinical incident must be documented appropriately in the patient's medical record as soon as practicable. Entries in the patient's medical record should include:

- **a factual account** of the clinical incident (as known at the time of reporting), medical sequelae, and any subsequent treatment required by the patient
- a record of whether the clinical incident has been **reported to a relevant authority**, in accordance with Department of Health policy
- a record of whether the clinical incident has been disclosed to the patient
- notes relating to meetings between the hospital/health service and the patient, including detailed descriptions on what has been disclosed to the patient, including details of any expressions of regret made by the hospital/health service
- copies of correspondence sent to the patient regarding the clinical incident and/or Open Disclosure Process
- copies of correspondence sent to the patient and other health care providers regarding ongoing care of the patient and any agreed plans for follow up action.²⁵

Information recorded in the patient's medical record may have to be disclosed during any future legal proceedings or in response to a Freedom of Information application. Therefore, documentation in the patient's medical record must be strictly factual. **Speculative comments on the cause of the incident must be avoided.**

(ii) Documentation that must NOT be included in the patient's medical record

Documentation that **must not** be included in the patient's medical record includes:

- documents created during an investigation (e.g. RCA) conducted through a State or Commonwealth qualified privilege scheme or documents that are subject to legal professional privilege
- minutes of meetings held during an investigation(s) into a clinical incident
- the findings and recommendations from a clinical incident investigation that is subject to qualified privilege or legal professional privilege
- copies of statements and other documents prepared by the hospital/health service and its legal advisers and/or RiskCover (or other insurers where relevant) and their legal advisers during the course of defending a civil action
- a document protected by qualified privilege or which may be subject to legal professional privilege.
NOTE: The presence or absence of the words "legal professional privilege" on a document are not necessarily conclusive of its status as a protected document, and sometimes the court's guidance will be required on this issue.

Further information about record keeping is available in Appendix B: Open Disclosure Legal Information. Hospitals/health services should liaise with RiskCover or their private insurers and legal representatives on a case-by-case basis to ensure that the patient's medical record has been adequately maintained and that relevant records are available, when they are required.

7. Roles and Responsibilities for Open Disclosure

The roles and responsibilities of hospitals/health services and health service staff, with respect to disclosing a clinical incident to a patient, are outlined below.

7.1 Ensuring the safety and wellbeing of patients and staff

In the event of a clinical incident, hospital/health service staff must ensure the safety of all patients and staff involved in the incident and that all necessary steps have been taken to support and treat the patient, and to prevent injury to others.

(i) Ensuring the safety of the patient

Where the patient requires further therapeutic management or rehabilitation, a senior member of the clinical team should consult with the patient and develop an agreed clinical management plan.^f These discussions, together with the clinical management plan should be documented and filed in the patient's medical record.

Where a patient requires ongoing medical treatment and support, which cannot be provided by the hospital, the organisation should make appropriate arrangements and provide advice to the patient, on how to gain access to that medical treatment and support, or to social and counselling services as appropriate.

(ii) Ensuring the safety of staff members

When a patient suffers a clinical incident, individual staff members involved in the incident may also require emotional support and advice. To support their staff, hospitals/health services must:

- actively promote an environment that fosters peer support and discourages the attribution of blame
- ensure that staff members are not discriminated against because of their involvement in the Open Disclosure Process
- provide appropriate support to staff involved in a clinical incident which is separate from the requirement to provide statements for the purposes of investigation
- provide information on the support systems that are available for staff members (e.g. Doctors' Health Advisory Service, medical defence organisations, professional and collegiate associations and trade unions, hospital counsellors, employee assistance scheme, referral to specialised mental health care where appropriate) and encourage timely consultation with these organisations
- provide information to staff members involved in the clinical incident or the investigation and its outcomes, as appropriate.

^f Consultation with the nominated relatives/carers of the patient may only take place with the consent of the patient.

7.2 Ensuring compliance with insurance and legal/legislative policies

All hospitals/health services must also ensure that the endorsed Open Disclosure Process is integrated with their overall clinical risk management systems. Hospitals/health services will therefore ensure that:

- integrated risk management and quality improvement processes are in place³⁰
- systems are in place to identify, manage and investigate clinical incidents
- designated key staff participate in and have responsibility for patient safety, quality improvement and risk management
- sentinel events are reported to the Director, Office of Safety and Quality in Healthcare within seven (7) working days of the incident occurring, and the sentinel event final report submitted to the Office of Safety and Quality in Healthcare within forty five (45) working days of initial notification²¹
- training and support is provided to relevant staff in communication skills, the Open Disclosure Process, investigation and grading of clinical incidents and risk management
- the *WA Open Disclosure Policy* is actively promoted and disseminated to all staff.

WA hospitals/health services must consult with RiskCover (or private insurers where relevant), the Legal and Legislative Services Directorate of the Department of Health or the State Solicitor's Office or their private insurers, to ensure that:

- the implementation of an Open Disclosure Policy will not be in breach of legislation, their insurance policy or self-insurance cover document
- appropriate open disclosure policies and protocols are developed and implemented to meet the needs of hospitals/health services, their legal representatives and their insurers or RiskCover
- all legal and insurance requirements are fully met.

Mental health services in Western Australia should also consult with the Office of the Chief Psychiatrist at the Department of Health in regard to implementing procedures for investigating and disclosing serious incidents and deaths that occur in mental health facilities throughout Western Australia.²

7.3 Ensuring compliance with registration and indemnity conditions for hospital/health service staff and non-salaried medical practitioners

Hospital/health service staff are obligated to comply with the terms and conditions of their registration with a relevant Registration Board.

In addition, as part of their administrative obligations²⁷, hospital/health service staff have an operational role/responsibility for implementing and monitoring clinical governance systems and processes. This includes a requirement for hospital/health service staff to identify, manage, investigate and disclose clinical incidents in accordance with relevant Department of Health policies.

Doctors who are eligible for cover under Department of Health Medical Indemnity are required to cooperate with the hospital/health service and participate in clinical governance, clinical quality assurance, quality improvement and risk management processes, projects or activities as reasonably required by that hospital/health service.³³ For further information, see the Department of Health's Medical Indemnity website at: <http://www.health.wa.gov.au/indemnity/home>

Appendix A – Definitions

Admission of liability – a statement that proves, or tends to prove a person’s liability and negligence for harm or damage caused to another.²⁷

Apology – has the same meaning as in section 5AF of the *Civil Liability Act 2002* namely “an expression of sorrow, regret or sympathy by a person that does not contain an acknowledgement of fault by that person”.²⁷

Clinical incident – an event or circumstance resulting from health care which could have, or did lead to unintended harm to a person, loss or damage, and/or a complaint. In the context of this definition, a ‘person’ includes a patient, client or visitor. Clinical incidents include:

- **near misses** – incidents that may have, but did not cause harm
- **adverse events** – an incident in which harm resulted to a person. Harm includes death, disease, injury, suffering and/or disability.³⁰

Health care practitioner – includes doctors, nurses and allied health professionals. They may be employed by the hospital/health service or be under a contractual arrangement e.g. non-salaried medical practitioners (VMP, VMO).

Mature minor – minors may consent to the release of confidential information on their own behalf provided they adequately understand and appreciate the reason for and consequences of the information to be released. The minor will need to have sufficient maturity and intelligence to understand:

- that a request for the information has been made and by whom
- the nature of the information to be disclosed
- his or her right to refuse consent
- the effect of giving consent.

Whether a patient who is a minor is sufficiently mature to make decisions concerning the release of confidential information on his or her own behalf, will vary from case to case. There is no fixed age rule. Consequently, it cannot be said with any certainty that a minor who has reached a certain age is capable of making a decision in respect of his or her own person. Equally, it cannot be said that below a certain age a minor is incapable of doing so.

Where a health care professional has appropriately assessed a child to be a ‘mature minor’, it will be more difficult for the patient’s parents to subsequently assert their parental rights have been interfered with in the event confidential patient information is released to third parties as agreed to by the ‘mature minor’.

Health care professionals who assess a patient as a ‘mature minor’ should make a note of the factors taken into account in reaching that conclusion.

If in any doubt as to the ‘maturity’ of the minor, it is prudent to obtain the consent of the minor’s parents or other persons vested with parental responsibility, unless the minor objects.

Where the patient is a minor, whilst parents and guardians may have an interest in the treatment, the minor’s wishes as to the giving of information to parents should not be disregarded lightly.

The above information has been sourced from the Legal and Legislative Services Directorate of the Department of Health intranet site.³⁴

Open disclosure – the open discussion of an incident that results in harm (or might result in future harm) to a patient while receiving health care. The elements of open disclosure are an expression of regret, a factual explanation of what happened, the potential consequences and the steps being taken to manage the event and prevent recurrence.¹

Sentinel event – an event that leads to catastrophic patient outcome. The sentinel events that must be reported to the Director, Office of Safety and Quality in Healthcare, Department of Health, within seven working days are:²¹

- Procedures involving the wrong patient or body part
- Suicide of a patient in an inpatient unit
- 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 leading to the 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

Serious incidents and deaths reportable to the Chief Psychiatrist - additional to the above sentinel events that must be reported to the Director, Office of Safety and Quality in Healthcare, a number of other 'matters to be reported to the Chief Psychiatrist apply in regard to serious incidents and deaths, which occur in mental health services throughout Western Australia':²

(i) Deaths

The Chief Psychiatrist is to be informed as a matter of priority, of any death of a patient while under the care of any mental health service. This applies to voluntary and involuntary inpatients and patients cared for in the community.²

(ii) Serious incidents

Notify the Chief Psychiatrist as a matter of priority, of any serious incident and associated issue that may reflect on the standards of mental health care in WA. The reporting will include advice as to the potential for media or public implications in regard to the incident or associated issue. Serious incidents may include, but are not confined to the following examples:²

- (a) Serious assaults on or by staff, other patients or visitors
- (b) Alleged sexual assault on or by staff, other patients or visitors
- (c) Serious medication error in regard to a mental health patient, which may require review
- (d) Absconding of any forensic patient
- (e) Absconding of any detained involuntary patient at serious risk of self-harm or harm to others
- (f) Serious misuse or mistake of a function performed under the *Mental Health Act*
- (g) Activity of any government or non-government organisation which is contrary to functions under the *Mental Health Act*
- (h) Serious or significant criminal activity, which occurs either in the community or a mental health facility, reported at a mental health facility, and which may receive attention by the media or the police service
- (i) Any incident which by its nature or persons involved may receive attention by the media or the wider community

Appendix B – Open Disclosure Legal Information

Disclaimer:

The information contained in this Appendix includes a summary of legal topics relevant to the operation of the *WA Open Disclosure Policy*.

The legal information is not intended to be comprehensive. Similarly, it is not intended to be, nor should it be relied upon as a substitute for, legal advice.

If you have a legal problem you should seek legal advice tailored to your specific circumstances from the Legal and Legislative Services Directorate of the Department of Health (or the State Solicitor's Office in the case of teaching hospitals only) before acting or relying on any of the legal information in this policy.

A. RiskCover and insurers

(i) RiskCover

The Insurance Commission of Western Australia (WA) is a statutory body created under the *Insurance Commission of Western Australia Act 1986*. The Insurance Commission is a statutory insurer in relation to Motor Vehicle Third Party Personal Injury claims under the *Motor Vehicle (Third Party) Insurance Act 1943*, and 'Industrial Disease' claims under the *Workers' Compensation and Injury Management Act 1981*. However in relation to public authorities, the Insurance Commission's role is the management of the WA Government's self-insurance scheme, titled RiskCover.

RiskCover is a Managed Fund which finances the risk of WA Government public authorities through risk management, self-insurance and reinsurance. The RiskCover Division of the Insurance Commission of WA manages the Fund on behalf of the WA Government. It is important to note that RiskCover is not an insurer but rather a risk management vehicle.

Public authorities which participate in RiskCover must comply with the Fund Guidelines. One of the Fund Guidelines prohibits a public authority from making any admission of liability in respect of a claim or potential claim without consent. If a public authority does not comply with the Fund Guidelines, then RiskCover may terminate the public authority's coverage or increase the fund contribution payable by the public authority for subsequent financial years, to compensate RiskCover for the additional cost incurred.

(ii) Insurance

Not all public authorities participate in RiskCover but instead have an insurance policy with a private insurance company.

An insurance policy is a contract entered into between the insurer and the insured. The insurer indemnifies the insured in consideration of payment of a premium by the insured. Like any other contract, the indemnity offered by the insurer is subject to terms, conditions and exclusions stipulated in the insurance policy.

In insurance law, subrogation is a principle by which the insurer is entitled to have the rights of the insured subrogated to him so that the insurer is, for example, entitled to sue in the name of the insured to recover from a third party responsible for the loss. The right of subrogation arises only where the insured has been indemnified by the insurer.

At common law an insured must not do anything to prejudice an insurer's right of subrogation: *State Government Insurance Office (QLD) v. Brisbane Stevedoring Pty Ltd* (1969) 123 CLR 228.

Many insurance contracts contain a clause which prevents the insured from making an admission or an admission of liability or from compromising a claim without the consent of the insurer. Such a clause is known as an admissions and compromises clause. In many cases, an insurance contract will provide that the insurer may refuse to pay the claim in respect of certain acts (including, for example, breach of an admissions and compromises clause).

B. Disclosure of information arising from investigations

A hospital/health service may opt to investigate a clinical incident:

- without the protection of a Qualified Privilege scheme or legal professional privilege
- under the State qualified privilege scheme via a declared quality improvement committee³¹
- under the Commonwealth qualified privilege scheme via the AIMS process.³⁰

It should be noted that each of the above pathways places its own inherent restrictions on what information can be disclosed to the patient.

Irrespective of whether an investigation has been carried out without qualified privilege, or is conducted by a registered quality improvement committee using State qualified privilege,³¹ under the Commonwealth qualified privilege (i.e. AIMS),³⁰ or is the subject of legal professional privilege, no information should be released about the investigation until legal advice and clearance has been sought and obtained from the Department of Health's Legal and Legislative Services Directorate or in the case of teaching hospitals, the State Solicitor's Office.

(i) Unprotected investigations

An unprotected investigation is an investigation which is not conducted under the protection of State or Commonwealth qualified privilege or legal professional privilege.

A hospital/health service may decide to conduct an investigation without qualified privilege or legal professional privilege, in which case all, or some, of the documents generated via the investigation process are not necessarily protected and may be available to the patient or their representatives (or in some cases, the public) under the *Freedom of Information Act 1992 (FOI Act)*. These 'unprotected' documents could also become available to patients or their representatives in legal proceedings through the discovery process, or their production may be required by a court (or tribunal or professional body) in response to a valid subpoena or similar process. No information should be released about the investigation until legal advice and clearance has been obtained.

If access to documents generated during the investigation process is sought by means of an application under the *FOI Act*, a summons, a subpoena or any other process, please contact the Department of Health's Legal and Legislative Services Directorate (or State Solicitor's Office, in the case of teaching hospitals) for advice as to whether or not the documents are required to be disclosed or produced.

(ii) Investigations protected by legal professional privilege

An investigation into a clinical incident may be subject to legal professional privilege.

Legal professional privilege is a rule of law that protects the confidentiality of communications made between a lawyer and his or her client¹⁴ if the communication is made for the dominant purpose of:

- seeking or giving legal advice or professional legal assistance
- use, or obtaining material for use, in legal proceedings that had commenced, or were reasonably anticipated, at the time of the relevant communication.

Documents subject to legal professional privilege contain exempt matter and are, therefore, not accessible under the *FOI Act*: see clause 7 of Schedule 1 of the *FOI Act*. In addition, documents subject to legal professional privilege are not available for inspection via discovery processes or under summons, subpoena or similar processes.

NOTE: 'Documents' can include communications in various forms, including emails. Any record of information, whether in hard copy or electronic format, may be considered a 'document' capable of attracting the privilege.

Clause 7 of Schedule 1 of the *FOI Act* provides:

Legal professional privilege

Exemption

(1) Matter is exempt matter if it would be privileged from production in legal proceedings on the ground of legal professional privilege.

Limit on exemption

(2) Matter that appears in an internal manual of an agency is not exempt matter under subclause (1).

If an investigation report is subject to legal professional privilege, the report or the content of the report is protected from disclosure unless legal professional privilege is waived. Waiver of legal professional privilege should only be made following appropriate consultation with the Legal and Legislative Services Directorate of the Department of Health, RiskCover or private insurer.

If access to documents generated during the investigation process is sought by means of an application under the *FOI Act*, a summons, a subpoena or any other process, please contact the Legal and Legislative Services Directorate of the Department of Health for advice as to whether or not the documents are required to be disclosed or produced.

(iii) Investigations carried out by a declared quality improvement committee

If a public or private hospital in WA wishes to conduct an investigation under qualified privilege it can utilise the State qualified privilege scheme via a declared quality improvement committee.

The *WA Health Services (Quality Improvement) Act 1994 (Quality Improvement Act)* and the associated *Health Services (Quality Improvement) Regulations 1995* provide for the establishment of approved quality improvement committees to review, assess and monitor health services with a view to improving the standard of health care in WA. An investigation into a clinical incident may be carried out by a declared quality improvement committee. Further information on the State qualified privilege scheme, including disclosure of information, can be found in the Department of Health's *Qualified Privilege Guidelines*.²⁶

There are a number of provisions in the *Quality Improvement Act* which impose restrictions on the release of information generated as a result of the activities of a declared quality improvement committee:

(a) Section 9 of the *Quality Improvement Act*:

Section 9 of the *Quality Improvement Act* provides:

- “(1) A person who acquires any information solely as a result of the performance of the Committee’s functions must not make a record of, or divulge or communicate that information to any person, *except*:
- (a) for the purposes of:
 - (i) the performance of the functions of the Committee; or
 - (ii) furnishing reports to the relevant governing body referred to in section 7(1);
 - (b) in accordance with any standards, in addition to the restrictions imposed by this Act, that may be established by the Minister for the making available to the public or a section of the public of information that does not either expressly or by implication, disclose the identity of an individual or individuals; or
 - (c) with the written consent of the person to whom the information relates. Penalty: \$5,000.
- (1a) Subsection (1) applies to a person who acquires information, whether the person did so directly or indirectly.
- (2) The Minister may from time to time determine, and publish in the manner prescribed by the regulations, standards for the purposes of subsection (1)(b).”

(b) Section 10 of the *Quality Improvement Act*

Section 10 of the *Quality Improvement Act* provides:

- “(1) A person who acquires information solely as a result of a Committee performing its functions is neither competent nor compellable in civil proceedings to divulge or communicate that information to any court, tribunal, board or person.
- (1a) A document that was created by or at the request of a Committee, or solely for the performance of a Committee’s functions, is not subject to discovery and is not to be used in evidence in civil proceedings before any court, tribunal, board or person unless the document has been made available to the public or given to the Minister or to the governing body of the Committee.
- (2) Subsections (1) and (1a) do not apply to:
- (a) a report which has been furnished, or information that has been made available, to a Committee which does not disclose, either expressly or by implication, the identity of an individual; or
 - (b) a requirement made in proceedings in respect of any act or omission by a Committee or by a member of a Committee as a member.
- (3) This section does not limit section 9.”

Further, pursuant to section 11 of the *Quality Improvement Act*, “a finding or recommendation by a Committee as to the need for changes or improvements in relation to a procedure or practice is not admissible as evidence in any proceedings that the procedure or practice is, or was, careless or inadequate.”³¹

The *Quality Improvement Act* has effect despite the *Freedom of Information Act*: see section 5(1) of the *Quality Improvement Act* and section 7 of the *Freedom of Information Act*.

The effect of section 9 of the *Quality Improvement Act* is that a person who directly or indirectly acquires any information, solely as a result of that person’s membership of, employment of, or association with, a committee must not make a record of, or divulge or communicate that information to any person, except:

- “(1) for the purposes of:
 - (a) the performance of the functions of the committee; or
 - (b) furnishing reports to the relevant governing body referred to in section 7(1) of the *Quality Improvement Act*.
- (2) in accordance with any standards, in addition to the restrictions imposed by the *Quality Improvement Act*, that may be established by the Minister for the making available to the public or a section of the public of information that does not, either expressly or by implication, disclose the identity of an individual or individuals.
- (3) with the written consent of the person to whom the information relates.”

It is important to note that if the disclosure of recommendations to the patient would directly or indirectly identify another individual (such as a health professional) then the consent of that other individual will have to be obtained in addition to the consent of the patient.

If the hospital/health service wishes to disclose to the patient the recommendations of an investigation conducted under the *Quality Improvement Act*, no such information should be released until legal advice has been sought on the consent process and whether any restrictions apply to the disclosure of information, thus ensuring that no criminal offence is committed.

(iv) Investigations carried out as part of a declared quality assurance activity (AIMS)

Hospitals/health services in WA may be able to investigate a clinical incident under the Advanced Incident Management System (AIMS) process, which has the protection of Part VC (Quality Assurance Confidentiality) of the *Health Insurance Act 1973*³⁵ (Cth) (the *Health Insurance Act*). Privately licensed health care facilities can utilise the Commonwealth scheme via the AIMS process only if AIMS is in place.

Part VC section 124V in the *Health Insurance Act* states:

- “(1) The object of this Part is to encourage efficient quality assurance activities in connection with the provision of certain health services.
- (2) For the purpose of achieving that object, this Part contains provisions:
 - (a) prohibiting:
 - (i) the disclosure of information that became known solely as a result of those activities; or
 - (ii) the production to a court of a document that was brought into existence solely for the purposes of those activities; and
 - (b) protecting certain persons engaging in those activities in good faith from civil liability in respect of the activities.”³⁵

Prohibition on disclosure of information arising out of AIMS

Public hospitals/health services can investigate a clinical incident under qualified privilege via the AIMS process. However, it must be noted that there are a number of prohibitions on the disclosure of information arising out of investigations of clinical incidents under the AIMS process.

Section 124Y of the *Health Insurance Act* provides:

- “(1) Subject to this section, a person who acquires any information that became known solely as a result of a declared quality assurance activity, whether the person acquired the information in the course of engaging in that activity, as a result of a disclosure under section 124Z or in any other way, must not, except for the purposes of that activity or in accordance with an authority given by the Minister, directly or indirectly make a record of that information or disclose that information to another person or to a court.

Penalty: Imprisonment for 2 years.

- (2) Subject to this section, a person cannot be required:
- (a) to produce to a court a document that was brought into existence solely for the purposes of a declared quality assurance activity; or
 - (b) to disclose to a court any information that became known solely as a result of such an activity; except when it is necessary to produce the document or disclose the information for the purposes of this Part.
- (3) Subsections (1) and (2) do not apply to information that does not identify, either expressly or by implication, a particular individual or particular individuals.
- (4) Subsection (2) does not apply to a document that does not identify, either expressly or by implication, a particular individual or particular individuals.
- (5) This section does not prohibit a disclosure of information if the person, or each of the persons, who would be directly or indirectly identified by the disclosure consents to that disclosure of the information.
- (6) This section does not prohibit the disclosure of information to the Minister for the purpose of enabling the Minister to decide whether to authorise the disclosure of the information under section 124Z.
- (7) If a quality assurance activity ceases to be a declared quality assurance activity, this section nevertheless continues to apply in respect of information that became known, or a document that was brought into existence, at a time when the activity was a declared quality assurance activity.”

The effect of section 124Y of the *Health Insurance Act* is that a person, who acquires any information that became known solely as a result of a declared quality assurance activity, must not directly or indirectly make a record of that information, except:

- for the purposes of that activity (section 124Y (1))
- where information does not identify, whether expressly or by implication, a particular individual or particular individuals (section 124Y (3)).

Further, the effect of section 124Y of the *Health Insurance Act* is that a person who acquires any information that became known solely as a result of a declared quality assurance activity, must not directly or indirectly disclose that information to another person or to a court, except:

- for the purposes of that activity (section 124Y (1))
- in accordance with an authority given by the Minister (sections 124Y (1) and 124Z)
- where information does not identify, whether expressly or by implication, a particular individual or particular individuals (section 124Y (3))
- if the person, or each of the persons, who could be directly or indirectly identified by the disclosure consents to the disclosure of the information (section 124Y (5))
- to the Minister for the purpose of enabling the Minister to decide whether to authorise the disclosure of information under section 124Z (section 124Y (6)).

If the hospital/health service wishes to disclose to the patient the recommendations of an investigation conducted under qualified privilege under the AIMS process, no such information should be released until legal advice has been sought on the consent process and whether any restrictions apply to the disclosure of information, thus ensuring that no criminal offence is committed.

C. Apologies

Part 1E of the *Civil Liability Act 2002*²⁷ (the *Civil Liability Act*) relates to apologies.

Part 1E of the *Civil Liability Act* does not apply unless the civil liability giving rise to the claim arises out of an incident happening on or after 1 December 2003: see section 5AG(3) of the *Civil Liability Act*.

Section 5AH of the *Civil Liability Act* provides:

- “(1) An apology made by or on behalf of a person in connection with any incident giving rise to a claim for damages –
- (a) does not constitute an express or implied admission of fault or liability by the person in connection with that incident; and
 - (b) is not relevant to the determination of fault or liability in connection with that incident.
- (2) Evidence of an apology made by or on behalf of a person in connection with any incident alleged to have been caused by the person is not admissible in any civil proceeding as evidence of the fault or liability of the person in connection with that incident.”

An apology is defined in section 5AF of the *Civil Liability Act* and means “an expression of sorrow, regret or sympathy by a person that does not contain an acknowledgment of fault by that person”.

Therefore, if a person makes an expression of sorrow, regret or sympathy in relation to an incident giving rise to a claim for damages and the apology does not contain an acknowledgment of fault, then that apology does not constitute an admission of fault or liability and is not relevant to the determination of fault or liability in connection with the incident.

D. Patient confidentiality

Health care practitioners are obligated to maintain the confidentiality of all information that comes to them in the course of providing medical treatment and care to a patient. The duty of confidentiality applies even where a patient has died.

Persons participating in the Open Disclosure Process are required to comply with Operational Circular 2050/06 entitled “*Patient Confidentiality and Divulging Patient Information to Third Parties*”. Information cannot be disclosed under the Open Disclosure Process to a person other than the patient where such disclosure would involve a breach of confidentiality.

Where consent to the disclosure of information has been given by a competent patient then no breach of confidentiality arises.

Consent to the disclosure of confidential patient information may also be given on behalf of a patient. For example, the parent(s) of a patient who is a minor and the legal guardian of a mentally incompetent adult patient.

However, if a question arises as to whether another person (for example, a guardian or parent) may provide consent on behalf of a person for the purposes of section 9(1)(c) of the *Quality Improvement Act* or section 124Y(5) of the *Health Insurance Act*, hospital/health service staff will need to seek legal advice.

E. Defamation

Defamation is a tort at general law which consists in the publication of defamatory matter about a person. *The Defamation Act 2005* (WA) has modified the general law relating to the tort of defamation. A person who has been defamed may take civil action seeking damages for defamation.

Criminal defamation is an offence contrary to section 345 of *The Criminal Code 1913* (WA). Section 345 of the *Criminal Code 1913* relevantly provides:

- “(1) A person who, without lawful excuse, publishes matter defamatory of another living person (*the victim*) –
- (a) knowing the matter to be false or without having regard to whether the matter is true or false; and
 - (b) intending to cause serious harm to the victim or any other person or without having regard to whether such harm is caused;
- is guilty of a crime and is liable to imprisonment for 3 years.

Summary conviction penalty: imprisonment for 12 months and a fine of \$12 000.”³⁶

F. Guidelines for good medical record keeping

The following guidelines on medical record keeping has been sourced from the Legal and Legislative Services Directorate of the Department of Health intranet site.³⁷

The medical record is, in general, a contemporaneous record of events that have taken place and reflects the facts of treatment. Whilst it primarily serves as a clinical record for the management of patients, it is also a useful tool in court proceedings.

The importance of accurate record keeping cannot be over-emphasised. Frequently, the information contained in the medical record provides the basis for advice given to a patient by a solicitor whether to sue a public health authority or health care professional. It not only serves as a starting point in civil litigation but can form the basis of a Coroner's decision whether to hold an inquiry into a death in hospital.

When creating, or making an entry in, a medical record it is recommended that:

- All documentation be filed in chronological sequence.
- Progress notes be integrated, i.e., medical, nursing and allied health professionals all using the same record.
- Each record page be clearly identified with the patient identification.
- All entries in the medical record be legible and clear.
- All entries in the medical record be dated, timed, signed and include the position/office of the author. It is important that the author is identifiable. Where signatures are illegible, staff should print their surname alongside the entry.
- All entries be concise, accurate, relevant, in chronological order and treated confidentially.
- Leaving applicable data items blank on forms be avoided.
- The use of non-specific terms such as "*had a good day*" be avoided.
- All entries be objective, i.e., facts only. Subjective or emotional statements and moral judgments should be avoided.
- An example of a subjective comment in relation to a patient would be a notation to the effect that the patient "*appears drunk*". An example of an objective comment would be "*the patient was unsteady on his feet, speech slurred and his breath smelt strongly of alcohol*".
- Another example of a subjective comment would be "*the patient was uncooperative*". Recorded objectively the entry might read "*the patient refused his medication and stated he did not wish to have a shower*".
- There may be times when it is necessary to record opinion for clinical purposes (e.g., where problem-solving approaches to patient care are used). Where such opinion is expressed, the objective data and clinical observations upon which the opinion is expressed should be recorded as well as the opinion(s) formed on the basis of that information. For example, "*Mrs Peterson is pale, sweating, has a feeble pulse with a blood pressure of 90/40. Query shock*".
- Wherever possible, only those events the author has direct knowledge of (e.g., matters you saw, heard, did, said or felt) be recorded.
- Where it is necessary to record hearsay information, state the source of your information. For example, where a patient informs you he or she fell out of bed but you did not witness the event, the entry should read "*the patient says she fell out of the bed during the night...*". Do not write "*the patient fell out of bed during the night*" as the patient's legal counsel could try to use such a statement in court as an admission by the health service the event in fact took place.
- Gaps are not to be left between entries.
- Only authorised or approved forms be used to document patient information.
- Every patient encounter be documented, including telephone conversations and failed attempts to make telephone contact. If any conversation takes place at home or whilst in the middle of ward rounds an entry in the patient's medical record should be made at the next available moment, and dated appropriately. There is nothing to stop health care professionals from making a brief note at the time of the conversation, which can be properly entered into the medical record subsequently.

- When recording telephone advice include in your notation who you spoke to, the person's designation, what their instructions were and what action you took as a result of that advice.
- Every encounter (including telephone conversations and failed attempts to make telephone contact) with the referring or treating medical practitioner, consultant or specialist, be documented.
- Wherever possible, entries be contemporaneous. Document as close as possible to the time the event occurred. If additional information is added later, note '*Late Entry*' and write the time and date of the addition and then sign.
- The sooner after the event an entry is made the more inclined a court will be to accept it as a true record of events. The fact that an entry must be made contemporaneously is also relevant to a rule of evidence regarding witnesses refreshing their memory from documents. The general rule is that a witness at trial may only refresh their memory from a document if it was made at the time or shortly after the event.
- Avoid the practice of writing notes ahead of time. For example, a notation written by night staff at 4 am that "*the patient had 6 am medication as charted*" when the patient dies at 5 am.
- When a word, line or extra note is written in error do not erase, "white out" or otherwise totally obliterate the entry. Do not write over an existing entry. Instead, correct the entry as soon as possible by:
 - Drawing a single line through each word or line of words
 - Write "mistaken entry" next to it before initialling, dating and signing the correction
 - Enter the correct information
 - Blue/black pen be used for recording information, not pencil.

Further information can be obtained by contacting Legal and Legislative Services Directorate of the Department of Health by telephone on (08) 9222 4038 or via the Legal and Legislative Services' intranet site at:

<http://intranet.health.wa.gov.au/LLSD/contacts/index.cfm>

References

1. Australian Council for Safety and Quality in Health Care. Open Disclosure Standard: A national standard for open communication in public and private hospitals, following an adverse event in health care 2003: Available from: www.safetyandquality.health.wa.gov.au.
2. Operational Circular 2061/06. *Matters to be reported to the Chief Psychiatrist*. Department of Health; 2006.
3. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med*. 1991 Feb 7;324(6):370-6.
4. Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med*. 1991 Feb 7;324(6):377-84.
5. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The Quality in Australian Health Care Study. *Med J Aust*. 1995 Nov 6;163(9):458-71.
6. Wilson RM, Harrison BT, Gibberd RW, Hamilton JD. An analysis of the causes of adverse events from the Quality in Australian Health Care Study. *Med J Aust*. 1999 May 3;170(9):411-5.
7. Hunter D, Bains N. Rates of adverse events among hospital admissions and day surgeries in Ontario from 1992 to 1997. *Canadian Medical Association Journal*. 1999;160(11):1585-6.
8. Weingart SN, Wilson RM, Gibberd RW, Harrison B. Epidemiology of medical error. *BMJ*. 2000 Mar 18;320(7237):774-7.
9. Ehsani JP, Jackson T, Duckett SJ. The incidence and cost of adverse events in Victorian hospitals 2003-04. *Med J Aust*. 2006 Jun 5;184(11):551-5.
10. Wilson RM, Van Der Weyden MB. The safety of Australian healthcare: 10 years after QAHCS. *Med J Aust*. 2005 Mar 21;182(6):260-1.
11. Clinton HR, Obama B. Making patient safety the centerpiece of medical liability reform. *N Engl J Med*. 2006 May 25;354(21):2205-8.
12. Liebman CB, Hyman CS. A mediation skills model to manage disclosure of errors and adverse events to patients. *Health Affairs*. 2004;23(4):22-32.
13. Department of Health. *Western Australian Clinical Governance Framework*. In: Office of Safety and Quality in Healthcare, editor. 2005.
14. Department of Health. *Sentinel Event Policy*. In: Office of Safety and Quality in Healthcare, editor. Perth: Government of Western Australia; 2008.
15. Operational Circular 2050/06. *Patient Confidentiality and Divulging Patient Information to Third Parties*. Department of Health; 2006.
16. Department of Health. *Clinical Incident Management Policy for WA Health Services using the Advanced Incident Management System (AIMS)*. In: Office of Safety and Quality in Healthcare, editor. Perth: Government of Western Australia; 2007.
17. Operational Circular OP 1453/01. *Reporting of Maternal Deaths*. In: Department of Health., editor. 2001.

18. Operational Instruction OP 1197/99. *Reporting of Deaths of Persons Under Anaesthesia*. In: Department of Health., editor.1999.
19. Operational Circular IC 0008/07. *Coroners Act 1996*. In: Department of Health., editor.2007.
20. Operational Directive OD 0087/07. *Assessment of the Extinction of Life and the Certification of Death*. In: Department of Health., editor.2007.
21. Operational Directive 0104/08. *Sentinel Events to be Reported to the Director, Office of Safety and Quality in Healthcare*. 2008.
22. Operational Directive OD 0106/08. *Clinical Incident Management Policy using the Advanced Incident Management System (AIMS)*. In: Department of Health., editor.2008.
23. Operational Circular OP 1850/04. *Non-Salaried Medical Practitioners: Protocols for Notifying and Managing Medical Treatment Liability Claims/Potential Claims*. In: Department of Health., editor.2004.
24. Operational Directive OD 0149/08. *WA Review of Mortality Policy*. In: Department of Health., editor.2008.
25. Department of Premier and Cabinet. *Administrative Instruction 707: Obligations of an Officer*. 1989.
26. Department of Health. *Qualified Privilege Guidelines*. In: Office of Safety and Quality in Healthcare, editor. Perth: Government of Western Australia; 2006.
27. Government of Western Australia. *Civil Liability Act 2002*. State Law Publisher.
28. Department of Health. *Clinical Incident Investigation Standard*. In: Office of Safety and Quality in Healthcare, editor. Perth: Government of Western Australia; 2006.
29. Department of Health. *Root Cause Analysis Guidelines*. In: Office of Safety and Quality in Healthcare, editor. Perth: Government of Western Australia; 2006.
30. Department of Health. *Clinical Risk Management Guidelines for the Western Australian Health System*. In: Office of Safety and Quality in Healthcare, editor. Perth: Government of Western Australia; 2005.
31. Government of Western Australia. *Health Services (Quality Improvement) Act 1994*. State Law Publisher.
32. Government of Western Australia. *Freedom of Information Act 1992*. State Law Publisher.
33. Operational Directive 1861/04. *Quality and Safety Requirements applying to Medical Practitioners Medical Indemnity – Version 2*. In: Department of Health., editor.2004.
34. Legal and Legislative Services Directorate. *Consent of minors on their own behalf*. Department of Health; 2009 [15 April 2009]; Available from: <http://intranet.health.wa.gov.au/LLSD/patient/index.cfm#3m>.
35. Commonwealth of Australia. *Health Insurance Act 1973*. Consolidated Acts.
36. Government of Western Australia. *Criminal Code 1913*. Perth: State Law Publisher; 1913.
37. Legal and Legislative Services Directorate. *Guidelines for good medical record keeping*. Department of Health; 2008 [cited 2009]; Available from: <http://intranet.health.wa.gov.au/LLSD/recordkeeping/index.cfm>



Delivering a **Healthy WA**



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

Produced by the Office of Safety and Quality in Healthcare
© Department of Health 2009