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Open Disclosure

Managers Handbook



**A HANDBOOK FOR HOSPITAL MANAGERS TO ASSIST WITH
THE IMPLEMENTATION OF THE OPEN DISCLOSURE STANDARD**



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While this document gives some guidance on legal issues, it does not claim to provide legal advice. Hospitals and other organisations implementing the Standard will need to seek their own legal advice on implementing the Open Disclosure Standard. Organisations implementing the Open Disclosure Standard remain fully responsible for managing their legal risks

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Open Disclosure

A family's perspective

MR SILVESTRO was admitted to hospital with pneumonia and Chronic Obstructive Pulmonary Disease. He lived with his wife in a retirement village and they had strong support from their children and families. While in hospital he had a fall and sustained a fractured femur that was not diagnosed for some time.

Eight days after the fall he was operated on. After the surgery he was transferred to the orthopaedic ward and Mr Silvestro's daughter asked the nurse looking after him why it took so long for the fracture to be discovered and acted on. The nurse was not sure so she said she would try to find out. Three days later Mr Silvestro's daughter again asked for an explanation as to why her father's operation had been delayed. Because she was upset and angry that she hadn't received any information or explanation the ward nurse immediately referred her to the Senior Nurse Manager.

A discussion with staff from the medical and orthopaedic teams followed. It was decided that the Senior Medical Specialist and Nurse Manager should discuss what had happened with Mr Silvestro, his wife and daughter. The Nurse Manager consulted with Mr Silvestro and his family regarding the need for an interpreter because Mr Silvestro and his wife were not fluent English speakers. The Specialist apologised to Mr Silvestro for the delay and was frank in providing information about procedures that had not been followed in review and reporting of the fall. He also outlined changes to requirements for examining patients after a fall even where there is no obvious injury. The ward initiated changes to ensure these procedures were followed and this was communicated to the Silvestros in a letter from the CEO.

Mr Silvestro and his family were pleased with the outcome as they felt that the hospital had, after the initial delay in response, taken the incident seriously and treated their concerns with sensitivity.

This handbook is designed to assist hospital managers in the implementation of the Open Disclosure Standard and forms part of the Open Disclosure Education and Organisational Support Package.

Pam McClean Cancer Communications Centre and the Northern Sydney Health Clinical Practice Improvement Unit developed the package in 2002-2003 for the Open Disclosure Project. The Education and Organisational Support Package has a number of components including the following:

- Interactive CD Rom
- Facilitators handbook for the:
 - Open Disclosure Workshop and Trigger Video
 - Ward In-service Training Module
- Managers Handbook
- Health Care Professionals Handbook
- Open Disclosure Implementation Toolkit

Implementation of the Open Disclosure Standard should be considered in the context of local policies and guidelines. This Handbook is designed to compliment existing local resources that provide guidance on many of the issues covered by the Standard. Information will be relevant for clinical managers as well as individuals responsible for clinical risk and patient safety.

What is Open Disclosure?

OPEN DISCLOSURE is about providing an open, consistent approach to communicating with patients and their family and carers following an adverse event. This includes expressing regret or sorrow for what has happened to them, maintaining a dialogue that gives them the facts about the event, providing information about their ongoing care, and communicating the steps taken to prevent recurrence. Inherent in the principle of changing systems is the requirement to accept the fallibility of individuals and to move beyond the culture of blame. The Open Disclosure Standard defines an adverse event as an incident in which unintended harm resulted to a person receiving health care.

The Ethical Basis for Open Disclosure

THE ETHICAL BASIS for the disclosure of information to patients and their families following an adverse event are the principles of being truthful, open and honest, respect for patient autonomy and putting the welfare of the patient first. Openness and honesty is the basis for the relationship of trust that patients have with their health professional team and the institution in which they are being treated.

Where an adverse event occurs that requires further treatment, communication about the facts of the event is essential for ensuring the patient has the necessary information to make decisions regarding their care and is part of the consent process. Communicating openly will assist patients to make the best, most informed decision with the information available.

Health care organisations are obligated to facilitate the disclosure of information to patients regarding their care by virtue of the patient-provider relationship which is based on trust. If a clinician refuses to disclose information to a patient and the organisation deems it to be the correct response, it is the ethical obligation of the health service manager to ensure that this occurs despite the objections of the individual clinician. An expression of regret, acknowledgment that an adverse event has occurred and disclosure of the facts of the event help to restore trust in the patient-provider relationship. It can provide some reassurance to the patient that the institution is acting in the best interest of the patient and is committed to the truth.

In those organisations where teaching health care professionals is a primary mission, disclosure of information is pivotal to their educational obligations to foster an environment of learning. Managers have the responsibility for ensuring systems are in place that assist individual and organisational learning to prevent recurrence of the adverse event.

The Challenges

THE CHALLENGE for managers is to:

- facilitate clinical management systems that are designed around the patient's perspective;
- foster a culture to support and encourage open discussion of adverse events and possible strategies to prevent them from recurring;
- abolish the blame culture and move away from focusing on individual error;
- provide avenues for managers and health care professionals to learn from adverse events;
- develop patient focused multi-disciplinary teams;
- empower managers and health care professionals to make changes to manage clinical risk.



HOW CAN THIS BE ACHIEVED?

Systems and process changes can be implemented in a relatively short timeframe but changes in behaviour and attitudes take time. General strategies to assist managers in achieving cultural change include:

Leadership — Enlist a clinician leader to champion the open disclosure cause who will positively promote the open disclosure process and lead by example. It takes leaders who are willing to create a clear vision of improved patient safety to change attitudes and provide hope for a different future.

Communication — Look for opportunities to get the message out, including meetings, telephone calls, e-mail, memos and newsletters. Keep in mind the “teachable moments” when errors occur and health care professionals are looking for answers and feedback these opportunities into the organisation to foster continuous improvement. Be persistent in order to encourage cultural change.

Enlist patients — Successes have been found when patients have been asked to become part of the solution. Health care professionals often relate better to patients' experiences and explore the issues together.

Continuous learning — Continue to learn and adapt, and involve health care professionals in the learning process. Health care professionals are curious and willing to learn about new ideas and approaches. Provide them with articles, run workshops and give them time out from normal duties to receive the training they need.

Listen — Listen carefully to health care professionals' concerns and try to understand their view of your efforts. For example, they may see this as “just one more” administrative project that will go away. You may need to find out if they are carrying around an old story or a grudge that is blocking their participation. You will need to explain to them the personal benefits of being involved in the open disclosure process. Invite experts from other organisations who have had success and learn from their experience - sometimes it takes an outside expert delivering the same message that you have, for people to hear.

Training — A series of interactive workshops utilizing case studies (see Ward-based Training Module) are also useful to explore the open disclosure process. Ensure training sessions or workshops are conducted by someone sufficiently skilled to deal with difficult, and emotional issues that may arise.

Key Personnel

INDIVIDUAL RESPONSIBLE FOR CLINICAL RISK

Health care organisations need to designate responsibility for the management of risks associated with the delivery of clinical care. The person responsible needs to be of sufficient seniority to have credibility and be able to drive change to effect improvements. He or she will oversee the implementation of the open disclosure process within the organisation. In a small organisation this may be a clinician leader or a senior manager.

EXECUTIVE SPONSOR

To successfully implement open disclosure executive support at the highest level is required. Executive sponsors at every level of your hospital and the health system, should be delegated with responsibility for overseeing implementation of the Open Disclosure Standard.

WORKSHOP FACILITATOR

When implementing the workshops described in the Support Package (Open Disclosure Introductory Workshop and Ward In-service Training Module) it is important that this is facilitated by someone who has appropriate training and is able to manage the emotional issues that may arise.

Strategies to Facilitate Open Disclosure

SPECIFIC strategies for increasing awareness of and commitment to Open Disclosure include:

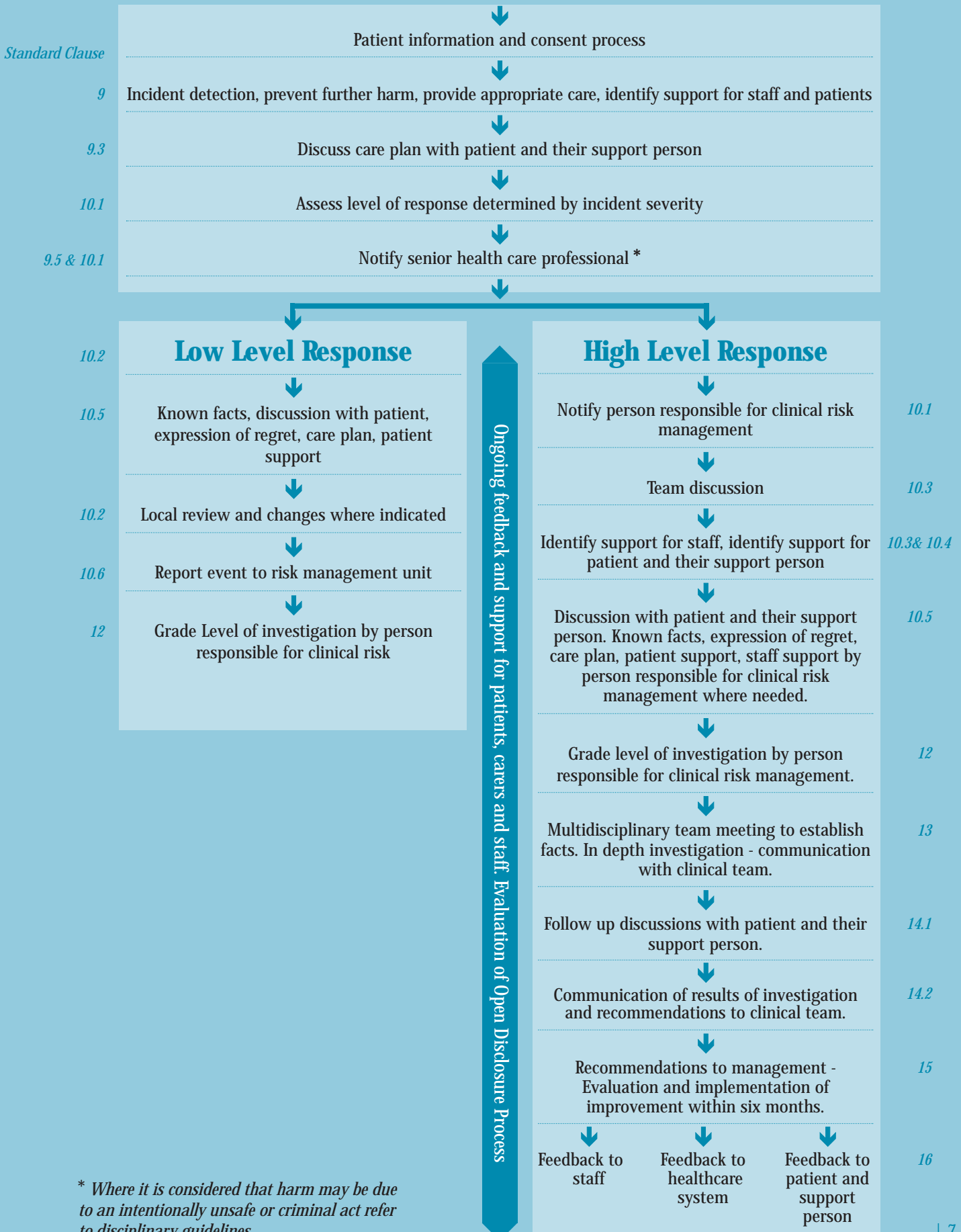
- presentation of open disclosure “cases” at grand rounds, hospital inservices or peer review meetings that include medical, nursing and allied health staff;
- scheduling an open disclosure session into your orientation program for all new staff;
- inclusion of open disclosure as part of your hospital’s ongoing performance appraisal;
- provision of training for health care professionals to assist them to see a situation and act from the perspective of the patient;
- identification and support of clinical champions in open disclosure;
- a facility for anonymous reporting of adverse events;
- training health care professionals to work together effectively in teams;
- ensuring that the teams involved in an adverse event have the opportunity to meet and informally debrief as soon as possible after the adverse event;
- organising regular multi-disciplinary team meetings to discuss adverse events at a local ward level;
- rewarding those who report adverse events and who participate in open disclosure through mechanisms such as improved career prospects or favourable insurance premiums;
- providing appropriate leave from the workplace for health care professionals traumatised by their involvement in an adverse event
- abolish disincentives to report adverse events. Reporting could be facilitated through professional colleges rewarding those who engage in open disclosure within their postgraduate training schemes; and
- include an open disclosure question during recruitment interviews.

“The way things are done”

Perspective of a Plaintiff Lawyer

***I HAD NUMEROUS** experiences where our firm would review a file and, in what we called the “sorry, we can’t take your case because we don’t believe there was malpractice” letter, I would explain just what had happened or what we had been able to piece together. On many occasions I would get a tearful “thank you” from patients and their families because they finally had answers to their questions. No one in the hospital would talk to them. No one would say “I’m sorry this happened to you,” and that more than anything made them angry and defensive about the situation. I found it incredibly sad and an indictment of “the way things are done” that the only place a patient or family could get answers to questions was a plaintiff’s lawyer who was saying “I’m sorry you went through this. There isn’t malpractice here but here’s what happened.” After that, we would get calls asking us “so why didn’t they just TELL us this in the first place?”*

Open Disclosure Flow Chart



Legal issues

THE LEGAL implications of the open disclosure process will vary between jurisdictions and types of organisations (eg, public and private). Organisations need to consider the legislation applying to them, both Commonwealth and State/Territory and general legal principles.

An organisation's internal open disclosure policy and training materials need to be consistent with relevant legal obligations. Insurance issues will also need to be taken into account. In a hospital setting there is a complex web of relationships, with attendant rights, roles and responsibilities. A range of health care professionals are likely to be involved in an adverse event. Responsibilities will be owed to the patient and the organisation, although the specific legal basis of the relationship with the organisation will vary depending on whether the health care professional is regarded, at law, as an employee or as an independent contractor.

PRIVACY AND CONFIDENTIALITY

Organisations and health care professionals will have to have regard to obligations of privacy of patients, staff and others, when conducting investigations, creating reports and making any disclosures under the open disclosure process. Care will also have to be taken to ensure that any information obtained as part of the open disclosure investigation is recorded and stored in accordance with the legislation.

Organisations should develop their own guidelines to ensure that the relevant privacy principles and other obligations of confidentiality are adhered to during the open disclosure process. It is important to note that this legislation also provides patients with the right to access information about their care such as their medical record.

The safest way to ensure there is not a breach of privacy or confidentiality is to obtain the consent of the patient to disclose specified information to nominated persons. This can be done at the time of admission.

Health care managers also have an obligation to ensure that incorrect or libellous information regarding individual health care professionals is not carelessly communicated in a manner that jeopardises their reputation or career. Consideration should be given to keeping information that is generated during the investigation process confidential; however, the patient should be given an accurate summary of the findings.

It is possible that a health care professional or other person could be defamed by virtue of a statement, either verbal or written, "published" by an organisation or health care professional to another person during the open disclosure process. For example, during the investigation a

health care professional may allege that another is incompetent. For an action of defamation to arise, it is only necessary for the communication to be made to one other person. It is not even necessary for a person to be referred to by name, in order to be defamed, if it can be shown that the person could be readily identified.

Health care organisations should ensure that health care professionals, in their training in open disclosure, are informed that they must be careful about information recorded and what is said to and about others during the open disclosure process. There also needs to be a process for independent review of the investigation process so that there is some avenue for resolution of complaints where a clinician or clinical team does not agree with the outcomes of the investigation.

LEGAL PROFESSIONAL AND QUALIFIED PRIVILEGE

In some circumstances, which should be detailed in the organisation's open disclosure policy, it may be necessary to undertake the open disclosure process in tandem with other legal or investigative processes so as to appropriately utilise:

- legal professional privilege
- qualified privilege legislation.

Legal professional privilege applies only in limited circumstances and may be used where an organisation or legal adviser requires documents to be created (e.g. reports, witness statements) for the purpose of obtaining or giving legal advice on the incident or for use in legal proceedings, should this eventuate.

Insurance Considerations

AN ADVERSE event may involve more than one insurer because of the range of health care professionals who make up a multidisciplinary team. In some cases there may be conflicting interests. It is important that those involved are fully aware of their own responsibilities in regard to their insurance policies.

Many policies of insurance granted by insurers and medical defence organisations will require the insured to notify and take early advice from the insurer of an adverse event, usually within a certain period of time following the adverse event (“the notification requirement”).

Insurance policies may also set out other requirements which the indemnifiers impose on the organisation, such as what can or cannot be said by staff before the insurer is notified of the adverse event (if the event is one requiring such notification). In order to comply with their indemnifiers requirements, each health care organisation should ensure that:

- their insurers are consulted regarding notification requirements before implementing an open disclosure policy;
- the manager responsible for overseeing the management of adverse events is aware of what events are to be notified under an insurance policy in force in respect of that organisation and the requirements for the timing of relevant notifications; and
- health care professionals are instructed to report adverse events to the appropriate manager promptly.

After completion of the investigation, feedback to the patient may take the form of a face-to-face interview, a letter or both. The interview and/or letter should include:

- reference to the clinical and other relevant facts;
- reference to details of the concerns or complaints of the patient and support person;
- an expression of regret for the harm suffered;
- a summary of the factors contributing to the adverse event; and
- information on what has been and will be done to avoid repetition of the adverse event, and how these improvements will be monitored.

In cases where litigation is anticipated they should seek advice on the content of the letter from the appropriate insurer.

For a more in depth discussion of the legal and insurance issues around open disclosure please consult the Open Disclosure Standard. Also, please note the Disclaimer on page 1 of the Handbook.

QUALIFIED PRIVILEGE LEGISLATION

Qualified privilege legislation, in some form, has been enacted by the Commonwealth, all States and the ACT and protects from disclosure to third parties certain information generated as a result of particular quality assurance activities¹.

The Commonwealth and State legislation (but not the ACT's) requires that persons who acquire information solely as a result of their membership of, or an association with, a committee or project that attracts qualified privilege must not make a record of or divulge information to any person, with limited exceptions.

Many of the adverse events which trigger the open disclosure process will not trigger a quality assurance activity under the legislation

(assuming that the legislation applies in a particular case). Therefore when an adverse event occurs, qualified privilege will rarely apply and the open disclosure process will not be affected by the qualified privilege legislation.

A health care organisation which has the qualified privilege legislation available to it should include in its internal open disclosure policy, the circumstances where it is likely that a quality assurance activity under the legislation will be invoked.

¹ Health Act 1993 (ACT), Health Administration Act 1982 (NSW) (ss.20D-20K), Health Services Act 1991 (Qld) (ss. 30-38), Health Commission Act 1976 (SA) (s. 64D), Health Act 1997 (Tas), Health Services Act 1988 (Vic) (s. 139), Health Services (Quality Improvement) Act 1994 (WA) and Health Insurance Act 1973 (Cth) (Part VC).

Frequently asked questions

WHY IS OPEN DISCLOSURE IMPORTANT?

As knowledge about health grows and the use of new technologies increases, the provision of health care is becoming more complex. In this context, health care organisations need to create an environment that encourages the identification and reporting of adverse events so that opportunities for learning can be identified and acted on. In working towards an environment that is as free as possible from adverse events, there is a need to move away from blaming individuals to focusing on establishing systems of organisational responsibility.

Open disclosure can:

- Improve patient safety through improved systems learning;
- Increase trust between patients and health care professionals;
- Assist patients in becoming more active participants in their care.

WHAT INFORMATION SHOULD BE PROVIDED TO PATIENTS?

Informing patients, families or support persons about what can be expected during their hospital stay is an important element in the duty of health care organisations. As well as informing them of what to expect normally, the information should also include information on what to expect if something should go wrong. However, it is important that this information be presented in the context of the larger framework of open communication with patients throughout their episode of care.

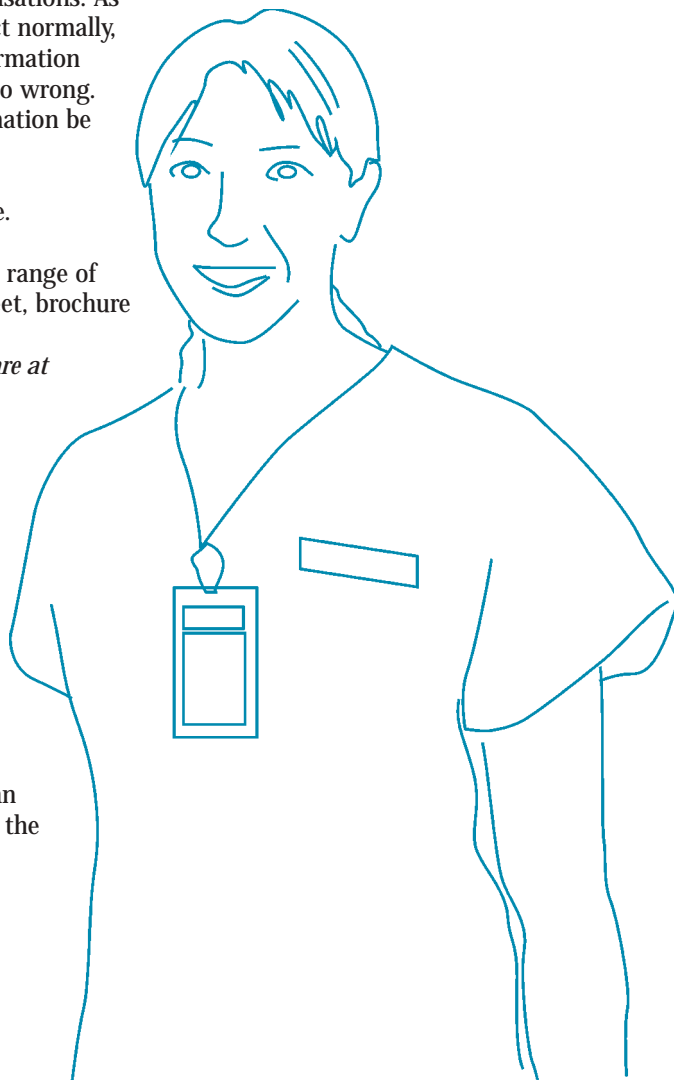
Possible strategies:

1. Include the following information in a range of formats. For example an information sheet, brochure or on the hospital website:

If something goes wrong during your care at hospital you can expect that:

- a member of your health care team will discuss with you what happened and any treatment that may be required as a result; and
- information will be provided to you on how the hospital is investigating what happened and what steps they are taking to prevent it from happening to someone else.

2. Have an information leaflet available on open disclosure for patients and their carers in the event of their experiencing an adverse event. An example is included in the Open Disclosure Implementation Tool Kit.



WHAT INFORMATION SHOULD BE PROVIDED TO STAFF?

A culture of awareness of patient safety should be fostered through communicating with staff about adverse events, recommendations to prevent recurrence and implementation of changes. Health care organisations should identify a staff member responsible for communication to staff on these issues.

Information about safety issues and altered policies or processes may be provided by:

- electronic messages to all staff;
- verbal reporting and discussions at staff meetings and shift handovers;
- the immediate replacement of outdated policies and guidelines in departmental information sources;
- regular clinical meetings to discuss recommendations, changes to be implemented and management of clinical risk as a routine part of the education and training of all staff;
- clinical risk handbooks;
- newsletters;
- noticeboards.

Where there has been a critical or sentinel incident, or one that attracts media attention, a bulletin should be sent to staff to ensure that they have access to accurate information prior to seeing media reports. Staff should also be advised of the person responsible for media liaison and public enquiries. (Appendix A)

AS A MANAGER, WHEN SHOULD I BE INVOLVED IN THE OPEN DISCLOSURE PROCESS?

There will be some situations where you should take an active role in the disclosure interview. This may be where:

- a critical or sentinel event has occurred. Your participation may help to provide assurance to the patient and their family that the incident is viewed seriously by the organisation;
- the senior health care professional involved requests your support;
- where the investigation has revealed significant management issues in the causes of the event;
- where there has been a breakdown in the relationship between the patient and the health care team.

WHAT CAN I DO AS A MANAGER TO ASSIST IMPLEMENTATION OF THE OPEN DISCLOSURE STANDARD?

The manager's role in assisting implementation of open disclosure is to create an organisational framework that:

- puts the patient's interests first - before that of the organisation, colleagues or self;
- focuses on changing system failings rather than blaming individuals;
- provides a supportive environment for staff involved in an adverse event; and
- ensure policies and guidelines as specified in the Standard are developed and implemented. (Appendix B)

SHOULD ADVERSE EVENTS BE DISCLOSED TO PATIENTS WHERE NO HARM IS APPARENT?

While disclosure is required where harm has occurred it may be appropriate to disclose even where no harm is immediately apparent. If there is reasonable likelihood of harm resulting in the future as a result of the adverse event then disclosure should be initiated. This is a matter of judgement by the health care team. Disclosing to the patient following the event allows them to take an active part in their care and to know potential signs and symptoms they should look out for. This will reduce the patient's concerns about any delays in their recovery and help to build trust between the patient and health care professional.

HOW CAN I DECIDE WHEN SOMETHING HAS HAPPENED THAT REQUIRES DISCLOSURE?

Some form of disclosure is required where a patient has suffered some unintended harm (physical or psychological) as a result of treatment. This may be a recognised complication, unanticipated incident or as a result of human or systems error. If the decision is made that the incident does not require disclosure this should be a decision that is defensible in public.

ARE THERE CIRCUMSTANCES IN WHICH UNINTENDED HARM HAS OCCURRED AND DISCLOSURE IS NOT REQUIRED?

The Open Disclosure Standard states that patient preference should be considered, that is, there may be some cases where the timing of providing the open disclosure information could have a significant effect on the patient's ability to make decisions regarding their life. These decisions should be made on a case-by-case basis and the reasons for non-disclosure at that particular moment must be documented in the medical record. There is flexibility in determining the timing of disclosure to patients and their carers (Standard 10.3.2) depending on several factors, including the condition of the patient and the availability of their support person.

WHAT SHOULD I DO IF A PATIENT HAS SUFFERED HARM WHILE UNDER THE CARE OF A CLINICIAN OR TEAM FROM ANOTHER INSTITUTION OR FROM OUTSIDE YOUR AREA OF RESPONSIBILITY?

An adverse event may have occurred in an organisation or in another ward or department other than that in which it is identified. For example, it may be recognised that a post-operative patient in the ICU has suffered an adverse event during the surgery. First, establish whether the disclosure process has been initiated. If not, notify the senior clinician looking after the patient or the individual responsible for clinical risk in your own organisation (This should be determined by local policy.) That person should establish whether:

- the adverse event has already been recognised;
- the process of open disclosure has commenced elsewhere;
- investigations are in progress.

If not, the open disclosure process should be initiated. Whenever possible, the investigation of the adverse event and the disclosure process should occur in the health care organisation where the adverse event originated. When this is not possible, the most senior clinician now looking after the patient should initiate the disclosure process. Care should be taken to disclose only known facts.

WHAT SHOULD I DO WHERE THERE HAS BEEN AN ADVERSE EVENT AND THE CLINICAL TEAM IS UNWILLING TO INITIATE THE DISCLOSURE PROCESS?

Your organisation should develop policies guidance on the mechanism and reporting lines when this occurs, particularly in the case of the adverse event requiring immediate medical care. Maintain open communication with staff and explain the open disclosure process. Be supportive and help staff establish what to discuss with the patient. If there is still an obvious reluctance to participate, you could explore the reasons why there is an unwillingness to disclose. If staff is concerned about litigation or loss of reputation, encourage them to contact their MDO/Professional Indemnifier to clarify their position and to consider gaining some form of legal protection for the investigation. You may wish to facilitate the open disclosure process by offering to organise a meeting of the team or by providing assistance with the disclosure interview.

DOES AN APOLOGY OR AN EXPRESSION OF REGRET MEAN ADMITTING LIABILITY?

The Open Disclosure Legal Review (see accompanying resource materials) identified that an apology is not an admission of liability; there are no legal impediments to an appropriately worded apology. It is not an admission of liability to:

- Explain how an adverse outcome occurred;
- Acknowledge that the patient is not happy with the outcome;
- Express your concern for the patient.

If you admit fault then you may be admitting liability. Avoid statements such as:

"I'm sorry – I appear to have made an error in judgement";

"I apologise for this mistake";

"It is my fault that this has happened".

Examples that may be useful are:

"I am very sorry this has happened";

"I am sorry that this hasn't turned out as expected".

DOES IT CAUSE MORE HARM TO LET PATIENTS KNOW WHEN AN ADVERSE EVENT HAS OCCURRED?

All adverse events that have caused harm or may have done so require disclosure. A patient may be unnecessarily concerned about a delay in their recovery or may not know why they are experiencing certain symptoms. An example of this could be someone who bled more than expected in surgery. The patient feels tired and listless, and is unsure why. Several days later, blood tests indicate there is a need for a transfusion. Telling the patient of the blood loss and the potential signs and symptoms when it occurred initially, would have allowed the patient more active participation in their care and caused them less worry. They are then more able to watch for signs that will guide them to seek medical intervention that may be required to prevent further harm.

WHEN AN ADVERSE EVENT OCCURS AND THE OPEN DISCLOSURE PROCESS IS INITIATED WHAT ARE THE RIGHTS OF HEALTH CARE PROFESSIONALS INVOLVED?

Health care professionals have rights that should be considered during the open disclosure process. The most relevant rights are:

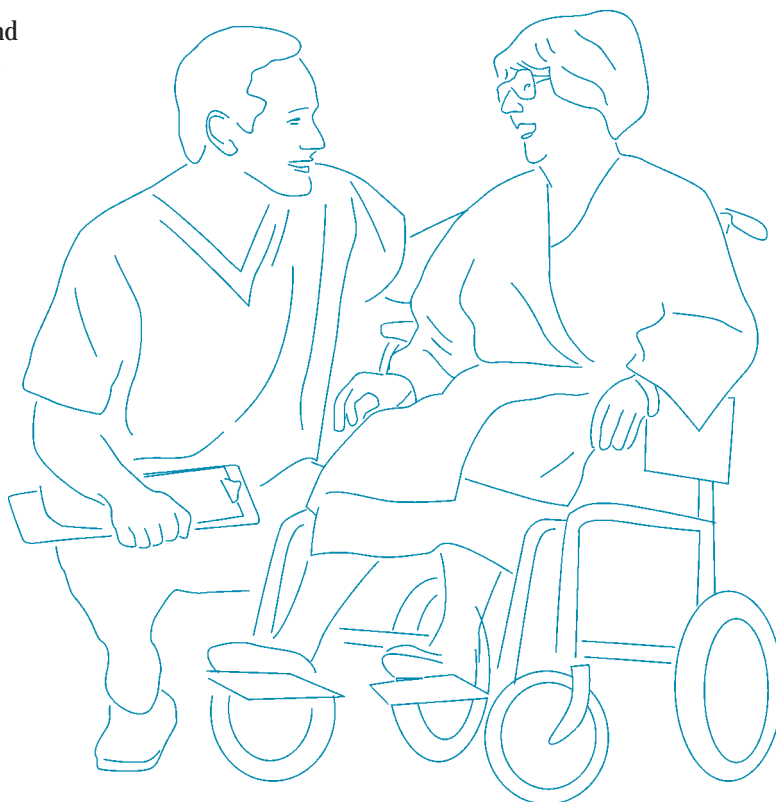
- The right to seek appropriate legal advice and to disclose information to legal advisers in a manner that ensures that it attracts legal professional privilege;
- The right to be treated fairly by the institution and to receive natural justice and procedural fairness;
- The right not to be defamed;
- The right – and on some occasions, the contractual obligation – to seek appropriate advice and guidance from their “indemnifiers” (be they insurers or medical defence organisations).

Reference: *Open Disclosure Project: Legal Review*¹

WILL OPEN DISCLOSURE INCREASE LITIGATION?

There is no conclusive evidence that open disclosure increases or decreases litigation. Current literature states that if a patient is told about an adverse event and they are treated quickly and harm prevented or minimised, the patient may be less inclined to sue. In taking a pro-active approach you or your clinical staff may be able to talk to the patient in a way that diffuses their anger and restores their trust. In some cases it may be appropriate, after consultation with the clinical team, management and insurers, to recommend a prompt and fair out of court settlement. When you offer support for follow up or additional treatment, it doesn't necessarily mean your organisation is accepting liability

Litigation may be reduced if patients appreciate the fallibility and honesty of the health care professional. If you or your clinical team does not disclose and serious mistakes come to light later on, the patient may think it is an attempt to cover up and become more angry and litigious.



1. Open Disclosure Legal Review (2002) prepared by Corrs Chambers Westgarth for the Open Disclosure Project. Copies of the Legal Review are available on the Open Disclosure CD Rom or from the Australian Council for Safety and Quality in Healthcare.

Guidelines on Investigation

THERE are a variety of methods for analysing adverse events and determining the factors that may have led to an incident. These methods range from very simple processes to complex investigation methods such as root cause analysis. Investigation methodology is an increasingly sophisticated field of study. The person responsible coordinating the investigation of serious or sentinel adverse events within your organisation should receive training in adverse event investigation. However, clinical staff should be informed of the basic steps required by your organisation to investigate low level incidents. Basic steps that should be included in an investigation process are:

Determine what happened

- Discover the details of the events and the departments/services involved. Look at the steps leading up to the event (map the process).

Determine why it happened

- Discover why it happened and what factors and system failures influenced those processes. Identify the steps in the process that allowed the event to happen.

Define action required to prevent it from happening again

- Identify what needs to be rectified in the system to reduce the risk of another adverse event.

Implement action plans and measure effectiveness of preventing recurrence

- Follow up to ensure action plans have been implemented and monitor progress through tracking to determine if changes have been effective.

GRADING LEVEL OF INVESTIGATION

Grading to determine the level of investigation should be done by the individual responsible for clinical risk. Health care organisations need to designate responsibility for the management of risks associated with the delivery of clinical care. The person responsible needs to be of sufficient seniority to have credibility and be able to drive change to effect improvements. (Standard Clause 12-16). The adverse event should be graded according to the consequence or degree of harm caused to the patient, and the likelihood of occurrence. The grading only affects the degree of the investigation process, not the disclosure. All adverse events should be subjected to an appropriate level of local investigation and analysis to determine the cause so that improvements may be recommended and implemented to minimise the risk of recurrence and the severity of outcome.

ADVERSE EVENTS CAUSED BY THE MALFUNCTION OF MACHINERY OR MISUSE OF EQUIPMENT OR THERAPEUTIC AGENTS

When an adverse event occurs as a result of the malfunction of machinery or misuse of equipment or therapeutic agents, health care organisations should have guidelines in place detailing how evidence should be preserved and what are the associated responsibilities of staff members. This should include information on:

- preserving of all written records;
- retaining equipment;
- recording of equipment settings;
- withdrawal of defective equipment from circulation to prevent further incidents;
- informing statutory bodies;
- informing manufacturers in relevant cases;
- instructing hospital engineers to investigate the circumstances of servicing requirements, service history, contracting arrangements and other relevant matters.

EXAMPLE OF GRADING MATRIX from AS/NZS 4360 for the purpose of determining the level of investigation. This simple qualitative scale classes risk by combining the likelihood and consequence of the adverse event.

TABLE 1 — QUALITATIVE MEASURES OF CONSEQUENCE OR IMPACT

Level	Descriptor	Example detail description
1	Insignificant	No injuries, low financial loss
2	Minor	First aid treatment, on-site release immediately contained, medium financial loss
3	Moderate	Medical treatment required, on-site release contained with outside assistance, high financial loss
4	Major	Extensive injuries, loss of production capability, off-site release with no detrimental effects, major financial loss
5	Catastrophic	Death, toxic release off-site with detrimental effect, huge financial loss

Measures used should reflect the needs and nature of the organisation and activity under study.

Source: ??

TABLE 2 — QUALITATIVE MEASURES OF LIKELIHOOD

Level	Descriptor	Description
A	Almost certain	Is expected to occur in most circumstances
B	Likely	Will probably occur in most circumstances
C	Possible	Might occur at some time
D	Unlikely	Could occur at some time
E	Rare	May occur only in exceptional circumstances

These tables need to be tailored to meet the needs of an individual organisation.

Source: ??

TABLE 3 — QUALITATIVE RISK ANALYSIS MATRIX—LEVEL OF RISK

Likelihood	Consequences				
	1 Insignificant	2 Minor	3 Moderate	4 Major	5 Catastrophic
A (almost certain)	H	H	E	E	E
B (likely)	M	H	H	E	E
C (moderate)	L	M	H	E	E
D (unlikely)	L	L	M	H	E
E (rare)	L	L	M	H	H

The number of categories should reflect the needs of the study.

Legend

- E extreme risk; immediate action required
- H high risk; senior management attention needed
- M moderate risk; management responsibility must be specified
- L low risk; manage by routine procedures

*This matrix is taken straight from AS/SNZ 4360 - it is of general application.
Other examples of scoring system include the SAC (Safety Assessment Code) Score.*

Source: Risk Management (1999) Standards Association of Australia

Appendix A

Management of a Serious or Sentinel Adverse Events

A **SERIOUS** or sentinel adverse event is a situation in which significant attention is likely to be drawn to the health care provider's services, either from the media, the legal profession or both. Examples include events affecting multiple patients (incorrect interpretation of results from screening programs for cancer, incorrect interpretation of specimens, clinical workers infected with transmissible diseases), abducted neonates, suicide or murder on hospital premises, major transfusion reactions and equipment malfunction that may have implications for other patients.

Such events often produce significant legal, media and other interest, which, if not properly managed, may result in damage to the health care organisation's reputation or its assets.

The health care organisation should have guidelines for the rapid follow up of such incidents that cover:

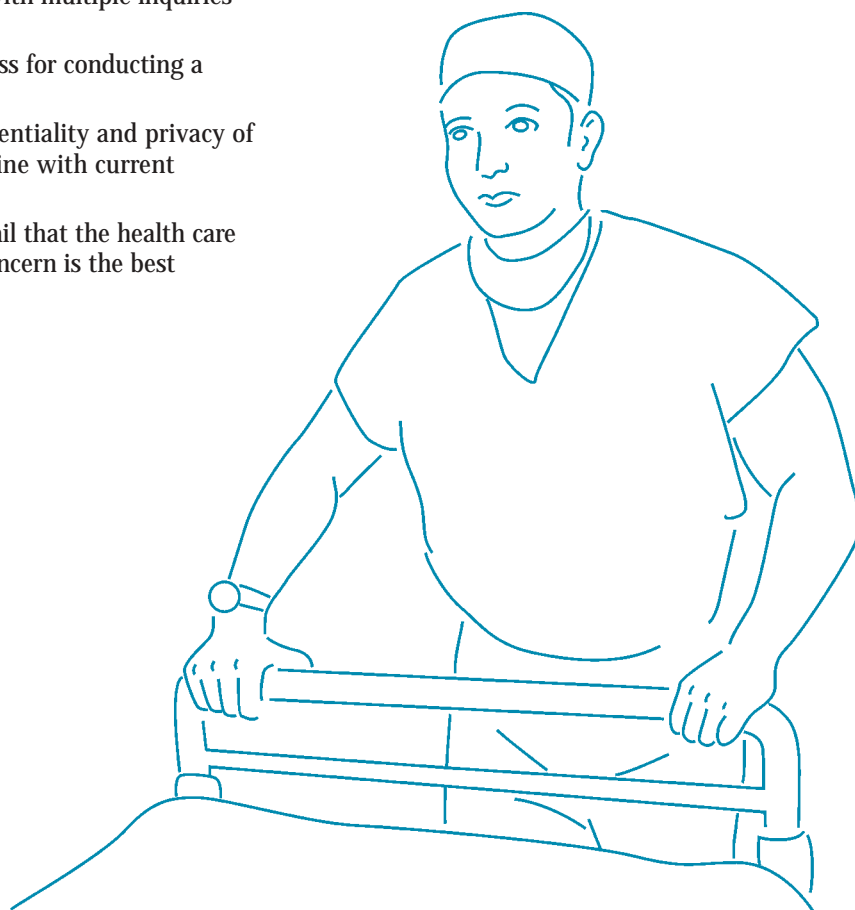
- the responsibility for the management of the incident;
- the detailed record keeping of the incident;
- who should be informed;
- media relations - who will be responsible for managing communication with the media;
- a strategy for dealing with multiple inquiries ("hotline");
- guidelines on the process for conducting a detailed investigation;
- maintaining the confidentiality and privacy of individual patients in line with current privacy legislation.

The guidelines should detail that the health care organisation's principle concern is the best interest of the patient.

MANAGEMENT RECORD

When a serious or sentinel adverse event occurs, in addition to documenting the open disclosure processes and patient records, a management record should be created. This should include:

- a chronological record of the information given, to whom and by whom;
- an objective factual account of the investigation;
- the name and job title of the individuals providing the information;
- a record of all statements to media, politicians and other outside parties in chronological order;
- itemised, timed contacts with patients (especially where patients are being traced for follow-up investigation);
- details of the progress of the investigations.



Guidelines for Media Communication and Public Relations

HEALTH care organisations should have policies to deal with routine media enquiries to ensure, as far as possible, that any stories appearing in the media, are fair and balanced and based on an analysis of the true facts. As with the open disclosure process it is important not to attribute blame, speculate as to the causes of the adverse event or admit liability. The positive outcomes of clinical risk management, where system improvement takes place should be communicated to the media.

Health care organisations should have local guidelines on media training and public relations, which include:

- a strategic communications plan;
- the identification of those on the management team who will take responsibility for media relations;
- the provision of media training for selected individuals;
- encouragement of a culture of good public relations; and
- co-operation with the media to provide feedback to healthcare users on improvements in healthcare services.

INCIDENT FILE

The person with responsibility for risk management may create a file for all incidents graded moderate severity or above. Consideration should be given to including details of:

- the explanations given to patients and support persons during the course of the investigation;
- statements from staff, patients, support persons and from other witnesses (by any of the above means);
- analysis of the evidence;
- a record of reports provided to Clinical Risk/ Quality/ Safety committee;
- the outcome of the investigation;
- any recommendations for systems changes;
- a record of changes made; and
- how the effects of those changes will be monitored and audited.

A Framework for Effective Management of Clinical Risk

MANAGING risk provides opportunities for managers and staff at every level, to continuously improve performance. Any improvements achieved must be measurable in order that the improvement becomes tangible and can be communicated to all interested parties including management, staff and the community.

A model framework for risk management, as outlined in AS/NZS 4360, should result in the following outcomes:

- establishing an appropriate accountability framework which encompasses management structures and practices (committees, reporting structures, policies and strategies etc);
- ensuring that the core processes required to produce the desired outcomes are in place as the basis of continuous improvement activities, this includes risk management processes where all risks are systematically identified, assessed and treated;
- management and the governing body should continuously monitor and review these systems to ensure they are working effectively and to improve any aspect of the system and deliver better outcomes;
- ensuring proper communication and consultation at all levels both within the organisation and with external stakeholders.

Appendix B

Local Policies referred to in the Standard

IT IS essential that each organisation's policy and procedure meets its unique needs and resource availability, while reflecting the specific legal, regulatory, institutional and cultural considerations relevant to them.

In particular, policies need to take into account the following:

- The requirements of those who provide insurance to health care organisations and professionals. Insurers should be involved in policy development at an early stage and proactively educate their constituents in open disclosure.
- The necessity of appropriate training and education for relevant staff to ensure a coordinated and informed approach to open disclosure and avoid admissions of liability (in either verbal or documentary form).
- The need for involvement of consumers and health care professionals in developing policies and processes.

The standard specifies that local guidelines are required in particular, in the following areas:

SCOPE - STANDARD CLAUSE 2

Organisations should have guidelines in place on how and when to make a referral to a disciplinary process. In developing and amending these guidelines, care should be taken to avoid potential conflict between disciplinary and open disclosure investigations. This includes ensuring that the rights of the person subject to the disciplinary process are recognised and respected, such as the right to be given an opportunity to respond to findings by the open disclosure investigation and to have legal, union or other representation.

PATIENT ISSUES - STANDARD CLAUSE 4

Health care organisation need to create an environment that facilitates open and effective communication. Policies and practices should address the following:

- A.** They should ensure early identification of the patient's needs including, but not limited to, documentation at the time of admission of –
- the names of particular individuals to provide assistance and support to the patient;
 - the names of those individuals (who may be different to the patient's next of kin or those identified above) that the patient has chosen to receive information about their health care, and any restrictions on disclosure; and
 - whether an interpreter service may be required for the patient. (See Standard Appendix C.7 and C.9).

B. They should encourage patients to notify the clinical team of any issues or conditions that may affect their care.

C. Where an adverse event has occurred, policies and practices should provide assurance that an ongoing care plan will be developed in consultation with the patient and their support person, and that the plan will be followed through; facilitate inclusion of the patient's support person in discussions about an adverse event where the patient agrees.

D. Policies, processes and practices should provide appropriate opportunities for the patient and their support person to obtain information about the adverse event.

E. They should provide information about the open disclosure process to patients and their support person in verbal and written format. For low level response events where requested and for high level response events as a matter of course.

F. Where a patient has died as a result of an adverse event, subject to the requirements of the coroner and legislation, policies and practices should ensure that the support person is provided with known information, care and support. The support person should also be referred to the coroner for more detailed information.

STAFF ISSUES – STANDARD CLAUSE 5

Organisations must also take into account in their policies and practices the rights of health care professionals. This should include ensuring in policies and practices that –

- the open disclosure process focuses on safety and not attributing blame, leaving issues relating to individuals to disciplinary processes, if this is considered appropriate;
- criticism and adverse findings against individual professionals is avoided. If adverse findings do have to be made, treat the professional fairly and afford natural justice, including giving the person the opportunity to comment on any adverse findings and taking those comments into account. This will also help to avoid defamatory statements (both verbal and written); and
- recognise the obligation and/or right of professionals to seek appropriate advice and guidance from their indemnifiers and other relevant advisers and to act in accordance with such advice.

ORGANISATIONAL ISSUES – STANDARD CLAUSE 6

The organisation will need to determine whether the open disclosure process is to be implemented into existing systems and policies, such as risk management and identification of adverse events, or whether those systems need to be amended to take account of the open disclosure process.

LEGAL AND INSURANCE CONSIDERATIONS – STANDARD CLAUSE 7

Organisations and individuals disclosing information to patients and their support person after an adverse event should do so in the context of the local legal and insurance environment. Legal issues that require consideration in relation to patients, staff and organisations are:

- Confidentiality;
- Privacy requirements;
- Insurance and other contractual obligations;
- Legal professional privilege; and
- Qualified privilege.

Organisations should develop their own guidelines to ensure that the relevant privacy principles and other obligations of confidentiality are adhered to during the open disclosure process. It is important to note that this legislation also provides patients with the right to access information about their care such as their medical record.

NOTIFICATION OF MANAGEMENT - STANDARD CLAUSE 10.6.3

Notification of management will usually occur via the individual responsible for clinical risk. However, when a major incident occurs that may attract media attention or where a criminal act is suspected, the CEO should be notified immediately, in accordance with the organisation's incident policy.

NOTIFICATION TO RELEVANT STATUTORY AND OTHER APPROPRIATE AUTHORITIES - STANDARD CLAUSE 10.6.6

Where there are adverse outcomes health care organisations may need to respond to a variety of external requirements, reviews or queries, including requirements of State, Territory and Commonwealth regulatory bodies. The organisation's policy on adverse events and open disclosure should clearly state these requirements to ensure that an organisation's legal and insurance needs are met.

INCIDENT REPORT - STANDARD CLAUSE 11.3

Clinical or other staff should submit an initial incident report in accordance with the organisation's policy on adverse events or incident reporting.

INVESTIGATION AND ANALYSIS - STANDARD CLAUSE 13.1

In serious adverse events (major or sentinel health event), a root cause analysis, or another investigation method of similar intensity, should be considered. In these circumstances, the services of outside experts may also be used. Cases of moderate severity may be investigated by a small number of designated people. Low-risk cases may be investigated by a small team or subjected only to aggregate review (data trending). The decision about the level of investigation should be determined by grading the event to determine the level of investigation (see Clause 12) and be in accordance with the organisation's policy.

PERSONNEL TO BE INVOLVED IN THE INVESTIGATION – STANDARD CLAUSE 13.2.1

An individual who has the knowledge and status to make authoritative recommendations should conduct the investigation in association with appropriate clinical advisers. This will usually be a senior health care professional or manager (as designated in the organisation's policy). All health care professionals involved in the incident should be given the opportunity to have input into the investigation.

PRELIMINARY FOLLOW-UP WITH THE PATIENT AND THEIR SUPPORT PERSON – STANDARD CLAUSE 14.1

A written record of the discussion should be made and filed, according to internal policy and legal requirements.

FINANCIAL SUPPORT – STANDARD APPENDIX B

Health care organisations should develop guidelines in consultation with insurers and other relevant agencies for providing assistance to patients who have experienced adverse events.

PARTICULAR PATIENT CIRCUMSTANCES - STANDARD APPENDIX C

Occasions may arise where an individual coroner requests that discussion of the case between hospital staff and family should not take place until he or she has considered the evidence. Directions for disclosure of information should be included in local guidelines.



