Open disclosure for Victorian health services

A guidebook
Foreword

The principles of open disclosure are being increasingly accepted among health care professionals. This, and the development of accepted open disclosure processes, is perhaps one of the most important developments in clinical risk management in the past decade.

Open disclosure focuses on ensuring that a patient affected by an adverse event understands what has happened and what the health service is doing to prevent it happening again. The process not only facilitates communication among health care professionals but also between health care professionals and patients. It is fundamental to continuing to develop trust and accountability within Victoria’s health care system.

There is an expectation that all health services will have a formal and effective open disclosure policy, procedures and framework in operation. In April 2008 the Australian Health Ministers’ Advisory Council agreed to support the national rollout of open disclosure. This document is intended to assist health services to implement an open disclosure process or review and further develop existing processes. It is not prescriptive and the intention is that health services will adapt the guideline to meet local practices and organisational structures.

The tools provided were developed from sites involved in a state pilot project, and I would like to thank them for their participation and making these available for all to share.

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Foreword

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1. Introduction

‘Open disclosure’ refers to the process of open communication with patients and their families following an adverse event. The principles underlying the approach to open disclosure outlined in this document are based on the value of open disclosure to quality and safety and an appreciation of the need and rights of patients and their families to receive information and to be appropriately supported.

Although most health professionals have commonly practised some form of open disclosure, there has not always been a consistent process to ensure that the techniques used are effective. The process should ensure that all patients who experience adverse events receive appropriate information and that support is provided to professionals involved in these often difficult situations.

This handbook has been developed following review of both national and state projects that include the implementation of the National standard on open disclosure and a pilot project recently concluded and published in Victoria. In addition, the Department of Human Services was grateful to receive materials and tools generously provided by a number of Victorian health services.

It is anticipated that health services will use this handbook and the associated information to either review their existing open disclosure processes or to assist with commencing a formalised process within their organisation.

Further information can be found on the department’s website at www.health.vic.gov.au/clinrisk.

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1 The term patients and families has been used throughout this document and generally refers to any consumer of health services and his or her next of kin, carer, guardian or support person. Whenever information is provided to someone other than the patient, privacy and confidentiality obligations must be considered.

2 An adverse event for the purposes of this document is defined as any unplanned event resulting in, or having the potential to result in injury to a patient or an unintended outcome.


4 Department of Human Services 2007, Open disclosure statewide pilot project evaluation report 2007, Melbourne.
2. Background

There is a common concern among health professionals and executives that the disclosure of adverse events, especially to patients who would not otherwise be aware that an adverse event had occurred, will increase the risk that a patient will turn to litigation and the number of claims experienced by a service will consequently increase. However, evidence has suggested that this is not necessarily the case.

A random survey of 149 patients in an outpatient’s clinic was undertaken to ascertain patients’ attitudes towards physician mistakes. The results showed that 98 per cent desired acknowledgement of even minor errors, which strongly supports the notion that patients want to be told about what happened, even if there was no adverse effect.

Additionally, 12 per cent of patients in this sample indicated they would sue if they were advised that a moderate mistake had occurred during their treatment. However, if the patient was not informed and found out about the mistake by other means, the rate increased to 20 per cent.

In the United States a hospital in Lexington implemented a full disclosure policy that included mandatory reporting of errors to the patient and/or family even if the patient was unaware of the error. As a result, the hospital reported a decrease in court cases and reduction in liability payments in the years following the full disclosure policy’s implementation.

In a survey of 258 emergency department patients, 76 per cent said they wished to be informed immediately of any medical error and 88 per cent wanted full disclosure of the error’s extent.

In 2002 the Australian Council for Safety and Quality in Health Care (now the Australian Commission on Safety and Quality in Health Care) developed the National standard on open disclosure. This was endorsed by the Australian Health Ministers Conference in July 2003.

Both before and after the national standard was published, several health services or individual clinicians had various forms of open disclosure in place; however, the national standard introduced a consistent approach and clarified some of the legal issues that had concerned many.

The national standard outlines a clear and consistent process that includes:

1. an apology or expression of regret
2. a factual explanation of what occurred, including actual and potential consequences
3. the steps being taken to manage the event and prevent its recurrence.

The report of the National Open Disclosure Pilot Standard summarises three years of implementation and the experience of 42 hospitals from across Australia that participated in an evaluation. The main issues that have emerged from the pilot were:

• there is a difference between the principles of open disclosure applicable to all events and the explicit process of formal institutional disclosure for certain events
• the training intervention and implementation models used have varied significantly from localised to centralised, and from minimally to highly structured
• the legislative framework around apology varies in each jurisdiction, which affects implementation
• the legislative framework around root cause analysis (RCA) privilege varies from no privilege, through partial privilege to complete privilege (which prevents sharing RCA information with affected patients and staff)
• review of RCA documents by insurers has assisted in reducing clinicians’ concerns about legal discovery
• the time and resources required for organisations to engage in formal open disclosure was reported as a barrier
• the extent to which jurisdictions have implemented open disclosure during the pilot currently varies from preparatory phase only to full implementation.

Victoria commenced a rollout of the national standard in February 2004 that included an expression of interest to participate in an evaluation of the standard. Six metropolitan and six regional hospitals were invited to participate and the results of this were published in 2007.

The objectives of the evaluation were to determine the organisational, cultural and structural features that support or hinder implementing open disclosure in health services and thereby identifying the barriers and enablers. The key findings include:

• open disclosure is not a new concept; many clinicians incorporate this into their current practice, though there was no consistent way of managing this process
• there was no standardised approach to the disclosure process within all pilot sites involved
• education and training were key elements to successful implementation
• where there was a strong culture of quality and safety reporting, this process was more readily adopted
• the disclosure process complements the clinical risk management strategies used in Victorian hospitals
• where this process was integrated into the organisation’s clinical risk management framework, there was greater awareness and uptake
• documentation of discussions with the patient/family was poor overall and this raised medico-legal concerns regarding the content of discussions and where these were documented
• some patients and their families did not wish to engage in this process
• the language was felt to be suspicious and negative in its connotation, most sites rephrased the language to fit their clinical risk or governance framework.
2.1 The Victorian charter of human rights and responsibilities

In the past, the obligation to discuss adverse events with affected patients has been an ethical one. It is now a legal obligation for public entities (including public health services) in Victoria. The Victorian parliament passed the *Victorian Charter of Human Rights and Responsibilities 2006 (Vic)* to protect human rights in Victoria and ensure that government departments and public bodies observe these rights when making decisions and developing policy.

The Act, which came into effect in July 2007, contains 20 civil and political rights. Section 15 of the legislation refers to the right to freedom of expression that includes the right to receive information and is relevant to the open disclosure process. This right can only be qualified by the express limitations set out in section 7 of the Act.

All health professionals working in public health services should be aware of the implications of this legislation. Further information about the charter can be found on the Department of Justice’s website at www.justice.vic.gov.au.
3. The general principles of open disclosure

The national open disclosure standard published by the then Australian Council for Quality and Safety in Health Care in 2003 outlined some key principles of open disclosure:

• **Openness and timeliness of communication** – When things go wrong, the patient and their support person should be provided with information about what happened, in an open and honest manner at all times. The open disclosure process is fluid and may involve providing ongoing information.

• **Acknowledgment** – All adverse events should be acknowledged to the patient and their support person as soon as practicable. Health care organisations should acknowledge when an adverse event has occurred and initiate the open disclosure process.

• **Expression of regret** – As early as possible, the patient and their support person should receive an expression of regret for any harm that resulted from an adverse event.

• **Recognition of the reasonable expectations of patients and their support person** – The patient and their support person may reasonably expect to be fully informed of the facts surrounding an adverse event and its consequence, treated with empathy, respect and consideration, and provided with support in a manner appropriate to their needs.

• **Staff support** – Health care organisations should create an environment in which all staff are able and encouraged to recognise and report adverse events and are supported through the open disclosure process.

• **Integrated risk management and systems improvement** – Adverse events investigations must be conducted through processes that focus on managing risk (see AS/NZS 43601). Outcomes of investigations are to focus on improving systems of care and will be reviewed for their effectiveness.

• **Good governance** – To prevent recurrence, open disclosure requires that clinical risk and quality improvement processes are created through governance frameworks. It involves a system of accountability through the organisation’s chief executive officer or governing body to ensure these changes are implemented and their effectiveness reviewed.

• **Confidentiality** – Policies and procedures are to be developed by health care organisations with full consideration of the patient’s, carer’s and staff’s privacy and confidentiality, in compliance with relevant law, including Commonwealth and state/territory privacy and health records legislation.

These principles evidence how far Victorian health services have evolved in managing clinical risks since the national standards’ publication. All public health services in Victoria now have clinical governance processes in place and the importance of incident management is now widely accepted. Health services also participate in the Statewide Quality Branch’s Sentinel Event Program and key staff members have completed RCA training.
In addition to these principles, further lessons from the national and Victorian pilot programs (outlined below) can now be added.

**Flexibility within a framework**

Open disclosure processes need to be flexible but underpinned by a strong central framework that is understood by all. It is important to reduce risks associated with variations from the accepted and agreed open disclosure processes that may arise from poor communication or documentation.

*Some organisations have developed different processes for ‘low-level’ and ‘high level’ adverse events to trigger different responses that are appropriate for the situation.*

**Communication and information**

Good and effective communication of the open disclosure process is imperative. Most health services will only implement a ‘high level’ open disclosure a few times a year at most and different clinicians are likely to be involved on each occasion. Therefore, tools such as a ‘ready reference’, brochures or brief guidelines are useful to assist clinicians to quickly re-familiarise themselves with the health service’s open disclosure principles and processes and ensure that risks associated with the process are appreciated and managed.

**Understanding of responsibilities**

Clear guidelines to ensure that staff are aware of their respective roles and responsibilities in the open disclosure process are imperative to make certain the right people give the right information at the right time.

Health professionals who are good communicators are best placed to present information to a patient about an adverse event but relevant expertise and training to answer the subsequent questions the patient and family may have is also very important. Delay in providing information or attempts to answer questions by a person without the expertise, or who is perceived by the patient to lack knowledge, will create additional anxiety.

*For example, a patient who has experienced an adverse event that has resulted in forming a colostomy may receive the initial information about the event and its implications from a surgeon. However, the early involvement of a stomal therapist experienced in day-to-day stomal care may be better placed to answer specific questions.*

*A patient who received the wrong medication may receive the initial information from a nurse but questions about side effects and consequences may be beyond the scope of the nurse’s knowledge and therefore more appropriately answered by the patient’s doctor or a pharmacist.*
Patient access to open disclosure

To ensure that patients have access to the open disclosure program following an adverse event, prompts such as posters and an alert system that works alongside the adverse event reporting process will ensure the potential need for open disclosure is recognised.

*It may be useful to periodically review the medical records of patients who experienced adverse events to evaluate whether the open disclosure process was utilised and how effectively the health service’s processes were followed.*

Efficiency

Brochures, checklists and flow charts are useful for providing information to patients and their families about the open disclosure process. This will assist to ‘streamline’ a process and reduce the time health professionals spend providing and reinforcing basic information.

Information provided in advance may assist the patient and family to understand how the health service approaches clinical risk management and some of the important principles.

‘Ready reference’ tools for health professionals enable a quick re-familiarisation with the process without the need to read lengthy documents. This will improve compliance, promote practice standardisation and reduce variation.

Evaluation and continuous improvement

Evaluating the open disclosure program and regularly feeding back results to clinicians is important to understand the effectiveness of the process and provide an opportunity for further improvements. Sharing information across the health services assists with establishing a culture and consistent practices and understanding.

Discussing individual open disclosure events at relevant meetings and in case study presentations, clinical audit and mortality reviews promotes and raises awareness of the program and also provides valuable opportunities to learn from the experiences of others.

Access to ongoing support

Patients and their families respond differently to learning about an adverse event and their response will also vary with the type of incident and level of harm/injury.

Prompt and appropriate support is vital to ensure the experience of dealing with an adverse event is as positive as possible for the patient and family under the circumstances. The open disclosure policy and accompanying procedure should contain information about the names/positions of support personnel such as pastoral care and social workers who may assist in providing additional support for the patient.

Easy and prompt access to a qualified interpreter service is also important. Using family members to act as interpreters is not recommended.
Compensation and meeting out-of-pocket expenses

It is the experience of some health services that patients and more often family members will ask about whether they are entitled to compensation. This should be anticipated in the planning phase and discussed with the health service’s insurer and legal counsel (if available) in advance.

Offering an apology or ‘expression of regret’ and, if necessary, agreeing to reimburse a patient or family member for any out-of-pocket expenses, is reasonable but speaking to a patient or family member about the potential for compensation is not generally recommended, in particular without the prior consent of the insurer(s).

Offers to reduce or waive fees may be appropriate and does not constitute an admission of liability (see section 6.1 of this document).9

The patient and family may also be advised about the role of the Health Services Commissioner.
4. Introducing open disclosure within a health service

The following information offers a guide to health services that have not yet introduced a formal open disclosure process and has been developed from the results of the national and Victorian reviews. It may also be used by other health services to review and further develop the current processes.

Open disclosure is an important component of the quality and safety systems underpinning approaches to improve patient safety. Although many health services and health professionals already practice a form of open disclosure, the purpose of this document is to promote a more consistent approach within the health service that then facilitates communication within the health service, between health professionals and between health professionals and patients and families.

4.1 Underlying assumptions

The following general principles are predicated on an assumption that health services will develop and implement an open disclosure process that is:

1. consistent with the existing clinical governance framework and quality and safety policies and procedures
2. supported by senior health professionals using the process
3. consistent with Commonwealth and Victorian regulatory regimes
4. consistent with insurer requirements
5. consistent with the employment and other contractual obligations of the health service.

4.2 Developing an open disclosure process

The components necessary to developing a successful open disclosure process described below have been adapted from the work and evaluation of open disclosure that has occurred at a national and state level as well as from valuable input from various Victorian health services.

Consultation and inclusion

An inclusive and consultative process to develop policies and procedures that are tailored to the unique characteristics of the health service and its available resources is essential to the success of an open disclosure process.

During the developmental stage, it is strongly advised to include health professionals who will be using the process to ensure compliance and success of the program.

Poor compliance will result in many variations from the standard procedures that will create risks and possibly further harm. For example, a health care professional who undertakes an open disclosure process with a patient, without first discussing this with the wider team, could provide inconsistent or incorrect information that will only serve to create confusion, and distrust. It is essential that the patient has confidence in the process and information provided. A consistent approach and using relevant tools such as a checklist will improve communication between clinicians and assist the patient to accept the information and participate in the ongoing plan of care.
Developing a team to provide leadership and expertise

The health service may like to ensure consultation and inclusion by identifying a key group of clinical leaders and managers who have influence in the health service and will ‘champion’ the program.

This group should have the skills to:

1. work collaboratively to develop a process that will be accepted and supported by other clinicians
2. constructively review and critique policies, procedure, checklists, educational material and so on
3. be involved in facilitating educational and training programs.

Coordination

The health service might like to appoint a person to have key responsibility for developing and implementing the program and who is accountable for working with the appointed team to ensure its development and rollout across the health service.

Quality managers or patient liaison personal who are experienced and have good knowledge of clinical risk management are very appropriate for this role. Ensuring that a single person is managing the project avoids the risks associated with poor coordination.

Identify the work that needs to be undertaken

This will depend on how prepared the health service is and, to some extent, its size. It is assumed that a clinical governance framework and processes for reporting and managing clinical incidents has already been established. The open disclosure program should be a part of this system.

Specific issues that should be addressed are outlined below:

Policies and procedures

These should clearly outline the philosophy, approach, ‘rules’, expectations and duties of different staff members and managing risks associated with the process.

A ‘ready reference’ summarising the policy and procedure that is readily accessible may be helpful to provide a ‘refresher’ for health professionals who have not been involved in a open disclosure process for some time and need to quickly re-familiarise themselves with the process.

The open disclosure ‘trigger’

Health services will need to ensure a procedure is in place that triggers the open disclosure process whenever an adverse event occurs. This will involve quickly notifying a person(s) within the health service to coordinate the process and provide support for staff. In larger health services especially, adverse events can occur but not come to the attention of the responsible manager for some time and open disclosure may be inadvertently neglected.
It may also be useful to regularly review the medical records of patients who experienced an adverse event to evaluate whether open disclosure occurred and evaluate the effectiveness of the 'trigger'.

Education and training
The importance of widespread education and training of staff cannot be over emphasised. It is imperative that there is a common and consistent understanding of the process and the various responsibilities of the health care team members.

Education and training also ensures that the open disclosure process is effective and patients and their families receive consistent and accurate information from senior personnel who are able to anticipate questions and provide appropriate information.

Conflicting information provided sporadically from junior personnel or health care professionals who may be operating outside their scope of practice will be detrimental to the patient and the process and create additional anxiety.

Education and training may be tailored to different ‘levels’ of staff depending upon their respective roles and responsibilities in relation to the process adopted by the health service.

For example:
1. general staff may require information about the principles of the program, key features and how to ‘trigger’ the process
2. managers and executives may require education that addresses key responsibilities and accountabilities to ensure insurers are notified and legal risks addressed
3. senior health professionals who may be involved in discussions with the patient may require training targeted at communication skills and ‘breaking bad news’.

Brochures
Developing brochures for patients and staff raises awareness and provides readily available information.

These serve to explain the philosophy behind open disclosure, the process and outline the rationale as to why certain practices such as the ‘no-blame’ approach have been adopted.

It can be expected that many patients have little understanding of the open disclosure process and may be taken by surprise. Easy-to-understand information provided in brochure format may assist a patient to understand the process, his or her rights and how to get additional support and assistance.

*It is sometimes common for a patient or family member to want to know who is responsible for the adverse event and how they are being dealt with by the health service. Patients may not appreciate or be aware of the ‘no-blame’ approach for managing adverse incidents and view this suspiciously. Advance information that highlights the reasons behind the choice of a particular strategy, such as the importance of a systems approach to investigation and the importance of learning from adverse events, may be useful.*
It is important that a brochure containing information about adverse events is sensitively worded to ensure it assists the process and does not offend or appear to downplay the seriousness of the patient’s situation. A review of the wording by the health service’s consumer advisers or a sample of patients and families is highly recommended before it is introduced.

4.3 Relationship between open disclosure, root cause analysis and other investigatory processes

Open disclosure is closely linked with sentinel and adverse event management, RCA and other investigations that may take place in response to an adverse event. It is also incorporated into the health service’s clinical governance framework.

Health services will vary in their individual approaches but there are three important and interrelated components to the process of adverse and sentinel event management:

1. informing the patient and his or her family (as appropriate) about what has occurred in a sensitive but open and honest way (this includes an apology or some expression of regret)
2. an in-depth investigation as appropriate for the type of adverse event (this may involve an RCA)
3. identifying measures to address apparent weaknesses in the system highlighted in the investigation as contributing to the adverse event and a commitment to address these.
4.4 No-blame approach to adverse event investigation

It is a now generally accepted principle (although not always evident in practice) that focusing on blaming individuals when adverse events have occurred is unproductive and may have the effect of:

1. serving only to create an environment of fear and distrust in which the reporting of adverse events is unlikely to occur
2. obscuring the real underlying or root cause of the incident that must be addressed if a reoccurrence of the incident is to be prevented
3. disregarding the implication of organisational and system issues that contribute to adverse events, for example a culture of taking short cuts, failure to comply with hospital procedures, stress created through unplanned staffing crises, inexperience and the complexity of patient care.

The open disclosure process should incorporate the ‘no-blame’ approach and health professionals need to be consistent in their understanding of it.

Brochures explaining the health service’s commitment to quality and safety and the methods of adverse event management that highlight the ‘no-blame’ approach may assist a patient and his or her family members to appreciate and understand the reasons the health service has adopted this approach.

Clear policies and procedures in relation to disciplinary processes should be in place to assist health professionals managing an adverse event to access the process when necessary. These policies and procedures should recognise and respect the staff member’s right to fair treatment that includes the right to be heard, to be able to respond to any findings from an investigation and to have a support person present during any discussions. The open disclosure process and any disciplinary action are best managed separately although overlap is difficult to avoid in smaller health services.

Again, information contained within a brochure may assist patients and their family members to understand the reasons why the disciplinary process is managed separately from the adverse event investigation process.
5. The open disclosure process

In general, the open disclosure process should be invoked whenever a patient has suffered an adverse event that is rated in the moderate to severe category as determined by the health service. It is suggested that the process is flexible enough to be able to respond appropriately to 'high level' adverse events but at the same time, is able to be modified for lower level events. The considerations that should be taken into account include:

1. the patient’s and family’s need to and right to know
2. the clinician’s duty to apply professional and ethical judgement to their ways of working
3. the clinical team’s preparedness to discuss and analyse unexpected outcomes over and beyond the adverse event’s medical-technical dimensions
4. the organisation’s obligations to engage staff in lifelong learning and practice improvement (under clinical governance).

On occasions, an adverse event may attract a low risk rating but has obviously had an impact on the patient and some form of open disclosure may be necessary. Some health services have developed a modified approach to the open disclosure process to ensure that patients who have suffered a 'lower level' adverse event have access to the program.

"Waiting until all ‘the facts are in’ is not a good idea; it is perfectly acceptable to state the following to the patient, ‘As of now, here is what we understand happened. As I learn more details, I will share them with you immediately’. Waiting days to disclose can prompt an idea of collusion or conspiracy of facts. Moreover, patients will have questions. If these questions are not addressed by you they will seek to look for answers from perhaps less qualified providers."¹⁰

The flow charts contained in the toolkit provide a standard approach to open disclosure that has been adopted from the national standard. It is anticipated that these will be modified at a local level to suit the clinical risk management and governance framework of the organisation.

Key aspects of the open disclosure process that were highlighted by the Victorian and national reviews are outlined below.

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¹⁰ Weiss P 2007, ‘To err is human – to air is humane: disclosing adverse events to patients’, Obstetrics and Gynaecology 64(4) April, 217–218.
5.1 Planning

Once an adverse event has occurred and the open disclosure process triggered, a meeting of the relevant health care professionals should occur as soon as possible to plan the open disclosure process. This may occur in conjunction with planning an investigation into the adverse event.

**Identify key information that will be required**

Responsibility for obtaining information needs to be assigned to a staff member to ensure it is available prior to the first meeting with the patient.

1. Key information should be identified (much of which will be recorded on the checklist) such as:
   - what happened (known facts only)
   - the likely impact on the patient and his or her recovery, length of stay, ability to return to work and so on
   - details of the patient’s home and family situation that may be relevant to the ongoing management of the event
   - the need for an interpreter.
2. Once the initial checklist has been competed, those present need to agree on the approach and information to be provided before the first meeting takes place.
3. Concerns that may be raised by the patient and family should be identified so that appropriate answers can be prepared and additional information or the need for other personnel to be involved in the process can be anticipated.
4. Identify which health professionals need to be involved in the first meeting. Once the initial checklist has been completed, those present need to agree on the approach and information to be provided before the first meeting takes place.

**Planning prior to the first meeting**

1. Identify a suitable setting for the open disclosure meeting to occur where patient privacy and confidentiality can be assured.
2. If the patient is able to participate in the communication process, he or she needs to be approached first to ensure that when the first meeting takes place, the patient has had the opportunity to arrange for another person to be present.
3. If for various reasons the patient is not able to participate in the communication process, the next of kin should be contacted to arrange a time and date for the first meeting and have the opportunity to involve others.
4. Anticipate further information the patient may require so that the patient can be advised of when this information may become available.
Planning the open disclosure dialogue

1. The number of health professionals who are present for the initial open disclosure meeting with the patient will depend on the severity of the adverse event. Planning the dialogue and ensuring appropriate consultation and collaboration occurs between health professionals prior to the first meeting could be very important to ensure that there is:
   • agreement about the factual information to be provided
   • mutual understanding of the process and principles such as the ‘no-blame’ approach
   • agreement as to the ongoing plan of care.

2. The information that is known at this stage that can be discussed with the patient. This should include:
   • an apology or expression of regret
   • a description (in language the patient will understand) about what happened
   • the steps being taken to manage the event and prevent its recurrence.

3. Identify who will be the main spokesperson and plan the dialogue to avoid risks associated with:
   • admissions of liability (see section 6.1)
   • blaming an individual
   • defamation.

Additional considerations

1. The potential for the need for support from other personnel such as social workers or pastoral care workers should be identified.

2. What further investigation is to be done, for example, an RCA or other form of investigation, reporting a sentinel event if necessary, communication to senior managers or members of the executive according to the organisation’s policy.

3. Identify staff members who were involved in the adverse event and who may be involved in the ongoing care of the patient and ensure that effective communication occurs in relation to the open disclosure process.

4. Identify whether staff members involved in the adverse event require any additional support or counselling.

5. Ensure that the open disclosure process and outcomes are documented in the medical record.

6. Plan for an evaluation of the process and feedback to clinicians.
5.2 The first meeting with the patient

The following points have been adapted from the standard and should be modified as appropriate for the setting and situation.

Importantly, all health professionals and others present at the first meeting with the patient should agree about what is to be said so that any inconsistencies are resolved before the patient is present.

The discussion should include:

1. introductions including title and explanation about why each person is present to all people attending the meeting
2. an apology or expression of empathy and regret for what has happened (not an admission of liability) (see section 6.1)
3. a description of the known facts as agreed between the multidisciplinary team
4. listening to the patient/support person/family understanding about what has happened and address questions and concerns
5. indication to the patient/family that their views and concerns are being heard and taken seriously
6. a discussion of what will happen next (such as return to operating room, further investigations, referral to other consultants)
7. providing information in relation to the likely short-term effects (and long-term effects) if known
8. assurance to the patient and family that they will be kept informed of investigations and any other information that comes to light, and how this will be communicated
9. an offer of support for patient/family (such as referrals to other health care professionals, social workers, pastoral care workers, patient liaison officer or director of nursing)
10. information about how to take the matter further, which will depend on the patient’s response and needs and may include legal advice (if the issue is raised by the patient), details of the health service’s internal complaint process and information about the role and contact details of the Health Services Commissioner.
5.3 Anticipate the response

Expressions of anger, resentment and other emotions should be expected and the patient/family may want the names of ‘who is responsible’.

It is unwise to anticipate that the first meeting will be easy or quick, especially when the patient has been involved in a serious adverse event that has caused harm. The meeting should be open-ended if possible and closed only when the patient/family are ready; ending a meeting prematurely may make the patient feel resentful.

It may be necessary to answer the same questions several times and repeat what has been said. Avoid arguing with the patient or disagreeing with the view he or she is expressing as this will be likely to create greater resentment.

Communicating with patients and families when they may be experiencing anxiety and or grief may take time and information may need to be repeated, basic principles applied should be:

1. Work through the patient’s agenda rather than your own.
2. Strong emotions need to be dealt with empathically. **Empathy** is the experience of being heard and understood, empathy includes:
   • active listening
   • reflecting the patient/families experience back to them
   • acknowledging the emotions they may be feeling
   • meeting the needs of the patient.
3. Avoid being drawn into an argument.
4. Provide information in an objective and clear manner.

5.4 Further meetings and follow-up

These should occur as soon as possible and the patient/family advised when it is anticipated that further information will be available and how it will be communicated to them.

A face-to-face meeting may be appropriate but if acceptable to the patient, further information can be provided in a letter together with a contact number for the patient if they have further questions depending upon the nature of the adverse event and individual circumstances.

It may be appropriate either at the first meeting or during subsequent meetings to advise the patient/family about what measures are being taken to prevent a similar adverse event from occurring again in the future. If this information is not immediately available, it should be explained to the patient that once the investigation is complete, recommendations about what further action is to be taken will be made.
5.5 Documentation

While maintaining confidentiality, it is important that those caring for the patient in the aftermath of an adverse event and early stages of the open disclosure process, will have knowledge of what has happened, the information that has been given to the patient and the forward plan (such as referral to other health care professionals or conducting an RCA) to ensure that the ongoing communication with the patient is accurate and consistent. Any confusion relating to conflicting information will be detrimental to the outcomes anticipated from the open disclosure process.

Accurate and effective documentation is essential to ensure effective communication between health professionals and also to manage potential medico-legal risks associated with the adverse event and open disclosure process.

1. Communication: accurate documentation supports continuity of care as it enables other members of the health care team (especially those taking over the responsibility for the patient during weekends and after hours) to understand what has been said to the patient and what information remains outstanding. When a referral has been made to another health professional, he or she will quickly be able to become familiar with the process by reading the patient notes and develop an approach to an aspect of care that is consistent with the overall plan and best meets the needs of the patient and family.

2. Managing potential medico-legal risks: during any communication process there is a risk that information is misunderstood or takes on a different meaning than intended. Accurate documentation about what is said to the patient is good risk management, should any confusion arise at a later time. This is especially important when facts recounted by the patient become material to a legal claim.

**Documentation should include:**

1. brief details of the background to the open disclosure discussion with the patient such as factual information describing the adverse event
2. detailed factual information reflecting what was said to the patient including where appropriate, the actual words used; areas to be included are:
   - the apology or expression of regret
   - the explanation of what occurred, including actual and potential consequences
   - the steps being taken to manage the event and prevent its recurrence
   (care should be taken to ensure that dates and times are consistent with other documents such as observation charts and medication charts)
3. the names of personnel present at the meeting, including the patient’s family and support people
4. the questions asked by the patient and information provided in response to the question
5. a description of the ongoing plan of care discussed with the patient including referrals and further treatments
6. how the patient appears to be taking the information and the perceived level of understanding
7. other information provided for the patient such as information brochures, names of other contact people such as the patient liaison officer or director of nursing
8. how the patient is to receive additional information and any representations made by those present in relation to how this will be supplied/provided, such as further meetings, a letter, phone call or at a subsequent outpatient appointment
9. any comments that the patient may make that indicate some contribution to the outcome such as failure to take medication prescribed
10. any other issues that are relevant to the process and the ongoing care of the patient.
6. Legal issues

The following information is provided in general terms only and is not intended to provide legal advice.

After any adverse event, there is a risk that a patient who has sustained a psychiatric or physical injury or experienced economic loss may commence legal action against the health service and/or relevant health professional. Seeking compensation for injuries that may have been the result of a breach in the expected standard of care is a patient’s legal right and, although there is no obligation on the part of the hospital to appraise a patient of his or her legal rights, the patient must not be discouraged or dissuaded from taking legal action.

A patient may seek legal redress regardless of whether the open disclosure process has taken place and, in fact, evidence suggests that the risk of litigation is lowered if the open disclosure process is instigated.

One of the greatest concerns to all involved in the process of incident investigation and open disclosure is that the health service’s potential exposure to legal risks is unnecessarily increased by erroneous, careless and inaccurate documentation or through providing inaccurate, conflicting or confusing information to the patient. A health service may be compelled to disclose information or a document unless the information is exempted by a privilege scheme or by statute. This can occur, for example, under the Freedom of Information Act or Health Records Act, through a subpoena issued by a court or tribunal and via the process of ‘discovery’ once litigation has commenced.

‘Documentation’ referred to above includes the following: hospital records, meeting minutes, the results of investigations such as RCAs, personal and hospital file notes or journal entries, emails, memos and other forms of written communication.

Great care should be taken to ensure that all documentation is accurate, factual and does not offer opinions that may turn out to be misleading or formed on the basis of incorrect or erroneous information. Statements or opinions about possible causes of the adverse event together with any admission of liability (see section 6.1) should be avoided. Information about documentation and writing styles to be used in association with an adverse event should be included in the health service’s RCA and adverse event reporting and investigation policies and procedure.

Freedom of Information

Under the Freedom of Information Act (FOI), a patient of a public health service has the right (subject to the exemptions outlined in the Act) to access certain documents such as the medical record. Applications can also be made by members of the public for certain documents if releasing the documents is in the public interest and the exemptions do not apply.

The Health Records Act contains similar provisions to enable patients to access their personal health record when held by non-public sector health service.

Legal professional/client legal privilege

Legal professional privilege, also known as client legal privilege, protects oral and written confidential communications between a client and lawyer where the dominant purpose of the communication is to seek legal advice in anticipation of litigation or when legal proceedings are in process. The privilege extends only to documents and not individuals and is generally invoked to protect documents that would be otherwise disclosed through ‘discovery’ or other devices.

Relevant to the open disclosure process is that the privilege is automatically ‘waived’ by the client if the details of the communication are disclosed and the confidential nature of the communication is then lost.

Statutory immunity

The statutory immunity provisions of the Health Services Act (see section 139) protect the confidential activities and the participants of a prescribed quality assurance committee that has a clinical focus.

Statutory immunity has the effect of rendering the activities of the prescribed committee inadmissible as evidence and preventing committee members from being subpoenaed to give evidence in legal proceedings. The intent of the provisions is to promote full and open discussion of clinical quality issues and ensure that improvements can then be made without fear that the information obtained or derived can be produced before a court, tribunal or health professional’s board.

Statutory immunity is not automatic and a health service wishing to utilise the statutory immunity provisions must first make an application to the Department of Human Services. Once the application has been granted, the health service must comply with the strict requirements of section 139(3) a member of the prescribed committee cannot make a record or divulge or communicate information that comes to the committee or is a result of the deliberations of the committee. Therefore, when an adverse event is referred to a prescribed committee for investigation, the subsequent information that can be provided to the patient for the purpose of open disclosure is limited.

To prevent conflict of interest from arising, health services with prescribed quality assurance committees need to develop clear guidelines as a part of the incident management process to ensure that open disclosure and clinical quality assurance processes are not compromised. This may include developing a separate pathway for open disclosure when the prescribed committee is to be involved in conducting the investigation to ensure that the patient is not promised information that cannot be provided because it attracts privilege. The following is a guide only.

Further information can be found on the department’s website www.health.vic.gov.au/statim.
Information that can be provided to the patient includes any information that goes to the prescribed committee such as:

- the known facts about events leading up to the adverse event
- the results of any subsequent tests
- information that would ordinarily be documented in the medical record
- a consequential medical opinion/diagnosis
- possible implications for the patient; and the outcome of the adverse event.

Information that can not be provided to the patient because of the restrictions of the legislation includes:

- the outcomes of the subsequent investigation and the deliberations of the prescribed committee
- information that relates to any further questions asked by the prescribed committee or requests for further information
- information known by committee members that has come to the member by virtue of his or her membership of the prescribed committee
- information contained in any documents and minutes of the committee
- information contained within staff statements prepared for the prescribed committee.

6.1 Apologies and admissions of liability

An admission of liability can be defined as the assumption of legal responsibility (either verbally or in writing) by the health service or one of its employees or agents for the harm or injury to a patient arising as a result of an adverse event.

Insurance policies generally contain clauses restricting admissions of liability made by or on behalf of the insured (the health service or one of its employees). An admission or inference of liability in relation to an adverse event may be grounds for an insurer to deny indemnity to the insured, that is, the health service or health practitioner may not be ‘covered’ in the event that the patient initiates legal proceedings.

An apology is defined as an expression of sorrow, regret or sympathy but does not include a clear acknowledgment of fault. Legislation in Victoria specifically protects health professionals and health services that offer an apology to a patient who has suffered an adverse event.

Under the Wrongs Act an apology to the patient or a family member(s) of a patient who has sustained harm or injury as the result of an adverse event does not constitute an admission of liability or of unprofessional conduct, carelessness or incompetence (for the purposes of a complaint to a health professional registration board). If however a factual matter is disputed during legal proceedings, the statements used in the apology may be admissible to the extent that they prove or disprove a fact.

10 Wrongs Act 1959 (Vic), s 14J
Similarly, an offer to a patient who has suffered an adverse event to reduce or waive fees does not constitute an admission of liability or of unprofessional conduct, carelessness or incompetence.

What does this mean?

Health professionals and those acting on behalf of the health service are encouraged to offer an apology to a patient without assuming fault. For example, statements such as, ‘I am very sorry that this has happened to you’ or ‘I apologise for the experience you have had’ are expressions of regret without constituting an admission of liability.

Statements such as, ‘I am very sorry that you were harmed as a result of my mistake’ or ‘I apologise that my error resulted in your injury’ may be interpreted as an admission of liability and should be avoided.

6.2 Defamation and libel

Claims of defamation and libel arise when a person’s reputation has been damaged or he or she feels insulted or aggrieved by the written or spoken comments of another.

Blaming another health professional for incompetence or any other fault that reflects upon his or her professional competence or reputation may result in a formal complaint of a legal claim against the person making the comments. This risk can be avoided by:

• stating the facts of what happened without insinuating that there is a causal link between the health professional’s standard of practice or competence and the adverse event
• ensuring that any statements made are not exaggerated but are factual and can be verified (care should be taken when providing information that is yet to be confirmed by the RCA investigation)
• avoiding ‘hearsay’ and opinions or conclusions that cannot be logically supported.

Blaming individuals for adverse events is not helpful to the open disclosure process as it both discourages health professionals from being open about adverse events and it creates additional legal risks. Adverse events that raise concerns about a health professional’s competence or professional conduct are best managed through the health service’s disciplinary process.

12 Wrongs Act 1959 (Vic), s 14K
6.3 Privacy concerns and confidentiality issues

In the first instance respect for patient autonomy and privacy concerns dictate that the conversation should be with the patient and the patient should then be given an option to have others present. Obviously this option cannot be exercised if the disclosure occurs at the same time and therefore, some pre-warning needs to be given so that the patient can make arrangements for others to be present.

Often however, for various reasons the patient may not be able to receive the information due to loss of consciousness or other factors such as dementia.

Providing information to people other than the patient, without the patient’s consent, may constitute a breach of the patient’s privacy and the confidentiality provisions of the health service. However, health professionals are generally aware of these risks and accustomed to discussions with patients and families involving sensitive and difficult issues. Family dynamics that have become known during the initial planning phase of the open disclosure process will be taken into account when the next of kin or patient support person is invited to participate in the initial disclosure process. The involvement of others from that point will depend on various circumstances. In the case of a family dispute about responsibility for decision making, it may be appropriate to follow the organisation’s consent policy or contact the Office of the Public Advocate. In some situations, when the majority of the communication is with the patient’s family, it might assist the process to identify or ask the family to nominate one or two key family members who the open disclosure team can communicate with. These family members will be the key contacts and will then keep the other members informed.
7. Particular patient circumstances

Children and young people
The involvement of children and young people in the open disclosure process will have to be assessed on a case-by-case basis, taking account of whether the child is mature enough to receive the information and having regard to the wishes of the child and the parents where appropriate.

Patients with a mental illness
Timing of the disclosure should be subject to the clinical team’s assessment of how the information will affect the health of the patient and the patient’s ability to understand what is said.

Patients with a cognitive impairment
Where applicable, guardianship orders or power of attorney must be carefully considered in assessing whether disclosure of an adverse event and decisions to be taken can be made by a third party in the absence of the patient’s informed consent to do so.

Language or cultural diversity considerations
Where someone has difficulty communicating in English or at the patient’s request, a professional interpreter or a health care professional that can speak the patient’s language should be used. An interpreter from the same language and cultural background may also be able to advise on other issues (e.g. whether the gender of the health care professional who makes the disclosure is an issue that needs to be considered).

Breakdown in the relationship between patient and provider
Offer the patient and their support person another contact with whom they may feel more comfortable. (If this is not acceptable to the patient notify the relevant person in your organisation, ie the Consumer representative/advocate, or Risk manager).
8. The future

Given the Minister’s decision to support a national rollout of open disclosure there is no going back. This was also supported in the state and national evaluation reports from staff who were keen to see this evolve and continue, as something we should be doing.

The department will expect the disclosure process to become part of everyday practice within health services, and this will be further supported through future projects and policy development, such as the Victorian Health Incident Management System project, and a planned incident management policy.

The commission has continued to support this project nationally, and will be undertaking evaluation of the process in 2009, and more information is available from their website www.safetyandquality.org/internet/safety/publishing.nsf/Content/PriorityProgram-02.

This guidebook, along with the Standard and tools included as part of this package will assist organisations in their development and integration of disclosure into their services, and planned education and training in communication skills will assist clinicians in its delivery.