

## Open Disclosure Policy

**Summary** This policy sets out the minimum requirements for implementing open disclosure within NSW Health facilities and services, describes when open disclosure is required, defines the two stages of the open disclosure process - clinician disclosure and, where indicated, formal open disclosure -, outlines key steps, and outlines the roles and responsibilities for NSW Health staff in relation to open disclosure.

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**Distributed to** Public Health System, Divisions of General Practice, Environmental Health Officers of Local Councils, Government Medical Officers, Health Associations Unions, NSW Ambulance Service, Ministry of Health, Public Health Units, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

**Audience** All clinical;management and executive staff of public health organisations in NSW

## OPEN DISCLOSURE POLICY

### PURPOSE

This Policy Directive sets out the minimum requirements for a consistent open disclosure process within NSW Public Health Services, to ensure that patients and their support person(s) and health service staff are:

- Communicating effectively about a patient safety incident
- Provided with an opportunity to recount their experiences, concerns and feelings and are listened to
- Treated respectfully and provided with ongoing care and support for as long as is required.

### MANDATORY REQUIREMENTS

The mandatory requirements for Health Services in the implementation of the open disclosure policy following a patient safety incident in NSW are based on the principles outlined in the *Australian Open Disclosure Framework*<sup>1</sup>. These principles address the complex interests of patients, clinicians, managers, Health Services and other key stakeholder groups such as healthcare consumers, medical indemnity insurers and professional organisations.

The mandatory requirements are as follows:

1. **Acknowledgement** of a patient safety incident to the patient and/or their support person(s), as soon as possible, generally within 24 hours of the incident. This includes recognising the significance of the incident to the patient.
2. **Truthful, clear and timely communication** on an ongoing basis as required.
3. Providing **an apology** to the patient and/or their support person(s) as early as possible, including the words “I am sorry” or “we are sorry”.
4. Providing **care and support to patients** and/or their support person(s) which is responsive to their needs and expectations, for as long as is required.
5. Providing **support to those providing health care** which is responsive to their needs and expectations.
6. An **integrated approach to improving patient safety**, in which open disclosure is linked with clinical and corporate governance, incident reporting, risk management, complaints management and quality improvement policies and processes. This includes evaluation of the process by patients and their support person(s) and staff, accountability for learning from patient safety incidents and evidence of systems improvement.

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<sup>1</sup> Australian Commission on Safety and Quality in Health Care (2013), *Australian Open Disclosure Framework*. ACSQHC, Sydney.

7. **Multidisciplinary involvement** in the open disclosure process.
8. Compliance with legal requirements for **Privacy and Confidentiality** for the patient and/or their support person(s), and staff delivering health care.

*The Open Disclosure Policy Section 5 provides further detail about these requirements.*

## **IMPLEMENTATION**

### **The Clinical Excellence Commission is responsible for:**

- Collaborating with key stakeholders, including the Health Education and Training Institute, to develop an open disclosure education framework for all clinical staff, and other staff as deemed necessary for their role
- Collaborating with Health Services to provide advice and support for clinicians and health managers on open disclosure issues and scenarios
- Providing evaluation tools for open disclosure
- Providing information to support open disclosure for clinicians
- Providing information about open disclosure for patients and their support person(s)
- Providing information about open disclosure for Health Services Boards, Clinical Councils and peak quality committees.

### **Health Services Boards, Clinical Councils and staff are responsible for:**

- Actively committing to open disclosure for all patient safety incidents, to create and support an environment where the focus is on patient-based care
- Enabling timely open disclosure through actively promoting a just and fair culture that ensures all staff in the Health Service are supported and encouraged to identify and report when a patient safety incident has occurred
- Building a positive culture by learning from all patient safety incidents.

### **Chief Executives are responsible for:**

- Leading and overseeing the implementation of the NSW Health Open Disclosure Policy
- Ensuring that systems and processes are in place for all staff in the Health Service to identify and report when a patient safety incident has occurred, so that open disclosure can be initiated
- Ensuring that all clinical staff (and other staff as deemed necessary for their role) access and complete role-relevant open disclosure education and training
- Allocating responsibilities and resources to maintain effective open disclosure processes
- Ensuring the availability of effective clinician support services
- Ensuring the availability of trained Open Disclosure Advisors to support formal open disclosure.

**Implementation at Local Health District/Specialty Network level is addressed in Section 3 in the Open Disclosure Policy: Procedures.**

## REVISION HISTORY

Version	Approved by	Amendment notes
September 2014 (PD2014_028)	Deputy Secretary, Governance, Workforce and Corporate	This revised policy contains changes to the open disclosure process and replaces PD2007_040 and GL2007_007.
GL2007_007	Director General	New guideline
PD2007_040	Director General	New policy

## ATTACHMENTS

1. Open Disclosure Policy: Procedures

## Open Disclosure Policy



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**Issue date:** September-2014

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## 1 BACKGROUND

### 1.1 About this document

This policy:

- Sets out the minimum requirements for implementing open disclosure within NSW Health Services
- Describes when open disclosure is required
- Defines the two stages of the open disclosure process – clinician disclosure and, where indicated, formal open disclosure
- Outlines the key steps in the formal open disclosure process, including the appointment of an open disclosure coordinator and the establishment of a team with an open disclosure advisor
- Outlines the roles and responsibilities for NSW Health staff in relation to open disclosure
- Includes open disclosure as a key element of the early response to a patient safety incident.

### 1.2 What is Open Disclosure?

Open disclosure is a process for ensuring that open, honest, empathic and timely discussions occur between patients and/or their support person(s) and Health Service staff following a patient safety incident.

Open disclosure is an integral part of incident management in NSW Health, and is a key element of the early response and investigation of serious patient safety incidents.

Open disclosure discussions between patients and Health Service staff are required whenever a patient has been harmed, whether that harm is a result of an unplanned or unintended event or circumstance, or is an outcome of an illness or its treatment that has not met the patient's or the clinician's expectation for improvement or cure.

Open disclosure is<sup>1</sup>:

- A patient's and consumer's right
- A core professional requirement of ethical practice and an institutional obligation
- A normal part of an episode of care should the unexpected occur, and a critical element of clinical communications
- An attribute of high-quality health services and an important part of health care quality improvement.

### 1.3 Objectives

NSW Health is committed to providing an organisational culture of safety and quality strengthened by:

- Creating a supportive environment in which patient safety incidents are identified and reported without attribution of blame
- Encouraging staff to openly inform, listen to and support the patient, their support person(s), and colleagues who may have been involved in a patient safety incident
- Sharing lessons learned from patient safety incidents to identify and develop strategies to prevent potential incidents.

The objectives of the NSW Health Open Disclosure Policy are to:

- Establish a culture which supports open communications between patients, their support person(s) and clinicians after a patient safety incident
- Ensure that communications with and support for all affected patients, their support person(s) and Health Service staff occur in a timely and empathic manner
- Ensure that all NSW Health Services have a consistent process for open disclosure.

### 1.4 Associated documents

- The Australian Open Disclosure Framework<sup>1</sup> is the reference document for this policy. <http://www.safetyandquality.gov.au>
- Open disclosure and the respectful management of patients, families and staff is an intrinsic part of the complaints management and incident management process. This policy should be read in conjunction with the following NSW Ministry of Health policies and guidelines, which are available at <http://www.health.nsw.gov.au/policies/pages/default.aspx>
  - Policy on Incident Management
  - Your Health Rights and Responsibilities
  - Policy on Complaint Management
  - Guideline on Complaint Management
  - Policy on Standard Procedures for working with Health Care Interpreters
  - Respecting the Difference – An Aboriginal Cultural Training Framework for NSW Health
  - Policy and Implementation Plan for Culturally Diverse Communities 2012 – 2016
  - Policy on Complaint or Concern about a Clinician - Principles for Action
  - Complaint or Concern about a Clinician - Management Guidelines



Other related policies and resources are listed in Appendix 8.1.

- Open Disclosure is mandated in the National Safety and Quality Health Service Standards (NSQHS) Standards (Standard 1, Criterion 1.16 - Implementing an open disclosure process based on the national open disclosure standard<sup>2</sup>) and is subject to accreditation.

## 2 KEY DEFINITIONS

<p><b>Apology</b></p>	<p>An apology is an expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter whether or not the apology admits or implies an admission of fault in connection with the matter<sup>3</sup>. It should also acknowledge the consequences of the situation to the recipient<sup>4</sup>.</p> <p><b>It must include the words “I am sorry” or “we are sorry”.</b></p> <p><i>Under Section 69 of the NSW Civil Liability Act 2002<sup>3</sup>, the effect of apology on liability:</i></p> <ul style="list-style-type: none"> <li>(1) An apology made by or on behalf of a person in connection with any matter alleged to have been caused by the person:             <ul style="list-style-type: none"> <li>(a) does not constitute an express or implied admission of fault or liability by the person in connection with that matter, and</li> <li>(b) is not relevant to the determination of fault or liability in connection with a matter.</li> </ul> </li> <li>(2) Evidence of an apology made by or on behalf of a person in connection with any matter alleged to have been caused by the person is not admissible in any civil proceedings as evidence of the fault or liability of the person in connection with that matter.</li> </ul>
<p><b>Clinician</b></p>	<p>A health care provider who is trained as a health professional, and who provides direct patient care.</p>
<p><b>Clinician Disclosure</b></p>	<p>An informal process where the treating clinician discusses with a patient and/or their support person(s) the occurrence of a patient safety incident; actively seeks input and feedback from, and listens to, the patient and/or their support person(s); and provides an apology for the occurrence of the event<sup>5</sup>.</p> <p>Clinician disclosure is required whenever a patient has been harmed as a result of receiving treatment or care, and may be required if there is a potential for harm to result from ongoing risk.</p>
<p><b>Formal Open Disclosure</b></p>	<p>A structured process which follows on from clinician disclosure, to ensure effective communications between the patient and/or their support person(s), the senior clinician and the organisation occur in a timely manner<sup>5</sup>.</p> <p>Formal open disclosure may be required for any patient safety incident, as determined by the Director of Clinical Governance and/or the Facility/Operations/Service Manager, the patient and /or their support person(s).</p>

<b>Harm</b>	Impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological <sup>6</sup> .
<b>Health care facility</b>	For the purpose of this policy, a health care facility is any facility or service that delivers health care services. Health care facilities include hospitals, multi-purpose services, aged care facilities, emergency services, ambulatory care services, aboriginal medical services, community health services, ambulance stations and community based health services such as needle and syringe programs.
<b>Health Services</b>	For the purposes of this policy, the term “Health Services” refers to Public Health Organisations and NSW Ambulance <sup>7</sup> .
<b>Open Disclosure</b>	<p>Open disclosure is defined in the <i>Australian Open Disclosure Framework</i><sup>1</sup> as “an open discussion with a patient (and/or their support person(s)) about a patient safety incident which could have resulted, or did result in harm to that patient while they were receiving health care. Essential elements of open disclosure are:</p> <ul style="list-style-type: none"> <li>• an apology</li> <li>• a factual explanation of what happened</li> <li>• an opportunity for the patient to relate their experience</li> <li>• a discussion of the potential consequences</li> <li>• an explanation of the steps being taken to manage the event and prevent recurrence.</li> </ul> <p>The open disclosure process is a discussion between two parties and may include a series of discussions and exchanges of information that take place over several meetings.”</p>
<b>Open Disclosure Advisor</b>	A senior staff member specially trained in advanced empathic communications skills, who is available to support formal open disclosure in a health facility or service <sup>5</sup> .
<b>Open Disclosure Coordinator</b>	A staff member who has responsibility for coordinating and supporting clinician and formal open disclosure in a health facility or service.
<b>Open Disclosure Team</b>	A multidisciplinary team of senior clinicians and facility or Local Health District/Specialty Network (LHD/SN) executive representatives specifically put together to conduct, support and oversee the formal open disclosure process for an individual patient safety incident. The composition of the team may vary and should be appropriate for the size and structure of the Health Service, and the type of patient safety incident.

<b>Patient</b>	For the purposes of this policy, the term 'patient' is used to represent any person receiving health care, and may include the terms 'consumer', 'resident' and 'client'.
<b>Patient safety incident</b>	<p>Any unplanned or unintended event or circumstance which could have resulted, or did result in harm to a patient<sup>8,9</sup>. This includes harm from an outcome of an illness or its treatment that did not meet the patient's or the clinician's expectation for improvement or cure.</p> <p><i>Harmful incident:</i> a patient safety incident that resulted in harm to the patient, including harm resulting when a patient did not receive their planned/expected treatment (replaces 'adverse event' and 'sentinel event')<sup>6</sup>.</p> <p><i>No harm incident:</i> a patient safety incident which reached a patient but no discernible harm resulted<sup>6</sup>.</p> <p><i>Near miss:</i> a patient safety incident that did not reach the patient, and/or in which a potential for harm from ongoing risk may result<sup>6</sup>.</p>
<b>Public Health Organisations (PHO)</b>	This term refers to a Local Health District, a statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services as defined in the <i>Health Services Act 1997</i> <sup>7</sup> .
<b>Staff</b>	Any person working in any capacity within NSW Health, including contractors, students and volunteers.
<b>Support person</b>	<p>A person who has been identified by the patient as someone whom they would like to be present to provide assistance, comfort and support during the open disclosure process and to whom information about their health care can be given. A support person may be (but is not limited to) a family member, partner, carer or friend.</p> <p>Only the patient can determine who will be their support person(s). In cases of a dispute about who should receive information, the patient's wishes should be paramount.</p> <p>Where a patient does not have capacity to decide for themselves or is deceased an "authorised representative" can decide on their behalf<sup>10</sup>.</p> <p>A nominated next of kin is not necessarily an authorised representative.</p>

### 3 IMPLEMENTATION BY LOCAL HEALTH DISTRICTS/SPECIALTY NETWORKS

Local Health Districts (LHD) and Specialty Networks (SN) are required to have in place local processes to support the implementation of the open disclosure policy and the associated responsibilities. The roles described do not necessarily imply the need for additional staff resources, as some functions can be combined and responsibilities may overlap. The key requirement is for LHD/SNs to have appropriate governance and implementation frameworks to ensure each of the functions is adequately addressed.

### 3.1 All clinicians are responsible for:

- Completing education about open disclosure
- Ensuring that the patient is safeguarded from further harm
- Apologising to a patient and/or their support person following a patient safety incident, without attribution of blame or speculation about the course of events
- Participating in open disclosure as required
- Ensuring that a patient safety incident or complaint and associated open disclosure is recorded in the patient's health care record and the incident management system.

### 3.2 Senior Clinicians are responsible for:

- Ensuring appropriate treatment for the patient has been initiated following a patient safety incident
- Ensuring ongoing care is provided to the patient for as long as is required
- Leading and performing clinician disclosure
- Participating in formal open disclosure as required
- Ensuring that a record of the patient safety incident or complaint and the open disclosure is made in the patient's health care record and the incident management system
- Notifying the requirement for formal open disclosure to their Department Head and the Facility/Operations/Service Manager, in addition to the Chief Executive and Director of Clinical Governance
- Participating in local clinical review and morbidity and mortality meetings where open disclosure is reviewed.

### 3.3 Directors of Clinical Governance are responsible for:

- Implementing open disclosure within the Health Service, including development of local systems, processes and procedures for open disclosure
- Providing leadership, support and advice on open disclosure
- Appointing, in conjunction with the Chief Executive, a panel of appropriately trained Open Disclosure Advisors to guide the process
- Gaining assurance that an Open Disclosure Coordinator is appointed and an open disclosure team is established when formal open disclosure is required
- Overseeing the availability and completion of education and training in open disclosure for all clinical staff (and other staff as deemed necessary for their role) including Open Disclosure Coordinators and advisors
- Overseeing and facilitating access to and uptake of staff support services

- Monitoring and evaluating open disclosure processes and systems.

### **3.4 Managers with operational responsibilities at facility/service level are responsible for:**

- Actively promoting and supporting open disclosure
- Appointing the Open Disclosure Coordinator/s within a health facility or service, in conjunction with the Director of Clinical Governance
- Ensuring that an open disclosure team is established when formal open disclosure is required
- Monitoring and evaluating open disclosure processes and systems.

### **3.5 Department Heads are responsible for:**

- Ensuring ongoing care is provided to the patient for as long as is required, including where practicable when the patient and/or their support person(s) request a different care provider
- Participating in open disclosure should the senior clinician be unable to do so
- Ensuring their staff access and complete education and training in open disclosure
- Providing support to their staff who participate in open disclosure, both throughout the process and through promoting access to the staff support services
- Ensuring that the requirement for formal open disclosure is notified to the Director of Clinical Governance and the Chief Executive
- Incorporating the review of open disclosure practices into local clinical review and morbidity and mortality meetings.

### **3.6 Open Disclosure Coordinators are responsible for:**

- Coordinating and supporting clinician and formal open disclosure in a health facility. This person may also have other roles and responsibilities for example, as a patient safety or patient liaison officer
- Responding quickly upon notification of a patient safety incident, to gain an understanding of the event and the needs of the patient and/or their support person(s) and staff involved
- Establishing and coordinating the open disclosure team, including the appointment of an open disclosure advisor, as directed by the Facility/Operations/Service Manager or Director of Clinical Governance
- Coordinating the provision of 'just-in-time' training as required to assist clinicians to prepare for involvement in open disclosure
- Coordinating the open disclosure process, including
  - Ensuring the flow of information between the Health Service and the patient and their support person(s) during and after the investigation process

- Following-up with the patient and their support person(s) as required.

### 3.7 Open Disclosure Advisors are responsible for:

- Undertaking the advanced training in empathic communications skills and open disclosure processes
- Supporting the formal open disclosure team throughout formal open disclosure including planning for and attending meetings between the clinician involved (or delegated substitute) and their support person(s) and completing defined debriefing processes
- Mentoring colleagues preparing for and participating in open disclosure
- Acting as a source of expert advice throughout the open disclosure process.

## 4 GOVERNANCE OF OPEN DISCLOSURE

### 4.1 Legal and Legislative considerations

Open disclosure:

- Is a dialogue between two parties
- Is not a legal process
- Does not imply that an individual or service has blameworthy facts to disclose<sup>1</sup>.

The legal context within which the Open Disclosure Policy operates is provided by the following legislation, available from <http://www.legislation.nsw.gov.au/>:

- Apology: *Civil Liability Act 2002* Sections 67- 69
- Protection for quality assurance activities: *Health Administration Act 1982* (Part 2 Divisions 6B and 6C)
- Public access to information: *Government Information (Public Access) Act 2009*
- Privacy: *Health Records and Information Privacy Act 2002*; *Privacy and Personal Information Act 1998*
- Coronial investigations: *Coroners Act 2009 No 41*

Clinicians, health service managers and staff requiring assistance with participating in open disclosure processes may seek advice from:

- Medical Defence Organisations or professional indemnity insurers – for those who have the relevant insurance cover
- Their Local Health District Clinical Governance Unit and/or Manager responsible for insurable risk
- The Clinical Excellence Commission
- The Treasury Managed Fund (TMF) once a formal claim is initiated.



All practitioners should also be aware of the need to notify the Treasury Managed Fund or their professional indemnity insurer in accordance with that organisation's requirements for timely notification of incidents.

### **4.2 Open disclosure and the investigation of a patient safety incident**

When a patient has been harmed as the result of any patient safety incident, an investigation into the incident must commence as soon as practicable. The circumstances of the incident, including the severity of harm and/or distress experienced by the patient and their support person(s), will determine the level and method of investigation. The findings from each investigation into a patient safety incident are an essential part of the information that is provided to a patient and their support person(s) during the open disclosure process.

Patients and/or their support person(s) are encouraged to participate in the ongoing investigation process. If they choose to do so, the Health Service should provide appropriate support to enable this to occur.

The NSW Health Incident Management Policy outlines a mechanism for early appointment of an investigation team member as part of the formally commissioned Root Cause Analysis (RCA) process. This team member has responsibility for the initial conversations with the patient and/or their support person(s) and staff members to obtain their account of the incident, as well as gathering any physical information associated with the incident. He/she is not responsible for initial open disclosure discussions, which will be usually conducted by the clinician most directly involved in the incident, the person who first recognises the incident, or his/her line manager.

The investigation team has responsibility for conducting a thorough multidisciplinary investigation to determine any underlying causes that may have contributed to the patient safety incident. Where issues are identified that have contributed to the incident, the investigation team will recommend quality improvement action/s to address these issues, aimed at preventing a recurrence. The Clinical Governance Unit will oversee their implementation and monitor the effectiveness of any interventions.

### **4.3 Restrictions on the release of information**

There are some restrictions on the information that can be released during open disclosure discussions. For example, Clinical Reportable Incident Briefs (RIBs) are protected by special privilege and the working documents of the Root Cause Analysis (RCA) team attract privilege if they have been created at the request of or for the purpose of the team's use. Client legal privilege can protect certain documents from being disclosed, specifically documents created, or communications made, in confidence for the dominant purpose of obtaining legal advice in relation to the incident, or for use in legal proceedings (including civil claims for compensation; coronial inquest hearings; and prosecutions before a disciplinary body).

## 4.4 Risk management

Preparation for open disclosure of a patient safety incident requires careful consideration and assessment of risks - to the Health Service, the patient, their support person(s), and staff, including the risk of media exposure or litigation. Undertaking risk management processes should not delay appropriate and timely open disclosure.

Implementing effective open disclosure requires that each Health Service operates within the integrated risk management and quality improvement processes. Identifying and learning from the underlying causes of patient safety incidents, complaints and claims, with the aim of implementing solutions to prevent recurrence adds value to both risk management and quality improvement.

A risk management plan needs to be developed to address identified risks. Any risk that is beyond a staff member's capacity or delegation of authority needs to be escalated to a higher level of management for acceptance and management of the risk.

Implementation of a risk management framework in line with standards established by the *Australian/New Zealand Standard Risk Management Principles and Guidelines AS/NZS ISO 31000:2009*, and the *NSW Health Risk Management - Enterprise-Wide Policy and Framework* provides a systematic process that determines when, how and by whom recommended actions and lessons learned should be cascaded, addressed and monitored.

Open disclosure must be managed to completion irrespective of other circumstances occurring at the same time for example, commencement of HCCC, coronial or legal proceedings.

## 4.5 Record management

If open disclosure is initiated with the patient and/or their support person(s) following any patient safety incident, including near misses and no harm incidents, the clinician responsible for the care of the patient must record that fact in the patient's health care record. Once the incident is notified in the incident management system, the notifier must document the unique identification (ID) number in the health record.

For formal open disclosure it is recommended that all records associated with the open disclosure process are kept together, for example, records of meetings and outcomes.

Patient safety incidents notified to the Ministry of Health using a Reportable Incident Brief (RIB) require that a record of whether open disclosure has occurred is made in the incident management system. The ID number must be documented in the patient's health record with the information about the patient safety incident.

Where open disclosure has occurred, managers should record that fact in the notes section of the incident management system. Health Services should establish a system for recording the open disclosure process including outcomes.



## 4.6 Processes for reimbursement of out-of-pocket expenses

Open disclosure is most effective if it is coupled with restorative action where appropriate. Early recognition and approval for reimbursement for out-of-pocket expenses incurred as a direct result of a patient safety incident sends a strong signal of sincerity. Evidence suggests that restorative action can be a determining factor in a person's decision not to litigate. Practical support offered through reimbursement does not imply responsibility or liability. Out-of-pocket expenses may include, but are not limited to, accommodation, meals, travel and childcare.

Offers of reimbursement are made at the discretion of the LHD/SN and on a case-by-case basis. It is important to note some of these expenses may not be recoverable from Treasury Managed Fund (TMF). Reimbursement of any out-of-pocket expenses must be documented in the open disclosure records.

If the amount requested is likely to exceed \$5,000 and/or the LHD/SN intends to seek reimbursement from TMF, then the LHD/SN must contact its manager responsible for insurable risk who will liaise with TMF prior to any agreement with the patient and their support person(s) for reimbursement for out-of-pocket expenses.

If the patient or support person(s) requests reimbursement for a significant amount, the patient or support person(s) should be advised to put their request in writing so the LHD/SN can refer the matter to TMF. In some circumstances, the LHD/SN may assist the patient and/or their support person(s) to write to the TMF in order to initiate the reimbursement process.

## 5 REQUIREMENTS FOR IMPLEMENTATION OF OPEN DISCLOSURE

Effective implementation of open disclosure contributes to improving the quality and safety of Health Services and requires an organisational focus on developing a safe and just culture, and fostering effective communications.

The *Australian Open Disclosure Framework*<sup>1</sup> outlines principles which guide an effective open disclosure process. These principles address and balance the complex interests of patients, clinicians, managers, Health Services and other key stakeholder groups such as health care consumers, medical indemnity insurers and professional organisations.

The mandatory requirements for Health Services in the implementation of open disclosure in NSW are based on these principles and are as follows:

- 1. Acknowledgement** of a patient safety incident to the patient and/or their support person(s), as soon as possible after the incident has occurred and any immediate action needed to support the patient's care has been taken, generally within 24 hours. This includes recognising the significance of the incident to the patient, even if there has been no or minimal clinical impact arising from the incident.

**2. Truthful, clear and timely communications** on an ongoing basis as long as required to appropriately support the patient and/or their support person(s) and health care staff involved in the incident. This involves (a) providing information to the patient and their support person(s), (b) providing an opportunity for the patient and their support person(s) to recount their experiences, concerns and feelings, and (c) listening and responding appropriately to the patient and/or their support person(s).

**3. Providing an apology** to the patient and/or their support person(s) as early as possible, including using the words “I am sorry” or “we are sorry”.

Communications that go part way towards meeting the essential elements of an apology and which may be appropriate in some circumstances, for example at clinician disclosure before the incident investigation process has been completed and where all relevant facts are not known yet, include the following<sup>11</sup>:

- Expressions of sympathy or empathy, for example “I’m sorry this happened to you”
- Expressions of regret for the act or its outcome, for example “I regret that this happened”
- Expressions of sorrow, for example “I’m very sorry for what has happened”.

**4. Providing ongoing care and support to patients** and/or their support person(s) which is considerate of their needs and expectations, for as long as is required, so that they:

- Are fully informed of the facts surrounding a patient safety incident and its consequences
- Are treated with empathy, respect and consideration
- Are supported in a manner appropriate to their needs
- Continue to receive appropriate treatment, including if the patient and/or their support person(s) request that the patient’s health care needs are taken over by another team.

**5. Providing support to health care staff** when they have been involved in a patient safety incident which respects their needs and expectations, in an environment in which all staff are:

- Able to recognise and encouraged to report patient safety incidents
- Prepared through training and education to participate in open disclosure
- Supported following involvement in a patient safety incident, and/or are able to support colleagues who have been involved in an incident
- Supported throughout open disclosure, for as long as those processes continue.

**6. An integrated approach to improving patient safety**, in which open disclosure is linked with clinical and corporate governance, incident reporting, risk management and quality improvement policies and processes. This includes evaluation of the process by patients and their support person(s) and staff, accountability for learning from patient safety incidents and evidence of systems improvement.

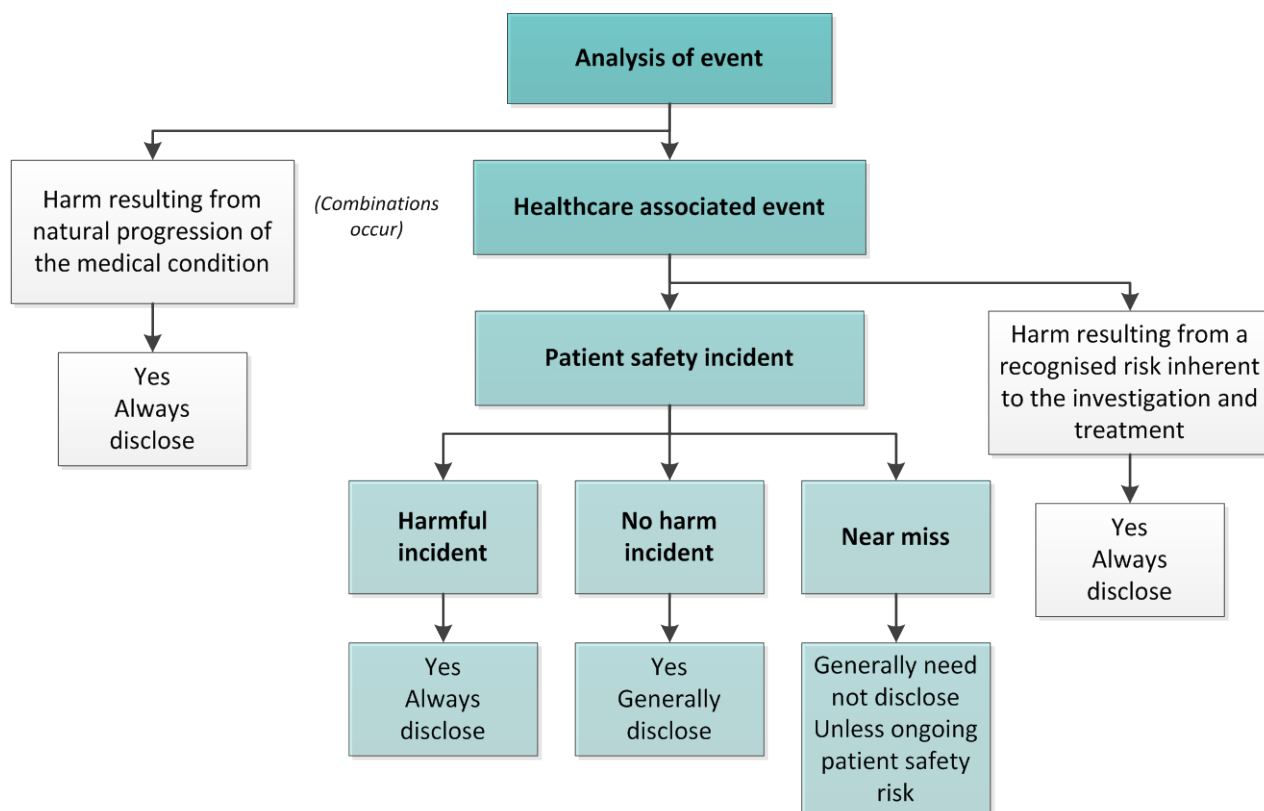
- 7. **Multidisciplinary involvement** in open disclosure, reflecting that most health care provision is through multidisciplinary teams and patient safety incidents are usually the result of systems failures rather than the actions of an individual.
- 8. Compliance with legal and ethical requirements for **privacy and confidentiality** for the patient and/or their support person(s), and health care staff.

## 6 THE OPEN DISCLOSURE PROCESS

Open disclosure begins with the recognition that a patient has been harmed or will potentially be harmed by an ongoing safety risk as a result of receiving or not receiving treatment or care.

**Open disclosure may be ongoing, involving multiple disclosure conversations over time.** Open disclosure involves two-way communications. The input and perspective of the patient and their support person(s) should be actively sought and welcomed in determining what happened, the impact on the patient and/or their support person(s) and in planning for any ongoing care requirements.

### 6.1 When to disclose<sup>9</sup>?



A disclosure discussion must occur **whenever a patient has been harmed**, whether that harm is a result of an unplanned or unintended event or circumstance, or is an outcome of an illness or its treatment that has not met the patient's or the clinician's expectation for improvement or cure. This includes disclosure when a patient has been harmed because they did not receive their planned/expected treatment.

The open disclosure process begins with clinician disclosure. The process may progress to formal open disclosure for any patient safety incident, as determined by the Director of Clinical Governance (DCG) and/or the Facility/Operations/Service Manager, the patient and/or their support person(s).

In the case of a **near miss** disclosure is discretionary, based on whether it is felt the patient would benefit from knowing, for example, if there is a residual safety risk. To guide decisions about open disclosure, expert advice may be required to assist with the determination of the level of risk. The timeliness of informing patients must always be considered.

All patient safety incidents should be appropriately investigated to understand all of the contributing factors involved. Being transparent about what happened, as well as how and why it happened, is very important for the understanding of patients and/or their support person(s) and health care providers.

## 6.2 Key steps in the open disclosure process include:

### 6.2.1 Detection of a patient safety incident

### 6.2.2 Immediate actions

- Ensuring personal safety
- Providing clinical care and support for the patient and safeguarding against further harm
- Providing support for clinicians and other health service staff
- Notifying relevant people, authorities and organisations for example the unit/department manager, the senior treating clinician, the after-hours manager.

### 6.2.3 Assessment and determination of the severity of harm to the patient and the level of open disclosure response required

### 6.2.4 Initiation of open disclosure: Clinician disclosure

When a patient has been involved in a patient safety incident, the patient and/or their support person must be informed as soon as possible. The initial clinician disclosure discussion should occur at a time which meets the needs of the patient and/or their support person(s), generally within 24 hours of the incident.

1. **Preparation for discussion with the patient** and/or their support person(s) includes assessing and preparing for any cultural considerations or special circumstances which may impact on the open disclosure meeting.

**2. The clinician disclosure discussion** with the patient and/or their support person(s) involves:

- Acknowledging and explaining (if the cause is known) the patient safety incident and its impact on the patient
- Offering an apology, including using the words “I am sorry” or “we are sorry”
- Providing an opportunity for the patient and their support person(s) to relate their experiences, concerns and feelings and to ask questions
- Listening and responding appropriately
- Agreeing on a plan for care which may include ongoing support and further discussions or meetings.

Practical support, for example an offer to reimburse out-of-pocket expenses incurred by a patient and/or their support person(s), may be discussed at this time or at a future meeting. An early offer of reimbursement sends a strong signal of sincerity.

**Open disclosure may be completed after this discussion, with the agreement of the patient and/or their support person(s).**

### 6.2.5 Formal open disclosure

Formal open disclosure follows on from clinician disclosure and may be required for any patient safety incident, as determined by the Director of Clinical Governance (DCG) and/or the Facility/Operations/Service Manager, the patient and /or their support person(s).

Formal open disclosure should begin as soon as practicable. Establishing effective early communication with the patient and/or their support person(s) is paramount, even if the investigation process has not yet been completed and the information available is limited.

If a Reportable Incident Brief (RIB) is being submitted, activation of formal open disclosure must be documented on the RIB, and in the patient’s health record and the incident management system<sup>12</sup>.

**1. Preparing for formal open disclosure includes:**

- Appointing the open disclosure coordinator
- Forming the open disclosure team
- Identifying a senior staff member experienced in open disclosure who will take responsibility for leading the discussion
- Contacting an Open Disclosure Advisor to provide necessary support to the team throughout the process

- Providing information gathered about the patient safety incident during previous discussions with the patient and/or their support person(s) (for example, during clinician disclosure or incident investigation)
  - Liaising with the patient and/or their support person(s) to arrange:
    - the time and place for the disclosure discussion/s
    - who should be there during the disclosure discussion/s
  - Assessing whether there are any cultural considerations or special circumstances which may impact on the open disclosure meeting and which require additional preparation
  - Preparing information for the patient and/or their support person(s) in an appropriate format.
- 2. Conducting the formal open disclosure discussion with the patient and/or their support person(s) and the open disclosure team involves:**
- Confirming acknowledgement of the patient safety incident and its impact on the patient and/or their support person(s)
  - Reaffirming or expanding on previous explanations given of the incident, using only known facts
  - Reaffirming an apology, including the words “I am sorry” or “we are sorry”
  - Explaining the formal open disclosure process
  - Providing an opportunity for the patient and/or their support person(s) to relate their experiences, concerns and feelings, and to ask questions
  - Listening and responding appropriately
  - Disclosing the findings of any review/investigation that are available at that time and a summary of factors that contributed to the patient safety incident, recommended actions, and any limitations on the information that can be provided
  - Avoiding speculation, attribution of blame, denial of responsibility or providing conflicting information
  - Agreeing on a plan for care which may include ongoing support and further discussions or meetings

An offer of practical support, for example an offer to reimburse out-of-pocket expenses incurred by a patient and/or their support person(s), may be raised at this time if not already discussed. A prompt offer of reimbursement sends a strong signal of sincerity.

## 6.2.6 Follow-up activities - coordinated by the Open Disclosure Coordinator

- Ongoing discussions between the patient and/or their support person(s) and the open disclosure team leader
- Open disclosure team review and discussion
- If not already done, informing the patient and/or their support person(s) of the findings of the review/investigation including a summary of factors that contributed to the patient safety incident and the recommended actions
- If not already done, liaising with the manager responsible for insurable risk on a case-by-case basis to coordinate an offer of reimbursement for out-of-pocket expenses incurred by patients and/or their support person(s) as a direct result of the patient safety incident - see section 4.5.

## 6.2.7 Completing the process

- Communicating with primary care providers and other relevant clinicians as necessary, to ensure that appropriate ongoing care and support is provided to the patient and/or their support person(s) for as long as is required
- Providing the patient and/or their support person(s) with contact details and information about ways to obtain further follow-up including being kept informed of the progress of any recommendations, and the avenues for making a complaint
- Completing documentation, including noting in the patient's health records that open disclosure has taken place and recording the related unique identification (ID) used in the incident management system and/or a reference to the open disclosure file, if kept separately
- Providing a summary of the open disclosure meetings and agreed outcomes to the patient and/or their support person(s)
- Providing feedback to relevant staff on the final outcome of the open disclosure meeting, including any system improvements agreed with the patient and/or their support person
- Providing opportunities for formal and informal debriefing for the clinical team and individual health care staff involved in the patient safety incident.

## 6.2.8 Evaluation and Review

- Evaluating and reporting on open disclosure at a local level, including internal auditing of a sample of open disclosure processes (refer to Appendix 8.2 *Measuring open disclosure for quality improvement* for suggested measures for facilitating quality improvement, monitoring and reporting to management)
- Enabling the patient, their support person(s) and health care staff to evaluate their experience of participating in open disclosure



- Enabling the contribution of patients and/or their support person(s), and/or consumer representatives to the ongoing improvement of the open disclosure process at a local and state level
- Including a regular review of cases requiring open disclosure at local clinical review and morbidity and mortality meetings (M and M meetings) to identify and provide advice on potential improvements to open disclosure practices
- Sharing lessons learned from cases requiring open disclosure with the health care system, including feedback provided by patients and their support person(s) and staff, and improvements to open disclosure practice.

### 6.3 Open disclosure in specific circumstances

The approach to open disclosure can vary depending on a patient's personal circumstances. Each situation should be addressed on a case-by-case basis.

Advice should be sought from an Open Disclosure Advisor when open disclosure involves:

- Death of a patient as a result of a patient safety incident, a known error or suspected suicide
- Children and young people, patients with a mental health condition, patients with cognitive impairment
- Patients with complex care requirements and language and/or cultural diversity
- A breakdown in the relationship between the patient and the provider
- Patient safety incidents occurring elsewhere or transfer of the patient to another facility or LHD/SN
- Delayed detection of a patient safety incident
- Issues of clinician accountability or suspected intentional unsafe acts.

#### 6.3.1 When formal open disclosure may be considered inappropriate

- The patient and their support person(s) or nominated contact person decline the offer to meet
- The patient is incapacitated or has died and no nominated support person or authorised representative has been identified or is available
- The nominated support person(s) or next of kin is incapacitated or is unavailable.

**The following resource is provided on the Open Disclosure page of the Clinical Excellence Commission website:**

- The Clinical Excellence Commission Open Disclosure Handbook  
[www.cec.health.nsw.gov.au/programs/open-disclosure](http://www.cec.health.nsw.gov.au/programs/open-disclosure)



## 7 REFERENCES

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[http://www.who.int/patientsafety/taxonomy/icps\\_full\\_report.pdf](http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf)
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[Incident Management Policy PD2014\\_004](#)
13. Victorian Government, *Victorian clinical governance policy framework – a guidebook* Department of Human Services, Melbourne, Victoria. 2009  
[http://health.vic.gov.au/clinrisk/publications/clinical\\_gov\\_policy.htm](http://health.vic.gov.au/clinrisk/publications/clinical_gov_policy.htm)

## 8 APPENDIX

### 8.1 Related Policies and resources

- The Clinical Excellence Commission Open Disclosure Handbook  
[www.cec.health.nsw.gov.au](http://www.cec.health.nsw.gov.au)
- PD2012\_018 Code of Conduct  
[http://www0.health.nsw.gov.au/policies/pd/2012/PD2012\\_018.html](http://www0.health.nsw.gov.au/policies/pd/2012/PD2012_018.html)
- PD2012\_069 Health Care Records - Documentation and Management  
[http://www0.health.nsw.gov.au/policies/pd/2012/PD2012\\_069.html](http://www0.health.nsw.gov.au/policies/pd/2012/PD2012_069.html)
- PD2005\_406 Consent to Medical Treatment - Patient Information  
[http://www0.health.nsw.gov.au/policies/PD/2005/PD2005\\_406.html](http://www0.health.nsw.gov.au/policies/PD/2005/PD2005_406.html)
- PD2014\_001 Appointment of Visiting Practitioners in the NSW Public Health System  
[http://www0.health.nsw.gov.au/policies/pd/2014/PD2014\\_001.html](http://www0.health.nsw.gov.au/policies/pd/2014/PD2014_001.html)
- PD2007\_075 Lookback Policy  
[http://www0.health.nsw.gov.au/policies/pd/2007/PD2007\\_075.html](http://www0.health.nsw.gov.au/policies/pd/2007/PD2007_075.html)
- PD2005\_234 Incident - Effective Incident Response Framework for Prevention & Management in the Health Workplace  
[http://www0.health.nsw.gov.au/policies/PD/2005/PD2005\\_234.html](http://www0.health.nsw.gov.au/policies/PD/2005/PD2005_234.html)
- PD2009\_039 Risk Management - Enterprise-Wide Policy and Framework – NSW Health  
[http://www0.health.nsw.gov.au/policies/pd/2009/PD2009\\_039.html](http://www0.health.nsw.gov.au/policies/pd/2009/PD2009_039.html)
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- Communicating and consulting about risk HB 327:2010 (Companion to AS/NZS ISO 31000:2009). Standards Australia/Standards New Zealand, 2009.
- SiCorp NSW Self Insurance Corporation- Treasury Managed Fund Statement of Cover, including TMF brochure and Travel: the Scheme Structure  
<https://riskinsite.nsw.gov.au/portal/server.pt/community/publications/272>
- Safety and Quality Improvement Guide Standard 1: Governance for Safety and Quality in Health Service Organisations (October 2012)  
<http://www.safetyandquality.gov.au/publications/rtf-safety-and-quality-improvement-guide-standard-1-governance-for-safety-and-quality-in-health-service-organisations/>  
Australian Commission on Safety and Quality in Health Care, Sydney, 2012
- Australian Commission on Safety and Quality in Health Care Open Disclosure Program  
<http://www.safetyandquality.gov.au/our-work/open-disclosure/>
- Australian Safety and Quality Framework for Health Care  
<http://www.safetyandquality.gov.au/publications/australian-safety-and-quality-framework-for-health-care/> Australian Commission on Safety and Quality in Health Care (ACSQHC), Sydney, 2010.
- The Australian Charter of Healthcare Rights  
<http://www.safetyandquality.gov.au/publications/australian-charter-of-healthcare-rights-the/>  
Australian Commission on Safety and Quality in Health Care (ACSQHC), Sydney, 2009.
- The Australian Safety and Quality Goals for Health Care  
<http://www.safetyandquality.gov.au/national-priorities/goals/>  
Australian Commission on Safety and Quality in Health Care (ACSQHC), Sydney, 2012.

## 8.2 Measuring open disclosure for quality improvement

### 8.2.1 National Safety and Quality Health Service Standards

Accreditation Actions required	Evidence
<b>1.16.1 An open disclosure program is in place and is consistent with the national open disclosure standard</b>	Reports on open disclosure are produced in the organisation Information and data on open disclosure presented to the executive and relevant committees
<b>1.16.2 The clinical workforce are trained in open disclosure processes</b>	Education resources and records of attendance at training Report on evaluation of the open disclosure training program

Information on evaluation requirements and criteria for open disclosure in the NSQHS Standards can be accessed at [www.safetyandquality.gov.au/our-work/accreditation/](http://www.safetyandquality.gov.au/our-work/accreditation/) and follow the links to *Health Service Standards and Accreditation*.

## 8.2.2 Suggested Measures for use within NSW Health

The measures suggested here are to facilitate quality improvement, monitoring and reporting to management. These measures should be integrated with other clinical governance reporting systems and mechanisms.

Measure	Evidence
<b>1. Governance measures</b>	
1. Open disclosure practice and outcomes included in case reviews at local Morbidity and Mortality meetings	Minutes of M and M meetings
2. Review of open disclosure cases included at LHD/SN Clinical Council meetings and peak Safety and Quality committee	Minutes of meetings of the Clinical Council and peak Safety and Quality Committee
3. Participation of an appropriately trained consumer* in reviews of local open disclosure practices	Minutes of facility and LHD/SN Quality and Safety committees
<b>2. Education and Training</b>	
1. Percentage of staff trained in open disclosure <ul style="list-style-type: none"> <li>Type of training – i.e. role-relevant</li> </ul>	Training records/LMS
2. Follow-up Staff survey about knowledge of OD process	Survey results
<b>3. Process measures</b>	
1. Did open disclosure occur when it needed to occur?	Internal records
2. Number and percentage of open disclosure processes triggered by complaints	Internal records
3. Number and percentage of complaints following open disclosure	Internal records
<b>4. Outcome measures</b>	
1. Survey (written or oral) of staff involved in Open Disclosure about their experience	Survey results
2. Survey (written or oral) of patients and support persons about their experience with Open Disclosure	Survey results

\* A consumer is a current or potential user of the health system who takes part in the decision making process on behalf of consumers, their family and carers.

**8.2.3 Organisational readiness for open disclosure: Checklist**

Health Services may wish to use this checklist to assist in reviewing operational capacity essential for effective open disclosure (modified from the *Victorian clinical governance policy framework – a guidebook*<sup>13</sup>).

	Yes	No	Notes	Review date
<b>Senior management commitment</b>				
Senior management is committed to open disclosure	<input type="checkbox"/>	<input type="checkbox"/>		
Appropriate resources are allocated to support open disclosure	<input type="checkbox"/>	<input type="checkbox"/>		
Senior management has established a governance reporting and monitoring requirement on the application of open disclosure	<input type="checkbox"/>	<input type="checkbox"/>		
The organisation consults with and provides advice to consumers about the open disclosure policy	<input type="checkbox"/>	<input type="checkbox"/>		
Training requirements are determined and scheduled	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Open Disclosure Policy</b>				
An open disclosure implementation plan has been developed by management and staff and signed by the chief executive officer	<input type="checkbox"/>	<input type="checkbox"/>		
Local open disclosure protocols and procedures have been developed based on the framework outlined in the Policy	<input type="checkbox"/>	<input type="checkbox"/>		
The implementation plan aligns with other operational policies and the organisation’s strategic objectives	<input type="checkbox"/>	<input type="checkbox"/>		
The Policy has been communicated to all staff	<input type="checkbox"/>	<input type="checkbox"/>		
The implementation plan is reviewed at least yearly	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Open disclosure - operational management</b>				
Responsibility for open disclosure has been assigned	<input type="checkbox"/>	<input type="checkbox"/>		
The roles and responsibilities of staff involved in open disclosure are clearly documented and communicated within the organisation	<input type="checkbox"/>	<input type="checkbox"/>		
The organisation has developed a performance monitoring tool to assess its requirements against the policy	<input type="checkbox"/>	<input type="checkbox"/>		
Open disclosure issues are discussed at the peak LHD/SN and facility safety and quality committees at least quarterly	<input type="checkbox"/>	<input type="checkbox"/>		
Open disclosure issues are discussed at morbidity and mortality meetings at least every two months and more frequently if required	<input type="checkbox"/>	<input type="checkbox"/>		

	Yes	No	Notes	Review date
The clinical workforce are trained in open disclosure processes (NSQHSS 1.16.2)	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Open disclosure monitoring</b>				
There are appropriate audit and monitoring systems in place to measure and evaluate open disclosure within the organisation	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Other considerations</b>				
A process is in place to guide the early response to a patient safety incident, including what and how information is gathered and communicated as part of the open disclosure process	<input type="checkbox"/>	<input type="checkbox"/>		