

## Open Disclosure Guidelines

**Document Number** GL2007\_007

**Publication date** 24-May-2007

**Functional Sub group** Corporate Administration - Governance  
Clinical/ Patient Services - Governance and Service Delivery  
Clinical/ Patient Services - Incident management  
Personnel/Workforce - Conduct and ethics

**Summary** To provide a framework for implementing open disclosure in NSW Health facilities in accordance with Open Disclosure PD2007\_037. All Health Services are required to have appropriate local procedures in place to ensure consistency and compliance with the policy.

**Author Branch** Quality and Safety

**Branch contact** Quality and Safety 9391 9200

**Applies to** Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations - Non Declared, Affiliated Health Organisations - Declared, Public Health System Support Division, Community Health Centres, Dental Schools and Clinics, Government Medical Officers, NSW Ambulance Service, Public Health Units, Public Hospitals

**Audience** All staff including manager, clinicians and contractors

**Distributed to** Public Health System, Community Health Centres, Dental Schools and Clinics, Divisions of General Practice, Government Medical Officers, Health Associations Unions, Health Professional Associations and Related Organisations, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres, Private Nursing Homes, Tertiary Education Institutes

**Review date** 24-May-2012

**File No.** 06/861

**Status** Active

# Open Disclosure Guidelines

May 2007

NSW DEPARTMENT OF HEALTH

73 Miller Street

North Sydney NSW 2060

Tel. (02) 9391 9000

Fax. (02) 9391 9101

**[www.health.nsw.gov.au](http://www.health.nsw.gov.au)**

This work is copyright. It may be reproduced in whole or in part for study or training purposes subject to the inclusion of an acknowledgement of the source. It may not be reproduced for commercial usage or sale. Reproduction for purposes other than those indicated above, requires written permission from the NSW Department of Health.

© NSW Department of Health 2007

SHPN (QSB) 07/047

ISBN 978-1-74187-109-8

Further copies of this document can be downloaded from the NSW Health website: [www.health.nsw.gov.au](http://www.health.nsw.gov.au)

May 2007

## Preface

---

**T**hese Guidelines provide a framework for implementing open disclosure in NSW Health facilities in accordance with the Open Disclosure PD2007\_037. All Health Services are required to have appropriate local procedures in place to ensure consistency and compliance with the policy.

For the purposes of this document, the framework is called “the open disclosure process”. The process describes guidelines for initiating communication with the patient and their support person and ensuring that the communication is open, honest and consistent.

Two levels of response are described: **high level response** for severe incidents (usually SAC 1 and SAC 2 incidents) and **general response** for less severe incidents (usually SAC 3 and SAC 4 incidents).

The focus of the open disclosure process is on ensuring that a patient who is affected by an incident knows and understands what has happened, and that actions will be taken to prevent such incidents from happening again.



# Contents

---

<b>Preface</b> .....	<b>2</b>
<b>Contents</b> .....	<b>3</b>
<b>1. What is the open disclosure process?</b> .....	<b>4</b>
The patient/clinician experience .....	4
When does the open disclosure process begin? .....	4
Flow diagram of the open disclosure process .....	5
<b>2. High level and general level responses</b> .....	<b>6</b>
Importance of the first meeting .....	6
The general level response .....	6
<i>If the incident escalates</i> .....	7
The high level response.....	7
<i>When does the Director of Clinical Governance become involved?</i> .....	10
Private patients in public health organisations .....	10
<b>3. Offering an apology</b> .....	<b>11</b>
Examples of apologies.....	11
What is a defamatory statement? .....	11
<b>4. Supporting the clinician</b> .....	<b>12</b>
Open disclosure networks .....	12
Training and education .....	12
<b>5. Feedback to the patient and compensation</b> .....	<b>13</b>
Restrictions on release of information .....	13
Compensation for expenses .....	13
<b>6. Record keeping</b> .....	<b>14</b>
Health care record .....	14
IIMS.....	14
<b>7. Measuring performance</b> .....	<b>15</b>
Compliance with timely implementation .....	15
Percentage of patient/family satisfaction .....	15
Percentage of staff satisfaction .....	15
<b>8. Dealing with complicated situations</b> .....	<b>16</b>
<b>Definitions</b> .....	<b>17</b>
<b>Related policies and resources</b> .....	<b>20</b>
<b>Appendix A: Frequently asked legal and insurance questions</b> .....	<b>21</b>
<b>Appendix B: What to notify to the Medical Defence Organisations</b> .....	<b>24</b>
<b>Appendix C: Saying sorry</b> .....	<b>25</b>
<b>Appendix D: Template for recording open disclosure discussions</b> .....	<b>26</b>
<b>Appendix E: Final outcome letter to the patient</b> .....	<b>27</b>

# 1. What is the open disclosure process?

---

Open disclosure is defined as the ...

*... process of providing an open, consistent approach to communicating with the patient and their support person following a patient related incident. This includes expressing regret for what has happened, keeping the patient informed, and providing feedback on investigations, including the steps taken to prevent a similar incident occurring in the future. It is also about providing any information arising from the incident or its investigation relevant to changing systems of care in order to improve patient safety.*

The open disclosure process provides an ethical framework for ensuring that staff inform patients, and where applicable their support person, in an open, honest and empathetic manner about a patient related incident and its implications for the health care of those patients.

The key principles of the open disclosure process, as stated in the *Open Disclosure policy*, are:

- openness and timeliness of communication
- acknowledgement of error
- expression of regret
- recognition of the reasonable expectations of patients and their support person
- support for health staff
- confidentiality.

## The patient/clinician experience

Open disclosure means that every patient receives an apology and appropriate information following an incident that may have happened during the delivery of their healthcare—whether or not harm was caused.

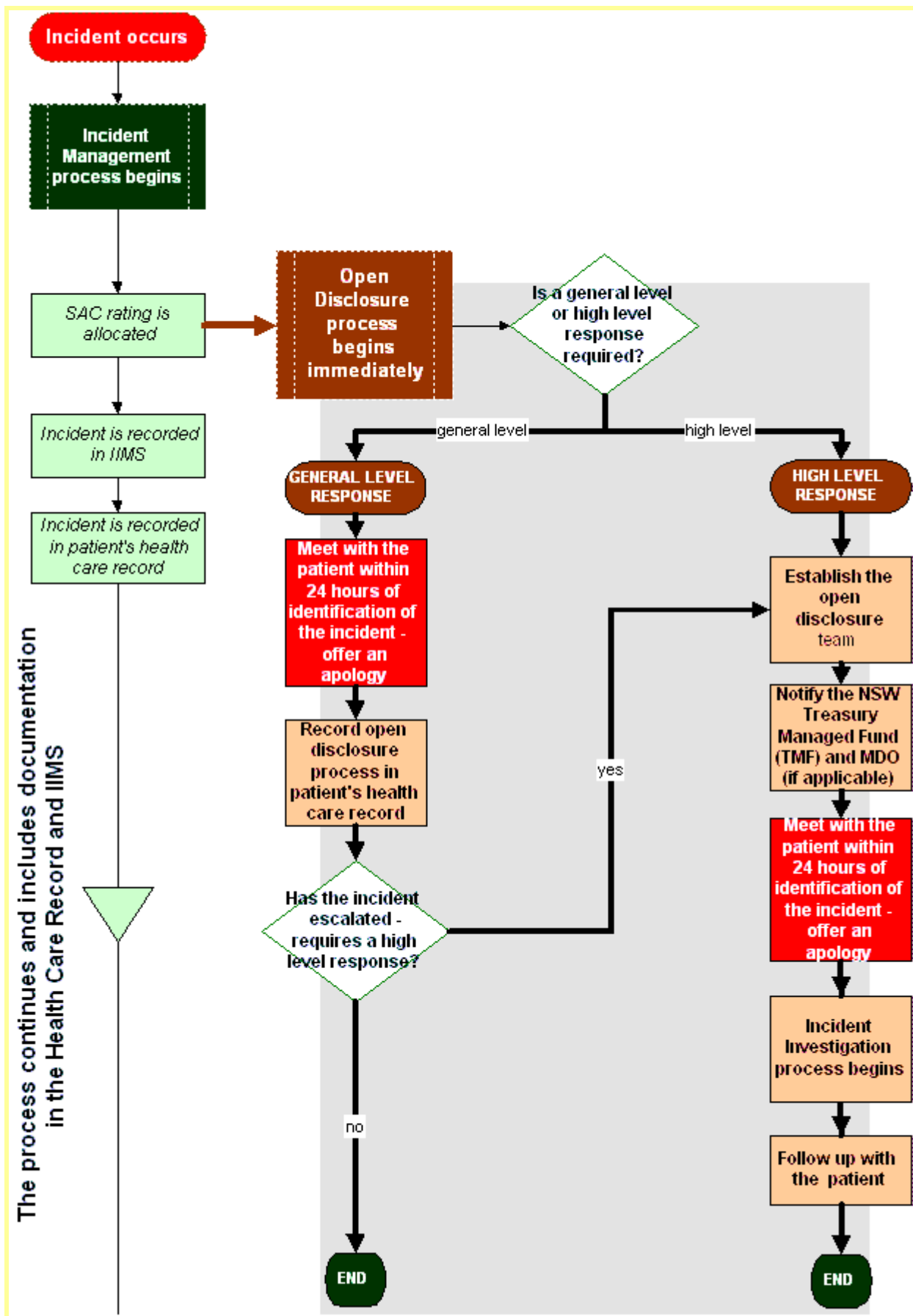
The focus of the open disclosure process is on ensuring that the patient's experience is positive and that communication with the patient and their support person is consistent and informative. Of equal importance is recognition of the clinician's sensitivities and the avoidance of unwarranted effects on their reputation (see [4. Supporting the clinician](#) on page 12).

## When does the open disclosure process begin?

The open disclosure process is part of the Incident Management Process (see [the \*Incident Management Policy PD2006\\_030\*](#)). As soon as an incident is identified and the Severity Assessment Code (SAC) allocated, the open disclosure response is graded as a **general level response** (usually SAC 3 or SAC 4) or a **high level response** (usually SAC 1 or SAC 2).

A diagram of the process is presented on page 5.

## Flow diagram of the open disclosure process



## 2. High level and general level responses

---

The level of open disclosure response is determined once the Severity Assessment Code (SAC) has been allocated. A SAC 1 or SAC 2 incident is usually graded as a **high level response** and a SAC 3 or SAC 4 incident is usually graded as a **general level response**.

Irrespective of the level of response to the incident, the patient must be advised of the known facts **within 24 hours** of identification of the incident by the Health Service.

### Importance of the first meeting

The purpose of the first meeting is to support and inform the patient.

If direct communication with the patient is hindered because of the patient's clinical condition or language/cultural/disability difficulties or his/her emotional state, consideration should be given to initiating communication with the support person.

### The general level response

A general level response is usually undertaken for SAC 3 or SAC 4 incidents, where harm to the patient was minimal.

The open disclosure process for general level responses involves the following steps:

#### 1. Meeting with the patient and their support person

In general level responses, the clinician directly involved in the incident is the most appropriate person to communicate with the patient and their support person. This may be a nurse, allied health professional or junior medical staff.

The general response involves:

- a meeting with the patient and their support person, where practicable
- an explanation of **what happened**, the immediate effects, and prognosis
- an **apology** (see [3. Offering an apology](#) on page 11)
- the **contact names** and phone numbers of people in the health facility who are available to address concerns and complaints, including psychological and social support contacts.

For a general level response, this first meeting with the patient and their support person may be the only meeting about the incident.

This meeting may simply be a conversation between the clinician and the patient at the bedside or a telephone conversation with the patient if discharged.

It is up to the clinician to initiate a follow-up, if necessary.

#### 2. Recording the incident

The incident must be recorded in the patient's health care record and in the Incident Information Management System (IIMS) (see [6. Record keeping](#) on page 14).

#### 3. Notifying the line manager

In most instances, the notification of an open disclosure response occurs via the IIMS. The line manager may be a nurse unit manager or a medical clinician manager.

In some cases, notification to Treasury Managed Fund (TMF) of a SAC 3 or SAC 4

incident may also be required (for further guidance, see TMF Policy-under development).

### If the incident escalates...

... to SAC 1 or SAC 2 incident a high level response should be initiated. A general level response can also be escalated to a high level response at the discretion of the senior clinician and the senior manager.

## The high level response

The high level response involves the full open disclosure process, as follows:

### 1. Establishing the open disclosure team

Senior management forms an **open disclosure team** as soon as the severity of the incident has been established.

The team's role is to:

- support and assist with managing the open disclosure process; and
- develop a robust plan to ensure that communication is consistent and accurate.

Team members may include the following:

- patient's senior clinician
- senior manager, eg. Director of Medical Services, Director of Nursing and Midwifery, Director of Clinical Division, General Manager, Risk Manager, or equivalents
- another involved clinician
- a patient advocate
- if required, Director of Clinical Governance or delegate (see
- 
- 
- *When does the Director of Clinical Governance become involved?* on page 10).

### 2. Developing the plan of action

The team meets as soon as possible after the incident to discuss the following:

- nominating the team leader who communicates with the patient and their support person
- immediate patient care
- ongoing patient care and support
- basic clinical and other facts relevant to the incident
- level of support for the patient's family and support person
- level of support for staff and responsibility for providing that support
- how to maintain a consistent approach in discussions with the patient and their support person.

### 3. Notifying the NSW Treasury Managed Fund (TMF)

All SAC 1 and SAC 2 incidents should be notified to the NSW Treasury Managed Fund (TMF) **within 48 hours** if a high level response is being prepared. The notification, however, must not delay the first meeting with the patient.

The notification includes:

- copy of the relevant pages in the patient's health care record
- brief description of the incident
- details of the contact person.

### If the incident involves a Visiting Medical Officer (VMO)...

... the notification must be sent via the Visiting Medical Officer Incident Reporting System (VMOIRS). The notification is verified by the Health Service and the NSW Department of Health's Finance Branch and then passed on to the TMF.

### If a Root Cause Analysis (RCA) is stopped...

... and the incident is referred for further investigation because of concerns or complaints about clinical practice or performance, the TMF must also be notified of this development.

Refer to [Complaint or Concern about a Clinician - Principles for Action PD2006\\_007](#), [Complaint or Concern about a Clinician - Management Guidelines GL2006\\_002](#), [Complaint Management Policy PD2006\\_073](#) and [Complaint Management Guidelines GL2006\\_023](#).

## 4. Notifying the Medical Defence Organisation

If the incident is significant or involves the high level open disclosure response, MDOs strongly recommend that medical practitioners contact their MDO at the earliest practical opportunity for advice and support, at the same time meeting any insurance notification obligations.

See *Appendix B: What to notify to the Medical Defence Organisations* on page 24 for guidance on the types of incidents that should be notified to the MDO.

## 5. Notifying other people/groups

Other notifications may include (subject to observing applicable privacy requirements):

- the patient's general practitioner
- the Coroner (refer to [Coroners' Cases and Amendments to Coroners Act 1980 PD2005\\_352](#))
- statewide committees:
  - Maternal & Perinatal Committee
  - Special Committee Investigating Deaths Under Anaesthesia
  - Special Committee Investigating Deaths Associated with Surgery
  - Mental Health Sentinel Events Review Committee.

Note that the patient's family and support person must be informed if the Coroner is notified.

## 6. Meeting with the patient

The initial disclosure meeting with the patient and their support person may involve the:

- team leader
- person(s) directly involved with the treatment that resulted in the incident
- responsible senior clinician.

The discussion should include:

- an explanation of what happened and the known facts, the immediate

effects, and prognosis

- an **apology** (see *3. Offering an apology* on page 11)
- the **contact names** and phone numbers of people in the health facility who are available to address concerns and complaints, including psychological and social support contacts
- names of people on the open disclosure team
- how the incident will be **investigated**, what tools will be used (eg. “we will speak with the relevant clinicians”, “we may seek expert opinion”, “a root cause analysis investigation process will be used”)
- steps for ongoing **feedback**
- anticipated **timelines** for investigating the incident
- a statement that an explanation of how or why the incident occurred may be **delayed** until investigations are complete.

### **If there is a break down in communication...**

... between the patient/support person and the team leader, the patient and their support person should be offered another person as team leader eg. General Manager of the health facility, Director of Clinical Governance.

## **7. Follow-up with the patient**

The purpose of follow-ups with the patient and their support person is to inform them of the progress of any investigations. Follow-ups must be undertaken either in face-to-face interviews or by letter or both.

If there are delays in the investigation, frequent updates should be supplied, together with an explanation of the reason for the delays.

Following discharge of the patient, a series of follow-up arrangements with the patient and their support person may need to be established to provide updates on findings of investigations. See *5. Feedback to the patient and compensation* on page 13.

## **8. Final follow-up interview and letter**

Issues covered in the **final** follow-up interview and letter are:

- an apology and expression of regret for the harm suffered
- acknowledgement of the concerns or complaints of the patient and their support person
- details of the Root Cause Analysis Final Report and explanation of the Report in plain English
- a summary of the factors contributing to the incident (as established (as established in the RCA Final Report) and information on measures to be implemented to prevent a similar incident from occurring
- how improvements will be monitored.

See *Appendix E: Final outcome letter to the patient* on page 27 for a template of the letter.

### When does the Director of Clinical Governance become involved?

The Director of Clinical Governance's role is to ensure that open disclosure is implemented effectively throughout the Health Service and that the open disclosure process is reviewed regularly.

The Director of Clinical Governance (DCG) becomes part of the open disclosure team if:

- the open disclosure process breaks down
- the Chief Executive requests the DCG's involvement
- progress is impeded because of conflicts among team members
- a Senior Complaints Officer has to be appointed.

### Private patients in public health organisations

If an incident affects a private patient admitted to a Health Service, the patient's admitting Visiting Medical Officer (VMO) should contact his/her Medical Defence Organisation (MDO) or insurer for advice prior to commencing the open disclosure process, if possible.

See also *Appendix A: Frequently asked legal and insurance questions* on page 21 for more on legal and insurance matters.

## 3. Offering an apology

---

Offering an apology or expressing regret is a **key component** of the open disclosure process.

The apology should include an expression of sorrow for the harm done to the patient, but it must *not* be an admission of liability. Staff must be careful *not* to make any verbal or written statement that admits liability. An admission of liability means admitting that the hospital or a staff member breached their duty of care to the patient, which led to the patient suffering harm or injury.

An apology:

- does not blame the health facility for harm caused to the patient
- does not blame a clinician for harm caused to the patient
- does not blame the Health Service for harm caused to the patient
- does not indicate that the incident could have been avoided.

### Examples of apologies

The following statement *does not admit liability*. It provides facts but no conclusions.



*"Your husband, John, was given an injection of penicillin shortly before his death. There were notes in his medical records that he was allergic to penicillin, but the person who gave the injection did not see the notes. We are sorry about this incident."*

The following statement *admits liability* by admitting breach and causation. Duty should not be an issue in an apology.



*"The nurse knew your husband, John, was allergic to penicillin, because it is written all over the notes; but she gave him the injection by mistake that caused him to have an anaphylactic reaction, from which he could not be resuscitated. We are very sorry about this incident"*.

### What is a defamatory statement?

A defamatory statement is a communication that insults or denigrates one person to another person, and that is capable of injuring a person's reputation.

An example is an allegation by one clinician that another is incompetent.

Some ways of avoiding defamatory statements are to ensure that:

- statements are **accurate** and verifiable
- conclusions are based on the **facts** and follow logically, fairly and reasonably from the information obtained
- rumours or material known to be false or irrelevant are **excluded**
- the manner and **extent** of the disclosure do not exceed what was reasonably required for the purposes of open disclosure.

See [Appendix C: Saying sorry](#) on page 25 for useful tips on making an apology.

## 4. Supporting the clinician

---

When an incident occurs, the clinicians involved in the incident and in the open disclosure process may require emotional and psychological support and advice on how to deal with their response to the incident.

Each health facility should have protocols and systems in place to ensure that staff are aware of and can access adequate support. Professional bodies, such as MDOs and local Employee Assistance Programs, can provide support at this time—particularly for staff who are interviewed during an incident investigation.

Opportunities for staff debriefing should be provided as required.

Staff involved in the incident should also be advised of the outcomes of the open disclosure process, including recommendations and implementation strategies.

### Open disclosure networks

Open disclosure networks are groups of senior clinicians trained in open disclosure, who are available to assist colleagues. Local health facilities may also have well-developed medical peer support systems in place.

### Training and education

Communicating with the patient and their support person during an emotionally intense period immediately following an incident can be critical for maintaining a relationship of compassion and trust.

All clinicians should be able to access education, training and other resources specifically designed for communicating bad news.

## 5. Feedback to the patient and compensation

---

Part of the investigation process involves identifying documents and other communications that can be released to the patient and their support person. As stated in the [Incident Management Policy PD 2006\\_030](#), if during the investigation an individual performance issue is identified, the course of action is redirected to the organisation's performance management system. See [Complaint or Concern about a Clinician - Principles for Action PD2006\\_007](#) and [Complaint or Concern about a Clinician - Management Guidelines GL2006\\_002](#).

### Restrictions on release of information

The following restrictions prevent the release of information to the patient, in some circumstances:

- **Special Privilege under section 23 of the Health Administration Act 1982**  
Clinical Reportable Incident Briefs prepared for the NSW Health Reportable Incident Review Committee are protected by statutory privilege. See [Research and Investigation Authorised Under the Health Administration Act 1982 PD2006\\_058](#).
- **Insurance contractual arrangements**  
VMOs have to be careful not to void their private medical indemnity arrangements with their MDOs by admitting liability when participating in the open disclosure process. Whilst open disclosure conducted in accordance with these Guidelines should not involve any admission of liability, VMOs may nevertheless like to seek advice from their MDO before participating in the open disclosure process.
- **Statutory Privilege under Division 6C of the Health Administration Act 1982**  
Documents that are created by, at the request of, or solely for the purpose of an RCA team during an RCA investigation are protected by statutory privilege. Such documents cannot be subpoenaed by a court, and members of an RCA team cannot be required to give evidence about RCA matters before a court or tribunal. The RCA team's report is not protected by the privilege, and may be required to be disclosed.
- **Client Legal Privilege**  
Client legal privilege can protect certain documents from being disclosed. Specifically, documents created, or communications made, for the dominant purpose of giving legal advice in relation to the incident or for use in legal proceedings (which could include coronial and Health Care Complaints Commission investigations), and which remain confidential, will be subject to client legal privilege.

### Compensation for expenses

Compensation to the patient and their support person for expenses incurred as a result of an incident (eg. out-of-pocket expenses, travel, disability aids) is the responsibility of the Health Service and at its discretion on a case-by-case basis.

However, any such expenses may not be recoverable from the TMF. It is important, therefore, that the TMF be consulted prior to any agreement with the patient and their support person for compensation for expenses, unless there are particular categories of compensation that are normally provided locally.

If a patient inquires about compensation for expenses during the initial meetings, the matter should be referred to the AHS Risk Manager or the Claims Manager.

## 6. Record keeping

---

The open disclosure process must be recorded in the patient's health care record and in IIMS. See *Appendix D: Template for recording open disclosure discussions* on page 26 for a template.

### Health care record

The senior clinician responsible for the care of the patient must record a summary of communication with the patient and their support person in the patient's health care record. All ongoing developments and communication during and at the completion of the open disclosure process must be recorded.

The recording includes the **date and time** of each entry, what the patient was **told**, and a summary of **agreed actions**. Confirmation that an **apology** was given must also be recorded.

The recording should include only known facts, be objective and not apportion blame.

### IIMS

Recording the open disclosure process in IIMS commences with the initial notification of the incident. If the incident is a SAC 1 incident a Reportable Incident Brief (RIB) is generated and the fields related to the open disclosure process are completed. Usually the General Manager of the health facility is responsible for ensuring that the open disclosure fields are completed before the RIB is submitted.

## 7. Measuring performance

---

The overall effect of the open disclosure process on the escalation of, or reduction in, complaints will provide a measure of the efficacy of the open disclosure process. Performance measures that may be considered by the Health Service are as follows.

### **Compliance with timely implementation**

Compliance with timely implementation is measured by notifying the completion of the RIB and notifying the “initial disclosure” in IIMS.

### **Percentage of patient/family satisfaction**

Patient/support person satisfaction rated through local audits and evaluation.

### **Percentage of staff satisfaction**

Staff satisfaction rated through local audits and evaluation.

## 8. Dealing with complicated situations

---

There may be some situations when the open disclosure process may not have been initiated for example when a potential SAC 1 incident is identified during a retrospective death audit.

In these situations it may be preferable to undertake an incident investigation, prior to initiating the open disclosure process. If the incident investigation confirms an incident has occurred then the open disclosure process should be initiated.

By adopting this stance the anxiety and grief of the family and the support person may not be increased nor prolonged.

## Definitions

---

<b>Apology<sup>1</sup></b>	<p>A key aspect of open disclosure is saying sorry or offering an apology to the patient and support person following an incident. 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.</p> <p>An apology does not constitute an admission of fault or liability and neither is it relevant to the determination of fault or liability in connection with a matter.</p>
<b>Clinician</b>	A health practitioner or health service provider regardless of whether the person is registered under a health registration act.
<b>General level response</b>	<p>A general level response does not include all the steps of the open disclosure process.</p> <p>Usually, it involves meeting with the patient, documentation of the incident, and notification of an open disclosure response to the line manager via IIMS.</p>
<b>Health Service</b>	<p>For the purposes of these Guidelines the term “Health Service” refers to public health organizations and the Ambulance Service of NSW.</p> <p>Public health organisations are area health services, relevant statutory health corporations, or relevant affiliated health organisations in respect of their recognised establishments or recognised services as defined in the <i>Health Services Act 1997</i>.</p> <p>For the purposes of these Guidelines, the relevant statutory health corporations and relevant affiliated health organisations are set out in Appendix B of the <a href="#">Incident Management Policy PD2006_030</a></p>
<b>High level response</b>	A high level response involves all the steps of the open disclosure process in accordance with these Guidelines.
<b>IIMS</b>	NSW Health Incident Information Management System <sup>2</sup> .
<b>Incident</b>	Any event resulting in, or with the potential for, injury damage or other loss. For the purposes of the open disclosure process an incident will <b>exclude a near miss</b> .

---

<sup>1</sup>[Civil Liability Act 2002](#). Refer to sections 68 and 69 of the Act.

<sup>2</sup> NSW Health Incident Information Management System (IIMS) incorporates the Advanced Incident Management System (AIMS®) software application as its underlying database.

<b>Incident investigation</b>	The management process by which underlying causes of undesirable events are uncovered and steps are taken to prevent similar occurrences <sup>3</sup> .
<b>Incident management</b>	A systematic process for identifying, prioritising, investigating and managing the outcomes of an incident.
<b>Medical Defence Organisation (MDO)</b>	A private professional indemnity provider.
<b>Open disclosure</b>	Open disclosure is the process of providing an open, consistent approach to communicating with the patient and their support person following a patient related incident. This includes expressing regret for what has happened, keeping the patient informed, and providing feedback on investigations, including the steps taken to prevent a similar incident occurring in the future. It is also about providing any information arising from the incident or its investigation relevant to changing systems of care in order to improve patient safety.
<b>Reportable Incident Brief (RIB)</b>	The method for reporting defined health care incidents to the NSW Department of Health. The RIB process encompasses clinical and corporate incidents occurring in the health care setting under four incident categories: clinical; staff, visitor, contractor; property, security, hazard; and complaints.
<b>Root Cause Analysis (RCA)</b>	A method used to investigate and analyse a SAC 1 incident to identify the root causes and factors that contributed to the incident and to recommend actions to prevent a similar occurrence.
<b>Senior Clinician</b>	The admitting medical officer, who is responsible for the clinical care of the patient throughout the admission, being a Visiting Practitioner, Visiting Medical Officer or Staff Specialist who has admitting rights to the health care facility.
<b>Severity Assessment Code (SAC)</b>	A numerical score applied to an incident based on the type of incident, its likelihood of recurrence and its consequence. A matrix is used to stratify the actual and/or potential risk associated with an incident (see <a href="#">Incident Management Policy PD2006_030</a> ).
<b>Support person</b>	May be any individual identified by the patient as a nominated recipient of information regarding their care. This may include the patient's family members, partner, carer or friends. In cases of a dispute between the patient's family members, partner, carer and/or friends about who should receive information, the patient's wishes should be paramount. Where a patient is unable to give consent, the 'next person responsible' should be approached.

---

<sup>3</sup> Woloshnowych M, Rogers S, Taylor-Adams S, Vincent C. *The investigation and analysis of critical incidents and adverse events in healthcare*. Health Technology Assessment, 2005 9 (9):vii.

<b>Treasury Managed Fund (TMF)</b>	The self-indemnification and risk management scheme established by the NSW Government to cover certain liabilities of the State and its agencies, such as public health organisations.
<b>Visiting Medical Officer</b>	A medical practitioner appointed under a service contract (whether the practitioner or his or her practice company is a party to the contract) to provide services as a visiting practitioner for monetary remuneration for or on behalf of the public health organisation concerned.
<b>Visiting Medical Officer Indemnity Scheme</b>	The NSW Government has, from 1 January 2002, indemnified all VMOs and HMOs for all work they perform on public patients in public hospitals in NSW, subject to their meeting certain conditions. The Indemnity Scheme is provided as a separate self-contained arrangement within the TMF.
<b>Visiting Medical Officer Incident Reporting System (VMOIRS)</b>	An Internet/Intranet based system that is used to support the administration of the Visiting Medical Officer (VMO) Indemnity Scheme provided by the NSW Government via the Treasury Managed Fund (TMF).

## Related policies and resources

---

[Open Disclosure PD2007\\_037](#)

[Incident Management Policy PD2006\\_030](#)

[Reportable Incident definition under section 20L of the Health Administration Act PD2005\\_634](#)

[Complaints Management Policy PD2006\\_073](#)

[Complaint Management Guidelines GL2006\\_023](#)

[Complaint or Concern about a Clinician – Principles for Action PD2006\\_007](#)

[Complaint or Concern about a Clinician – Management Guidelines GL2006\\_002](#)

[Lookback PD2006\\_070](#)

[Legal Matters of Significance to Government PD2006\\_009](#)

[Coroners' Cases and Amendments to Coroners Act 1980 PD2005\\_352](#)

[Health Administration Act 1982](#)

[Open Disclosure on the Department's website](#)

[Incident Information Management System \(Intranet only\)](#)

[Privacy Manual \(Version 2\) – NSW Health PD2005\\_593](#)

[Statutory Guidelines under the Health Records and Information Privacy Act 2002](#)

NSW Health, TMF Policy - under development. The policy will examine the role of the TMF in the open disclosure process.

[Treasury Managed Fund](#)

[Visiting Medical Officers and Honorary Medical Officers Public Patient Indemnity Cover: Explanation Document, April 2002](#)

[Australian Commission on Safety and Quality in Health Care](#)

[Risk Management: AS/NZS 4360:2004](#)

## Appendix A: Frequently asked legal and insurance questions

---

*Irrespective of the level of response to the incident, the open disclosure process must commence with the patient within 24 hours of identification of the incident by the Health Service.*

**I am a privately insured VMO or other medical practitioner. When should I notify my MDO?**

If you are a VMO or other medical practitioner who is insured with a medical defence organization (MDO), your insurance policy may set out when you must notify your MDO of an incident. If the incident is a notified incident under your insurance policy, you should notify your insurer if possible before commencing involvement in the open disclosure process.

Many MDOs also provide legal advice to their members, including legal advice and assistance in relation to the open disclosure process.

**I am a privately insured VMO or other medical practitioner. How can I ensure I do not jeopardise my insurance coverage by participating in the open disclosure process?**

If you admit liability this may fall within an exclusion clause of your insurance policy. This may result in your insurer refusing to indemnify you or provide you with legal representation or assistance in relation to any Court or other proceedings arising from the incident.

However, MDOs are committed to supporting their members in the open disclosure process. Early telephone contact with your MDO is the best way to obtain reassurance about how you can participate without jeopardising your insurance.

**What is an admission of liability / an apology**

An apology is defined by section 68 of the Civil Liability Act 2002 as 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.

An apology does not constitute an expression or implied admission of fault or liability and is not admissible in any civil proceedings as evidence of fault or liability.

**How should the open disclosure process be managed when more than one indemnity provider (ie TMF and an MDO) is involved?**

If necessary, representatives from MDOs and TMF will liaise to ensure that the information provided to patients as part of the open disclosure process does not jeopardise the insurance cover of any of the clinicians involved in the incident.

If written information is to be provided to the patient, TMF and MDOs may wish to review the draft version, to ensure that it satisfies their requirements.

**Do documents created during the open disclosure process have any special status?**

No. Any documents created during the open disclosure process should be treated in the same way as any other part of a patient's health care record. They should also be retained in accordance with the State Records Act and NSW Department of Health policy.

Documents relating to open disclosure may be provided to patients on request, produced under Freedom of Information legislation, or in answer to a subpoena. Patients can also request access to records relating to them, and request amendments to their records, if the records contain incomplete or misleading information, pursuant to the Health Records and Information Privacy Act 2002.

Just like clinical records, clinicians should take care when creating documents to ensure that they do not contain inappropriate language, and are accurate. As far as is possible, only verified facts should be contained in documents. Documents should not:

- attribute blame to any clinician or Health Service
- record opinions, unless the opinions are expert opinions and based on supporting evidence
- contain statements which are likely to be defamatory.

Although open disclosure documents will not be covered by client legal privilege, notifications of incidents to TMF / VMOIRs / MDOs may be privileged and should not be provided to patients without first seeking legal advice. In addition, documents created by an RCA team for the purpose of a RCA investigation (other than the Final Report) have a special statutory privilege and cannot be provided to patients. The RCA Final Report can be provided to the patient and their support person.

For a discussion of types of privilege (see [Subpoenas PD2005\\_405](#)).

### What about privacy and confidentiality?

Strict confidentiality requirements apply to persons working in the health system. These confidentiality requirements apply generally to patient information, including information gathered as part of the open disclosure process.

Clinicians have statutory duties of confidentiality imposed by section 22 of the Health Administration Act 1982 and section 289 of the Mental Health Act 1990. Clinicians also have a common law duty and an ethical duty to maintain patient confidentiality.

Health Services and clinicians also have an obligation to respect the privacy of both staff and patients during the open disclosure process. The open disclosure process should be conducted in accordance with the [Health Records and Information Privacy Act 2002](#) and the [NSW Health Privacy Manual \(Version2\)](#).

### Can a patient have two support people, and what happens if there is conflict between the support people?

For practical reasons, patients should nominate only one support person. However, in the circumstance where a patient nominates more than one that is acceptable. Common sense should prevail with regards to the actual number. In the case of minors these patients will regularly have two support persons (ie both parents). If a conflict arises between the support people as to how the open disclosure process will progress, this should be managed using strategies such as repeat discussion, mediation, and counselling.

If the parents of a minor (under 18 years of age) are divorced or separated, Health Services should assume that both parents have retained full responsibility for the minor, unless the Family Court has made an order stipulating that one or both parents have particular responsibilities. Unless Court orders have been made, parental responsibility is not affected by changes to relationships (ie if the parents separate).

This means that in order for a Health Service to discharge its legal obligations, discussion with, or the consent of, either parent is usually sufficient. There is generally no reason why the consent or participation of both parents would be required, however, in practice, there is no reason why both parents should not be involved in making treatment decisions, and in the open disclosure process. See section 26 of the [Consent to Medical Treatment - Patient Information PD2005\\_406](#) for further information.

However, Health Services should also be aware that whilst young persons (aged 16 or 17) may elect to have a parent/s as a support person, they can make medical decisions (as well as decisions in relation to open disclosure) for themselves, and the consent or participation of the young person's parent is not legally required.

### What happens if the support person is not the patient's guardian, or 'person responsible'?

In these cases, the open disclosure process should take place with the involvement of the support person, however, discussions relating to further treatment must involve the person who has the legal capacity to make treatment decisions on behalf of the patient.

### Who do I contact for assistance?

If you are a VMO with private insurance cover, you should contact your MDO for assistance relating to insurance or legal issues.

If you are a Risk Manager, Senior Manager or Director of Clinical Governance in a Health Service, you can contact the following:

- Insurance issues: NSW Department of Health Finance Branch/TMF.
- Legal issues: NSW Department of Health Legal Branch.

## Appendix B: What to notify to the Medical Defence Organisations

---

*This document has been provided as consolidated generic information from participating Medical Defence Organisations.*

*Note however that irrespective of the level of response to the incident, the open disclosure process must commence with the patient within 24 hours of identification of the incident by the Health Service.*

If you are required to participate in the open disclosure process it is always advisable to seek advice from your MDO beforehand. Written notification of the incident will be requested by the medico-legal advisor for insurance purposes.

The open disclosure process commences when the patient has suffered unintended harm during his/her episode of care. As soon as the incident is identified the Open Disclosure Guidelines requires that the patient receive prompt and appropriate clinical care and prevention of further harm

Without limiting the scope of the general guidance above, incidents that certainly require notification to your MDO include:

- **Inappropriate or incorrect medication** or dosage leading to an adverse outcome.
- **Failure to diagnose** where, in the circumstances, it would have been reasonable to diagnose a serious condition, but having failed to do so, you learn later that the condition existed at the time (e.g. breast cancer, other cancer, meningitis, acute abdomen, fracture, myocardial infarction, subarachnoid haemorrhage, obviously missed pathological or radiological diagnosis such as fetal abnormality).
- **Any major surgical complication** such as neurological impairment, paraplegia, incontinence, organ perforation, sexual dysfunction, nerve injury, blindness, loss of extremity or death.
- **A clear error** such as operating on the wrong site or the wrong level
- **Any major unanticipated fetal damage** such as neurological injury, Erb's palsy or death.
- **An unanticipated death** if death was not a likely possibility of the patient's disease.
- **Foreign bodies** left within the patient.
- **An adverse outcome** that has resulted in significant anger in the patient or a relative.
- **Significant patient dissatisfaction** with the results or elective procedures such as cosmetic surgery or laser eye surgery.
- **Conflict** between patient/family and hospital staff.
- **Patient complaint** relating to a serious incident.

MDOs appreciate that explanations and apologies for minor complications often occur spontaneously in circumstances where it would be impractical to provide prior notification. However, the guiding principle should be **if in doubt, notify** and this principle should certainly apply where the high level open disclosure process is to be undertaken.

## Appendix C: Saying sorry

---

Here are some guidelines on how to say sorry.

### Plan ahead

Before approaching the patient, know exactly what you are going to say.

### Provide the right information

Patients and families who have serious concerns about their health care seek an honest, straightforward explanation.

### Go slowly and genuinely

Have ample time to spend with the patient, support person and family.

Use plain and simple English. Do not use medical jargon.

Avoid words such as wrong, error, mishap, incorrect, mistake when saying sorry.

Avoid going overboard. There is no reason to offer an overwrought and emotional apology. Clinicians should never say “I’m sorry. I made such a mess of things” or “I feel so guilty I don’t care what happens to me.”

Here are some key discussion areas and examples.

Discussion areas	Examples of usage
Acknowledge	“As you know, there has been a problem with your medication and I understand that you may be disappointed with what has happened.”
Apology	“I am very sorry that this has happened.” “I realise it has caused great pain/ distress/ anxiety/worry”
Known facts	“We have been able to determine that... ” “We are not sure exactly what happened at present; however, we will be investigating the matter further and will give you more information as it becomes available.”
Patient story	“I’d really like to hear about things from your point of view. What do you already know about what’s happened? How do you feel about this?” “Mr [patient’s name], can I just summarise what you have told me?” “You may have a few <u>questions</u> you would like to ask, and I will try to answer them as best I can.” “You may have some <u>ideas</u> on how we should move forward from here.”
Medical plan	“I have reviewed what has occurred and this is what I think we need to do next.”
Investigation	“ We will be taking steps to learn what happened so that we can prevent this from happening to someone else.” <i>Explain the investigation process in plain English.</i>
Continuing contact	“ Would you like me to contact you to set up another meeting?” “Here is my phone number if you feel you need to go over it again or if you have any other questions.” “What would be the best way to contact you so we can keep you informed?”

## Appendix D: Template for recording open disclosure discussions

---

Date of discussion:

Time:

Persons present:

Name:

Designation/relationship:

Name:

Designation/relationship:

Name:

Designation/relationship:

Name:

Designation/relationship:

Brief factual summary of the incident

-----  
-----

Progress on the patient's clinical situation, if relevant, and summary of all points explained to the patient and their support person.

-----  
-----

Offers of support and response to offers

-----  
-----

Plans for follow-up—either treatment or further information or both. Include dates.

-----  
-----

Was an apology offered?  yes  no

*We hereby confirm that this is an accurate reflection of the discussion.*

\_\_\_\_\_  
Senior staff member

Date \_\_\_\_\_

\_\_\_\_\_  
Patient or their support person (*signature is optional*)

Date \_\_\_\_\_

## Appendix E: Final outcome letter to the patient

---

Date

Patient name  
Patient address

Dear [insert name]

I am writing to advise you of the final outcome of the investigation of the incident involving your care which occurred on [insert date].

Following thorough investigation of the incident, the following summary outlines the incident and the contributing factors.

[Provide description of incident or complaint or concern raised by patient /support person and findings of incident investigation.]

I would like to express my regret for your experience and to let you know of the measures that have been implemented to prevent or minimise the impact of future such incidents. As a result of your experience, we have instituted the following remedial actions.

[Provide list of remedial actions]

Please do not hesitate to contact me if you have any further inquiries regarding this incident.

Yours sincerely

Name  
Title