OPEN DISCLOSURE HANDBOOK







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INTRODUCTION

FOREWORD

Open Disclosure is about "doing the right thing" when a patient has been harmed while receiving health care. It enables staff to communicate with empathy – to walk in another's shoes – and to say sorry for what has happened.

However, it is about much more than that. Open Disclosure also ultimately means "doing the right thing" for everyone involved – including doctors, nurses, allied health and hospital administrators – and works toward restoring the trust of patients and staff in the health system.

In the past, clinicians and managers sometimes adopted a defensive approach to patient safety incidents. Even if a clinician wanted to apologise, and felt that it was the right thing to do, he or she was not always advised to do so. Patients and families were left feeling frustrated and angry when they were unable to get an explanation about what happened. Staff reported experiencing sadness, guilt and remorse as a result of not being able to provide information to patients and their families.

Full disclosure, apology, and open communication between health care providers and patients has been shown to more effectively address the needs of patients and carers, clinicians and managers. Clinicians need not fear that their apologies, or other empathic words or gestures will later be used against them in formal proceedings. In fact, patients and their families have indicated that receiving a sincere apology was the most meaningful aspect of open disclosure.

This Handbook supports NSW Health staff by providing the "how to" of open disclosure practice. It should be read in conjunction with the recently revised Open Disclosure policy PD2014_028 and its content is reinforced in a series of on-line modules available from HETI Online.

The transition to practising open disclosure is an important step in embracing a culture of openness and transparency. Irrespective of your work setting, all clinicians and managers have an important role to play in making that a regular practice and an accepted element of "how we do things around here".

Clifford F Hughes, AO
CLINICAL PROFESSOR
CEO, CLINICAL EXCELLENCE COMMISSION



OPEN DISCLOSURE

"Open and honest communication between caregivers and their patients and families starts the process of healing... for both the patient and the caregiver"

Lucian Leape, M.D. Professor of Health Policy, Harvard School of Public Health

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 care staff following a patient safety incident. It is an integral part of incident management in NSW Health services and is a key element of the early response and investigation of serious patient safety incidents.

Open disclosure is required whenever a patient has been harmed, whether that harm is

- a result of an unplanned or unintended event or circumstance, or
- an outcome of an illness or its treatment that has not met the patient's or the clinician's expectation for improvement or cure.

A disclosure discussion is also generally required when a 'no harm' incident has been identified, and may be required for 'near miss' incidents if there is an ongoing safety risk to the patient and the patient would benefit from knowing. See Chapter 3 What is open disclosure? for more more detail about when open disclosure is required.

Open disclosure can1:

- increase trust between patients and health care providers when information is exchanged and an apology is received
- assist patients to become more active partners in their care.
- improve patient safety through improved understanding of how things go wrong
- improve patient safety through learning how to prevent things going wrong

The NSW Health Open Disclosure Policy PD2014_028 sets out the minimum requirements for implementing open disclosure following a patient safety incident within NSW Health services. The policy outlines the two stages of the open disclosure process – clinician disclosure and formal open disclosure.

Local processes will need to encompass the NSW Health Open Disclosure Policy, which is supported by the guidance provided in this Handbook.

Effective open disclosure requires that health care facilities provide for staff and patients a just, fair and safe culture which values patient-based care, focuses on continuous learning and improving quality and patient safety, and discourages speculation and attribution of blame.

"An apology would go such a long way, it really would, simple apology, we don't want anything, we never have. An apology. How can you become so caught up with rhetoric and paperwork and policy that we just can't say to a family, 'We did the wrong thing and we are sorry'". [Patient's daughter]²

"And, ah, it was one of the most dramatic experiences I ever had. As soon as I offered that [statement about taking responsibility for the adverse event] to them, it's almost like there was a breath of fresh air coming into this room, and you really could see him physically change ... His tone changed, his body language changed, and he was saying things like, 'so where do we go from here? So that to me was a very eye-opening experience, very." [Medical Manager]³

^{1.} Australian Commission on Safety and Quality in Health Care (ACSQHC) Australian Open Disclosure Framework, Sydney, 2013

Iedema R, Allen S, Britton K, Piper D, Baker A et al. (2011). Patient's and family members' views on how clinicians enact and how
they should enact incident disclosure: the "100 patient stories" qualitative study BMJ 2011;343:d4423 published 25 July 2011

^{3.} ledema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. (2007). Final Report: Evaluation of the Pilot of the National Open Disclosure Standard. Sydney: University of Technology, Sydney. p50

ABOUT THIS HANDBOOK

This Handbook is available to view or download from the CEC website, both as a complete document and also by section at www.cec.health.nsw.gov.au

The Open Disclosure Handbook has been prepared by the Clinical Excellence Commission as a resource for clinicians and other health care staff working within a NSW Health facility or service. It outlines the steps and considerations involved in practising open disclosure according to the NSW Health Open Disclosure Policy PD2014_028 and the Australian Open Disclosure Framework published by the Australian Commission on Safety and Quality in Health Care in 2013.

To complement the Policy, the Handbook:

- defines a patient safety incident according to the International Classification for Patient Safety led by the World Health Organization (WHO)⁴.
- > describes when open disclosure is required
- distinguishes between the two stages of the open disclosure process – clinician disclosure and, when indicated, formal open disclosure
- addresses each step in the clinician and formal open disclosure processes, including preparing for open disclosure and making an apology to patients and their support people
- > expands on the roles of the open disclosure team, including the open disclosure coordinator and an open disclosure advisor
- addresses frequently asked legal and insurance questions.

The Handbook contributes to a set of resources to support open disclosure practice in NSW Health facilities and services. These include:

- Online education modules hosted by the Health Education and Training Institute (HETI)
 - Introduction to Open Disclosure
 - Clinician Disclosure
 - Open Disclosure Advisor.
- > Resources for patients and their family/carers from the Australian Commission on Safety and Quality in Health Care.

Communicating with a patient who has been harmed and/or their support person(s) about a patient safety incident is a sensitive undertaking which may be complex and difficult. There is not one standardised way to conduct open disclosure. Flexibility is required to meet specific circumstances and the needs of patients, their support person(s) and health care staff.

The Open Disclosure Handbook provides general advice based on national and international best practice. Each health care staff member involved in an open disclosure discussion is encouraged to embrace the general principles for open disclosure practice outlined in the NSW Health Open Disclosure Policy PD2014_028 and to implement them in a way that meets the needs of the situation at hand.

Acknowledgements

The Clinical Excellence Commission sincerely thanks all members of the Open Disclosure Working Party, who contributed their time and expertise to the revision of the Open Disclosure Policy and the content of this Handbook. The working party includes health consumers, clinicians and representatives from clinical governance, the NSW Ministry of Health Legal and Finance branches, the Health Care Complaints Commission, medical defence organisations, NSW Treasury Managed Funds, insurers and the Clinical Excellence Commission's Clinical Governance, Patient Based Care and Patient Safety directorates.

World Health Organization The Conceptual Framework for the International Classification for Patient Safety, Version 1.1
Final Technical Report Technical Annex 2, WHO, Geneva, 2009.



WHAT IS A PATIENT SAFETY INCIDENT?

A patient safety incident is any unplanned or unintended event or circumstance which could have resulted or did result in harm to a patient. 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.

Patient safety incidents may be classified as follows⁵:

A harmful incident:

A patient safety incident that resulted in harm to a patient, including harm resulting when a patient did not receive his/her planned or expected treatment. The term 'harmful incident' covers what used to be known as an 'adverse event' and/or a 'sentinel event.'

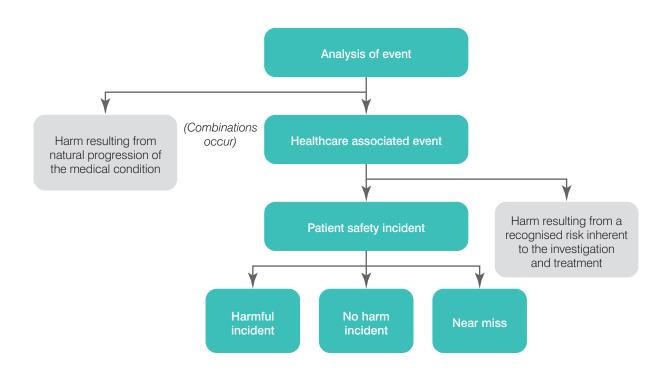
A no harm incident:

A patient safety incident occurs but does not result in patient harm – for example a blood transfusion being given to the wrong patient but the patient was unharmed because the blood was compatible.

A near miss:

A patient safety incident that did not cause harm but had the potential to do so – for example a unit of blood being connected to the wrong patient's intravenous line, but the error was detected before the transfusion started. An incident may have been caused:

- > because something has gone wrong during the patient's episode of care an event has occurred that was unplanned or unintended
- because the outcome of the patient's illness or its treatment did not meet the patient's or his/her doctor's expectation for improvement or cure – for example a patient develops brain metastases from underlying lung cancer
- from a recognised risk inherent to an investigation or treatment – for example a patient's bowel is perforated during a routine colonoscopy
- because the patient did not receive his/her planned or expected treatment – for example he/she did not receive his/her medications as ordered.



World Health Organization The Conceptual Framework for the International Classification for Patient Safety, Version 1.1
Final Technical Report Technical Annex 2, WHO, Geneva, 2009.

The NSW Health Incident Management Policy PD2014_004 indicates that patient safety incidents may be identified by staff, patients and their support person(s) through a number of processes⁶.

These may include:

- > direct observation
- > mortality and morbidity review meetings
- > team discussion
- > death review processes
- > Coroner's reports
- > chart reviews
- > staff meetings
- > clinical audits
- > patient concerns or complaints

A patient safety incident may be identified at the time at which it occurs or at any time after the event.



Immediate action: supporting the patient and the clinician

Any person working in any capacity within NSW Health, including contractors, students and volunteers, who identifies that a patient safety incident has occurred has a duty to take action.

The initial response to a patient safety incident may be by the person who identified the incident, or a responsible person who was notified, and involves:

- > ensuring personal safety
- > providing immediate and appropriate clinical care to the patient and safeguarding against further harm
- notifying relevant people for example, the unit/ department manager, the senior treating clinician and the patient and/or their support person(s)
- > providing support for health care staff if required
- assessing the incident for severity of harm and the level of open disclosure response required.

The next steps

Once immediate support has been provided for the patient, their support person(s) and health care staff involved in the incident, the next steps are:

- gathering basic information about the incident from clinicians and other health care staff involved while the details are still fresh (ensuring confidentiality is maintained)
- gathering basic information about the incident from the patient and their support person(s), if able, while the details are still fresh (ensuring confidentiality is maintained)
- the initial open disclosure conversation clinician disclosure.

The NSW Health Incident Management Policy outlines the steps for notifying and recording a patient safety incident. Reporting, investigating and analysing the causes of patient safety incidents should begin as soon as possible.

Staff members are required to record all patient safety incidents in the patient's health record and in the incident management system.

Open Disclosure is about "doing the right thing" when a patient has been harmed while receiving health care. It enables staff to communicate with empathy — to walk in another's shoes — and to say sorry for what has happened.



WHAT IS OPEN DISCLOSURE?

Open disclosure is defined in the Australian Open Disclosure Framework⁸ as:

"an open discussion or series of discussions 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."

The five essential elements of open disclosure are:

- > an apology
- > a factual explanation of what happened
- an opportunity for the patient to relate his or her experience
- > a discussion of the potential consequences
- an explanation of the steps being taken to manage the event and prevent recurrence.

In addition to the essential elements above, effective open disclosure also includes⁹:

- acknowledging to the patient and/or their support person(s) when things go wrong
- listening and responding appropriately when the patient and/or their support person(s) relate their experiences, concerns and feelings
- the opportunity for the patient and/or their support person(s) to ask questions and to have those questions answered
- providing support for patients and their support person(s) and health care staff to cope with the physical and psychological consequences of what happened.

The objective of open disclosure is to provide factual information with sensitivity and empathy, including discussing arrangements for further support and ongoing care if required.

Open disclosure may involve one discussion or may continue over a series of meetings. The duration will depend on the incident, the needs of the patient and/or their support person(s), how the investigation into the incident progresses, and whether there are ongoing health care needs as a result of the patient safety incident.

If a patient does not have the physical or mental ability ('capacity') to participate in the disclosure discussion, their support person(s)* must be notified and involved until the patient is able to fully participate and make decisions on their own behalf. If the patient has died (as a result of the patient safety incident or otherwise), the support person is the lead contact for open disclosure about the incident.

*See Chapter 11 Key Definitions and References



^{8.} Australian Commission on Safety and Quality in Health Care (ACSQHC) Australian Open Disclosure Framework, Sydney, 2013

^{9.} National Reporting and Learning Service, National Patient Safety Agency Being Open: Saying sorry when things go wrong, London 2009

When is open disclosure necessary?

Whenever a **harmful incident** occurs, the patient and/or their support person(s) must be informed. This includes harm from an outcome of an illness or its treatment that did not meet the patient's or the clinician's expectations, or harm resulting from a recognised risk inherent to the investigation and treatment.

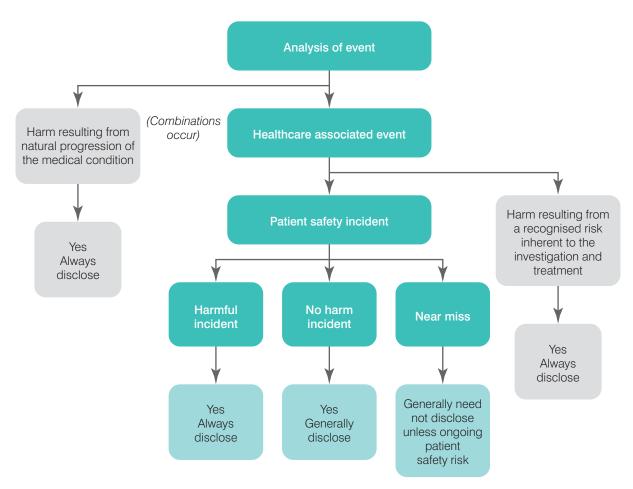
When a **no harm incident** has been identified, generally the patient and/or their support person(s) would be informed. Even though no harm is immediately apparent, an ongoing patient safety risk may be present and the patient and/or their support person(s) may be aware that some sort of mistake or incident has occurred.

For a **near miss incident,** disclosure is discretionary, based on whether it is felt the patient would benefit from knowing, for example, if there is an ongoing safety risk to the patient. Advice may be required from the senior treating clinician and/or open disclosure advisor to assist with the determination of risk. The timeliness of informing patients must always be considered. Near miss incidents must be entered into the incident management system.

Additionally, open disclosure is recommended when the patient has been harmed as a result of the **natural progression** of their medical condition, or from a **risk inherent** to the investigation and treatment of their medical condition.

The initial discussion with the patient and/or their support person(s) – clinician disclosure – may be all that is required. Alternatively, it may be determined by the Director of Clinical Governance (DCG) and/or the appropriate senior manager (for example the facility, operations or health service manager), the patient and/or their support person(s) that formal open disclosure is required.

The decision tree below shows when open disclosure is necessary, and has been modified from the *Canadian disclosure guidelines*¹⁰.



^{10.} Canadian Patient Safety Institute Canadian disclosure guidelines: being open and honest with patients and families, Edmonton, 2011

When does open disclosure begin?

Open disclosure forms a key step in clinical incident management, which begins as soon as a patient safety incident is identified. The open disclosure response may involve one discussion, or it may involve two broad stages over time – clinician disclosure and, where required, formal open disclosure. Each stage may consist of several discussions, depending on the patient's condition, understanding of events and any questions that may arise.

A patient and/or their support person(s) may indicate that they do not wish to participate in open disclosure, or they may request deferral of the formal open disclosure discussion. The health service should provide them with the name and contact details for a liaison person, and advise them that they are able to request that open disclosure proceeds at any time in the future.

Open disclosure and incident management

Open disclosure is closely linked with the incident management process which takes place in response to a patient safety incident. The NSW Health Incident Management Policy PD2014_004 requires that as soon as an incident is identified and immediate actions to mitigate the harm have been taken:

...a health provider shares with patients and/or their support person what is known about the incident, and what actions have been taken to immediately mitigate or remediate the harm to the patient. An apology can be extended at that time¹¹.

Patients and/or their support person(s), and health care staff who have been involved in an incident are often keen to know what is being done to address the factors that contributed to a patient safety incident. Section 2.9 of the Incident Management Policy acknowledges the importance of providing feedback to the patient and/or their support person(s), and staff during or following the investigation.

Open disclosure and incident management are incorporated into the clinical governance framework of each local health district/specialty network. Each contributes to the local and statewide quality improvement systems through identifying and addressing weaknesses in health systems which may lead to patient safety incidents. Incident management, open disclosure and quality improvement are interrelated components of a system which supports and promotes the delivery of open, honest and safe patient-based care.

Practical support for open disclosure

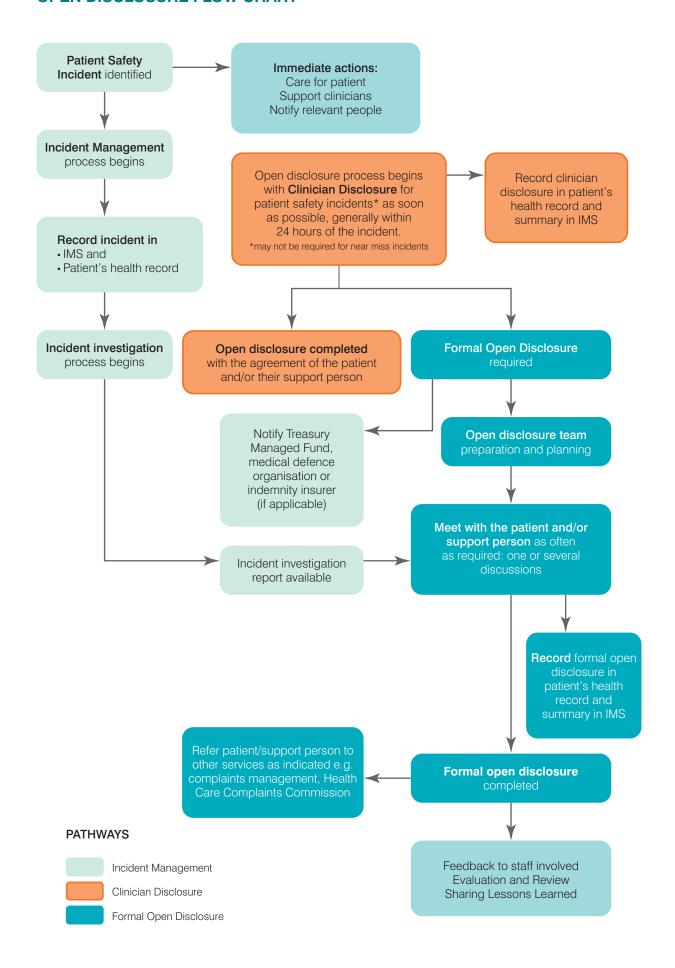
The NSW Health Open Disclosure Policy PD2014_028 supports an early offer of, and approval for, reimbursement for reasonable out-of-pocket expenses incurred as a direct result of a patient safety incident. Practical support such as the above, sends a strong signal of sincerity, and may be raised at a formal open disclosure discussion, if not already discussed during clinician disclosure. It is generally accepted that the practical support offered through reimbursement does not imply responsibility or liability. Reasonable out-of-pocket expenses may include, but are not limited to, accommodation, meals, travel and childcare.

At any stage in open disclosure discussions, questions may arise in relation to compensation. This should be anticipated in the planning stage and discussed with the health service's insurer and legal counsel in advance.

For more detail on the reimbursement process, please see Chapter 7 Practicalities of Open Disclosure – Financial considerations, and the Open Disclosure Guide for Managers Responsible for Insurable Risk.

^{11.} NSW Health Incident Management Policy PD2014_004 Section 2.3.4

OPEN DISCLOSURE FLOW CHART



Why does open disclosure matter?

The National Patient Safety Agency (NPSA)* in the United Kingdom identified the following benefits for three key groups with involvement in open disclosure¹²:

Patients and/or support person(s)	Health care staff	Health care organisations and teams
Receive a meaningful apology and explanation when things go wrong	Gain confidence in how to communicate effectively when things go wrong	Gain a reputation of respect and trust for the organisation and/or team
Feel their concerns and distress have been acknowledged	Feel supported in apologising and explaining to patients and/or their support person(s)	A culture of openness and safety is reinforced
Are reassured that the organisation will learn lessons to prevent harm happening to someone else	Feel satisfied that the process of communicating with the patient and/or their support person has been appropriate	The costs of litigation are potentially reduced
May feel that the trauma experienced when things go wrong is reduced	Gain an improved understanding of incidents from the perspective of the patient and/or their support person(s)	The patient experience and satisfaction with the organisation are improved
Have the opportunity to ask questions and to have those questions answered	Feel that their relationship with the patient and/or their support person(s) may have been improved through demonstrating integrity	Gain a reputation for supporting staff when things go wrong
Have greater respect and trust for the organisation	Know that lessons learned from incidents will help prevent them from happening again	Gain greater opportunities to learn when things go wrong
Are reassured that they will continue to be treated according to their clinical needs	Gain a good reputation for managing a difficult situation well	

^{*}The key functions of the NPSA were transferred to the National Health Service Commissioning Board Special Health Authority in 2012

^{12.} National Reporting and Learning Service, National Patient Safety Agency Being Open: Saying sorry when things go wrong, London 2009

THE IMPACT OF OPEN DISCLOSURE

The patient experience – 'nothing about me, without me'13

There are many good reasons for adopting the practice of openly informing and supporting patients when something goes wrong. The focus of open disclosure is on ensuring that communication between the patient and/or their support person(s) and health service representatives is respectful, timely, honest and clear.

Being open and honest is the basis for the relationship of trust between patients and their health care providers and the facilities in which they are treated. Patients who have been involved in a patient safety incident may lose trust or become anxious and fearful when they perceive that information is being withheld. Participating in open disclosure may help to restore the trust of the patient and/or their support person(s) when they receive a meaningful apology and appropriate information.

Patients, their support person(s) and other health care consumers have made it clear that if something goes wrong during their care, they want to¹⁴:

- > be told about it promptly with as much information as is known at that stage
- know that the health service and/or provider is/are sorry for what happened
- know what is being done to minimise any harm that may come from the patient safety incident
- > know how the incident is being investigated
- > know what is being done to prevent such an incident from happening again.

Patients and their families must also be openly informed of harmful incidents so that they can make decisions about further treatment and provide valid consent.

The Australian Safety and Quality Framework for Health Care¹⁵ specifies three core principles which contribute to safe and high-quality health care, namely that health care is:

- 1. consumer centred
- 2. driven by information
- 3. organised for safety.

This Framework requires health care teams, managers, executives and boards of health services to openly inform and support the patient when something goes wrong. For patients and their support person(s), it means that they can expect to be looked after by the health care team, receive an apology and a full explanation of what happened.

The requirement for open disclosure with a patient and/or their support person(s) following a patient safety incident is endorsed in PD2011_022 Your Healthcare Rights and Responsibilities¹⁶, which states that

A patient involved in an incident during treatment receives an apology and explanation. They are treated with empathy and honesty in an environment where health employees can openly discuss with the patient, relatives and/or carer what has happened, the effects, and what will be done to prevent it happening again.

Opportunities for the patient and/or their support person(s) to 'tell their story' and have their perspectives considered are central to this process and enable a patient's expectations of open disclosure to be addressed and health care communities to better understand the effects of patient safety incidents.

Delbanco T, Berwick DM, Boufford JI, et al. Healthcare in a land called PeoplePower: nothing about me without me. Health Expectations 2001; 4(3):144–150

Canadian Patient Safety Institute Canadian disclosure guidelines: being open and honest with patients and families, Edmonton, 2011

Australian Commission on Safety and Quality in Health Care, Australian Safety and Quality Framework for Health Care, Sydney, 2010.

^{16.} NSW Health Your Health Rights and Responsibilities – A guide for NSW Health staff PD2011_022

A patient's experiences of care and communication following a patient safety incident are key factors which may influence their decisions about future care and treatment, and about whether to make a complaint or initiate legal action.

- "... I liked the fact that it was never a rigid thing...you felt comfortable with these people, they spoke to you...not like an idiot, they spoke to you like you were a person." 17
- "...they seemed to talk above your head somehow. Even though they're trying to say it simply...I feel as though I'm...just a subject rather than a person, if you know what I mean...Well I had to press for it, to get the information I wanted."18



Jen's Story

"When my brother went for a spinal fusion, he clearly envisaged walking out of the hospital feeling at least better than he had felt going in. Following the surgery, pain levels did NOT reduce. I contacted the hospital many times to check if we should be getting concerned at the lack of improvement and was advised to wait until the post-operative check scheduled at 8 weeks.

The day my brother went for the post-op appointment the surgeon started with a scan to check the operation site. My brother called us to let us know that the scan showed that one of the screws was 'sticking into his sciatic nerve – which is why it's been hurting so much'.

My brother was taken directly to the pre-op ward and underwent corrective surgery the following morning to remove and replace the screw. The repeat surgery was much more successful. We were also much better prepared this time – through experience, rather than information.

The surgeon offered no excuse, no apology, no admission of error, and was dismissive of the idea that this was 'life-impacting' at all. He had FIXED the problem. He clearly hadn't 'walked a mile' in my brother's or our family's shoes.

Unfortunately, once a patient has lost trust in their clinician it affects their future choices to seek medical attention. This is particularly unfortunate when they have chronic disease.

Open disclosure should not be viewed as an opportunity to collect evidence to sue a health professional. Disclosure should typically provide the only vehicle to return to a level of trust in patient care."

ledema R et al. Patient's and family members' experiences of open disclosure following adverse events. International Journal for Quality in Health Care 2008;20(6):421-432

^{18.} Ibid p428

The experience of clinicians and health care staff

When a patient safety incident occurs, clinicians and other health care staff involved in the incident may be affected, sometimes in unexpected ways. Chapter 8 Support for Staff provides more detail about the range of reactions that a health care staff member may experience in the aftermath of the incident, in particular feelings of anger or guilt, sadness or withdrawal, and how to address or manage these reactions.

Each health facility or service should have systems in place to ensure that staff who have been involved in a patient safety incident and open disclosure discussions with patients and/or their support person(s) are aware of and have access to adequate information and personal and professional support. Open disclosure advisors are able to provide guidance to staff who are preparing for open disclosure discussions with patients and/or their support person(s), and support with debriefing following these discussions.

Department heads in health facilities are responsible for providing support to their staff who participate in the process, and for promoting access to staff support services including the Employee Assistance Program (EAP) or similar counselling support offered by each local health district/specialty network.

Professional bodies such as medical defence organisations, unions representing health care staff and insurers who provide professional indemnity insurance may also be able to provide advice and support.

Support for health care staff involved in patient safety incidents and/or open disclosure may include:

- access to formal or informal debriefing for those involved in a patient safety incident
- education and training on the management of patient safety incidents
- education and training to prepare health care staff to participate in open disclosure, embedding an understanding that apologising to patients and their support person is appropriate and not an admission of liability
- promoting the role of the open disclosure advisor to assist staff with preparation to attend the formal open disclosure discussions
- providing appropriate leave from the workplace
- appropriate opportunities for health care staff to share their experiences and any lessons learned, which may help reduce feelings of isolation and facilitate a culture of safety
- ensuring that health care staff are not discriminated against because of their involvement in a patient safety incident or open disclosure

Education and Training

Health care staff have a professional and ethical imperative to provide prompt and full information to the person inadvertently harmed (or potentially harmed) by a patient safety incident. Communicating with the patient and/or their support person(s) during an emotionally intense period immediately following an incident can be critical for maintaining a relationship of compassion and trust.

Education and training in open disclosure for health care staff should address the skills and knowledge required to deliver a sincere and effective apology and explanation about a patient safety incident, in the context of concern and distress which may be felt by the patient and/or their support person(s). These skills are often not innate and can be learnt and practised.

A series of open disclosure online education modules developed by the Clinical Excellence Commission is hosted by the Health Education and Training Institute (HETI) on HETI Online. These modules include Introduction to Open Disclosure, Clinician Disclosure and the Open Disclosure Advisor. They contribute to skills development for clinicians and managers, and can be used as stand-alone education or as preliminary study before further training.

Being open and honest is the basis for the relationship of trust between patients, their health care providers and the facilities in which they are treated.



CLINICIAN DISCLOSURE

Open Disclosure begins with clinician disclosure – the initial discussion with a patient and/or their support person(s) following a patient safety incident. The purpose of this discussion is to inform and support the patient and/or their support person(s) and to offer an apology for what has happened.

Clinician disclosure is an informal process involving:

- meeting with the patient and/or their support person(s) once the patient is removed from any harmful situation and has received treatment and support for the harm that may have occurred
- acknowledging the patient safety incident to the patient and/or their support person(s)
- **explaining** all known facts relevant to the incident, to provide context for the apology
- apologising for the occurrence of the event
- actively seeking input and feedback from and listening to the patient and/or their support person(s)
- consulting with the patient and/or their support person(s) on a plan for ongoing care if required, including the possible need for formal open disclosure
- providing contact names and phone numbers of people in the health service who are available to address concerns and complaints, including psychological and social support contacts.

During these discussions, it is important not to speculate, attribute blame to yourself or others, criticise individuals or imply legal liability. If you don't know the cause of the patient safety incident, say so, and explain what is being done to investigate the cause/s of the incident.

Are there any exceptions to initiating clinician disclosure?

The only exception is if the patient safety incident is recognised as a 'near miss incident'. In this case disclosure is discretionary, based on whether it is felt the patient would benefit from knowing, for example, if there is an ongoing safety risk to the patient. To guide decisions about open disclosure, advice from the senior treating clinician and/or open disclosure advisor may be required to assist with determining the level of risk. The timeliness of informing patients must always be considered. Near miss incidents must be entered into the incident management system.

Who should initiate clinician disclosure with the patient and/or their support person?

For patient safety incidents where the patient has suffered minor or no perceived harm, the clinician most directly involved in the incident or the person who first recognises the incident – generally a nurse, midwife, allied health professional or medical officer – is usually the most appropriate person to speak with the patient and/or their support person(s). Ideally other members of the clinical team are present so that they are aware that the incident has been discussed with the patient and/or their support person. If that person is not able to speak with the patient and/or their support person(s), they must notify their manager or senior treating clinician who will facilitate clinician disclosure.

For patient safety incidents where the patient has suffered anything more than minor harm, the senior treating clinician or manager should be engaged as promptly as possible and participate in clinician disclosure, unless the patient and/or their support person(s) requests otherwise. A serious patient safety incident represents a major threat to the patient's sense of control and trust in the health care team. It is essential that the initial communication be with a person with whom the patient has a trusting relationship, and that it convey care, concern and respect for the patient.

Irrespective of the degree of harm caused to the patient, a clinician disclosure discussion with the patient and/or their support person(s) should commence as soon as possible, and at the latest generally within 24 hours of identification of the patient safety incident by the health service.

If a patient does not have the physical or mental ability ('capacity') to participate in the disclosure discussion, their support person(s) must be notified and involved until the patient is able to fully participate and make his or her own decisions. If the patient has died (as a result of the patient safety incident or otherwise), the support person is the lead contact for open disclosure about the incident.

Completing Clinician Disclosure

The clinician disclosure discussion may be the only discussion that the patient and/or their support person(s) require following a patient safety incident. With their agreement, open disclosure may be concluded after this discussion.

However, clinician disclosure may progress to formal open disclosure for any patient safety incident, as determined by the director of clinical governance (DCG), and/or the appropriate senior manager (for example, the health service manager, or operations manager), and the patient and/or their support person(s).

Tools for Clinician Disclosure

Tools to assist Clinician Disclosure are available to download and print from the Open Disclosure page of the CEC website: www.cec.health.nsw.gov.au

CHECKLIST A – CLINICIAN DISCLOSURE identifies the steps to be completed for the initial clinician disclosure discussion with a patient and/or his or her support person(s).
The STARS® Tool, developed by the Patient Safety Unit at Queensland Health ¹⁹ , is a practical tool to assist clinicians to confidently and competently communicate with patients and families about patient safety incidents. It has been designed to be easily recalled to guide clinicians through a logical communication pathway.

See Chapter 7 of this Handbook for practical considerations for open disclosure, such as privacy and confidentiality and establishing the right environment for clinician disclosure.

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An example of appropriate wording for clinician disclosure





Sorry: Acknowledge, Apologise, Acknowledge

Acknowledge what happened:

"Mrs Smith, the staff have let me know that you didn't receive your insulin when it was due this morning".

Apologise:

"I am sorry that this has happened".

Acknowledge the impact of the patient safety incident:

"We will need to check your blood sugar more often today. I agree that things didn't go to plan. I can see that you are upset. I am really sorry".



Tell me about it

"To find out exactly what happened, I'd like to understand what you saw or experienced. This may help us to understand how this could have happened and how to prevent things like it happening in future".



Answer Questions

"You may have some questions that you need answered – you can ask questions at any time. What would you like to know?"



Response/Plan for care

"The problem was recognised quickly and we are now back on schedule with your insulin injections. With your permission, we will continue your treatment as planned. If you feel or notice anything unusual please let us know. We don't expect that you will need to stay here any longer than originally planned".



Summarise

"We still need to find out how this happened, and we will let you know as soon as possible what we find out. I will be here today until 5pm. If you have any questions or concerns, please contact me or the nurse in charge. Please feel free to ask the staff as well if there is anything you need or want to discuss.

Is there anyone that you would like us to contact for you? From your admission notes I can see you have nominated your son. Would you like me to explain to him what has happened?"

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FORMAL OPEN DISCLOSURE

Formal open disclosure is a structured process which follows on from clinician disclosure as soon as is practicable. It provides a format that facilitates effective and timely communications between the patient and/or their support person(s), clinicians, senior clinical leaders and the organisation.

To enable this process, a multidisciplinary open disclosure team is activated before meeting with the patient and/or their support person. A senior clinician or manager who is trained as an open disclosure advisor guides this team through preparation, delivery and debriefing the formal open disclosure discussion with the patient and/or their support person.

Formal open disclosure may be required for any patient safety incident, as determined by the Director of Clinical Governance (DCG), and/or the appropriate senior manager (for example, the facility, operations or health service manager), and the patient and/or their support person(s).

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 therefore limited. Any delays in communication may precipitate anxiety, distrust and feelings of abandonment in patients, support people and health care staff who have been affected by a patient safety incident.

The initial formal open disclosure discussion should be held as soon as possible after the patient safety incident, when:

- the patient is physically and emotionally able to participate, or their support person(s) is available to represent the patient while they recover; and
- the treating clinician and senior management have assessed the situation and prepared for the discussion, and the patient and/or their support person have confirmed that they are ready for a formal discussion.

The patient and/or their support person(s) may also request that a formal open disclosure discussion is postponed until they are ready – for example, until after the patient's condition has stabilised, or if the patient died following the incident, until after the funeral.

A series of discussions may be required. It is important that the same health care staff participate in these discussions to build trust, provide continuity in the information which is communicated, and show concern and respect for the experience of the patient and/or their support person(s).

Signalling the need for formal open disclosure

There are several signals that formal open disclosure may be required, including:

- if the patient and/or their support person(s) indicate to health care staff that their concerns have not been resolved, either on follow up by the clinician or manager, or through the local complaints mechanism
- where the Director of Clinical Governance (DCG) and/or the facility/operations/service manager determines that the response should be escalated to formal open disclosure.

Formal open disclosure may be required for any clinical incident, regardless of the Severity Assessment Code (SAC) (Incident Management Policy PD2014_004 Appendix B).

A retrospective review of clinical incidents in the incident management system may also reveal patient safety incidents for which formal open disclosure may be indicated. This is dependent on incidents being entered into the system and on sufficient detail being provided to assess the incident. In these instances, the requirement for open disclosure within 24 hours may not apply.

Following a patient safety incident, the patient and/or their support person(s) should be advised of the opportunity to request formal open disclosure, and if they wish, how to make a complaint to the health service and/or the Health Care Complaints Commission.

A patient and/or their support person(s) may approach any health service staff member with a request for more information, or to express their dissatisfaction with the incident and the care that they have received. That staff member should refer the request or complaint to their manager, who will liaise with the patient and/or their support person(s) about the formal open disclosure process.

Stages in Formal Open Disclosure

Formal open disclosure comprises four stages:

- Preparation for a formal open disclosure discussion
- 2. Engaging in a formal open disclosure discussion
- 3. Following up with the open disclosure team
- 4. Completing formal open disclosure

Stage 1: Preparation for a formal open disclosure discussion

The key actions to prepare for a formal open disclosure discussion include:

- Notifying all relevant people about the patient safety incident and the requirement for formal open disclosure
- > Documenting commencement of formal open disclosure
- Considering legal and insurance issues for the organisation and clinicians
- > Appointing the open disclosure coordinator
- Liaising with the patient and/or their support person to offer and arrange the formal open disclosure discussion
- Contacting an open disclosure advisor to provide support to the team
- Identifying a senior staff member experienced in open disclosure to lead the formal open disclosure discussion
- > Establishing the open disclosure team, with the assistance of the open disclosure coordinator
- > Meeting of the open disclosure team to prepare for a formal open disclosure discussion with a patient and/or their support person

Further information is provided for each key action, as follows:

Notifying all relevant people about the patient safety incident and the requirement for formal open disclosure

 Ensure the Director of Clinical Governance, senior clinical managers and senior facility/service executive are notified about the incident and the requirement for formal open disclosure

Documenting commencement of formal open disclosure

Initiation of the formal open disclosure process should be recorded:

- in the incident management system (IMS)
- in the patient's health record noting the IMS reference number

Considering legal and insurance issues for the organisation and clinicians

- Notify the manager responsible for insurable risk about the patient safety incident and seek advice from the LHD/SN legal advisor if required.
- Advise the clinicians involved in the patient safety incident to seek advice from their professional indemnity insurers.

Appointing the open disclosure coordinator

The open disclosure coordinator is appointed by the manager with operational responsibilities at facility or service level in conjunction with the Director of Clinical Governance, to coordinate all relevant parties, including the patient and/or their support person(s) and to support clinician and formal open disclosure processes.

The open disclosure coordinator may also have other roles and responsibilities within a health service, such as patient safety or patient liaison officer.

The open disclosure coordinator's responsibilities may include:

- 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 health care staff involved
- establishing and coordinating an open disclosure team for each formal open disclosure discussion, including the appointment of an open disclosure advisor, as directed by the DCG or the manager with operational responsibilities at facility or service level
- liaising with the patient and/or their support person(s) to arrange the formal open disclosure discussions at a time and place that is suitable for them and to ascertain what questions they wish to have answered
- organising the open disclosure team discussion meeting
- assisting open disclosure team members with preparation for formal open disclosure discussions, including just-in-time training as required
- preparing information for the patient and/or their support person(s) in an appropriate format
- ensuring the flow of information between the health service and the patient and/or their support person(s) during and after the investigation process
- arranging and following up the agreed actions from the formal open disclosure discussions, including sharing the lessons learned from any investigations.

Liaising with the patient and/or their support person to offer and arrange the formal open disclosure discussion

Consider the following when making arrangements for the formal open disclosure discussion:

- the clinical condition of the patient
- patient preference regarding when and where the discussion takes place, and who leads the discussion
- privacy and comfort of the patient and/or their support person(s)
- availability of the patient's support person(s)
- availability of key staff involved in the patient safety incident and in the formal open disclosure discussion
- availability of support staff, for example a health care interpreter or independent advocate if required
- arranging the discussion in a sensitive location a location away from where the harm occurred may be preferred
- a space that is free from interruptions.

The open disclosure coordinator should provide information to the patient and/or their support person(s) about the patient safety incident and the open disclosure process in a format, language or communication style which is appropriate to their individual needs.

Using a variety of methods to assist the patient and/or their support person to understand what happened can be helpful for the clinicians and the patient and/or their support person(s) and demonstrates a genuine commitment to transparency. Examples include:

- simple diagrams which illustrate how the incident occurred, the resulting injury or harm and future care plans, and the steps involved in the investigation and disclosure process
- asking the patient and/or their support person(s) if they wish to go through the patient's clinical notes with the senior clinician and be shown the results of clinical investigations, such as blood tests and x-ray results.

Contacting an open disclosure advisor to provide support to the open disclosure team

The open disclosure advisor is a senior staff member specially trained in advanced empathic communication skills, who is available to support formal open disclosure in a health facility or service. The open disclosure advisor is impartial, providing unbiased and informed advice and guidance.

Characteristics of an open disclosure advisor which would enable her/him to carry out the responsibilities include an ability to build rapport, leadership skills, analytical problem solving and organisational knowledge.

The open disclosure advisor's responsibilities may include:

- practising and promoting the principles of open disclosure
- being accessible to mentor and advise colleagues preparing for open disclosure discussions
- being a member of the open disclosure team and facilitating team discussions and planning for formal open disclosure discussions with the patient and/or their support person(s)
- attending open disclosure discussions with the patient and/or their support person as required
- completing the meeting summary documentation with the open disclosure team following formal open disclosure discussions

- facilitating debriefing meetings with clinicians following open disclosure discussions
- ensuring colleagues involved in formal open disclosure discussions are aware of the support services available to them
- reporting a summary of the open disclosure discussion to the health service executive and handing over implementation of the commitments made.

Identifying a senior staff member experienced in open disclosure to lead the formal open disclosure discussion

The senior clinician responsible for the patient's care should be the person to lead the formal open disclosure discussion with the patient and/or their support person(s). This could be the patient's medical consultant, nurse or midwifery practitioner or nurse/midwife consultant, or a senior allied health representative depending on the nature of the incident.

It is important to consider the wishes of the patient and/or their support person(s) about who will be leading this discussion. The patient may prefer the person they trust to lead the discussion and facilitate the contributions of the other staff.

The patient and/or their support person(s) should be provided with information about the staff members with whom they will meet, the roles they will play, and whether any staff member is participating because of her or his training and experience in the open disclosure process.

Where it is not possible for the most senior clinician responsible for the patient's care to be present and lead the disclosure discussion, a person who has appropriate seniority and who is trained in open disclosure, such as the open disclosure advisor or head of department, should lead the discussion.

Ideally, this person will:

- be known to and trusted by the patients and/or their support person(s)
- be familiar with the facts of the patient safety incident and the care of the patient
- have sufficient experience and expertise to demonstrate credibility for patients and/or their support person(s), and colleagues
- be able to communicate clearly in everyday language
- be willing and able to offer a meaningful apology, reassurance and feedback to patients and/or their support person(s)

- where possible and appropriate, be willing to maintain a medium to long term relationship with the patient and/or their support person(s)
- be culturally aware and informed about the specific needs of the patient and/or their support person(s)
- have received training in communication skills for open disclosure.

Establishing the open disclosure team, with the assistance of the open disclosure coordinator

The role of the open disclosure team is to support and oversee formal open disclosure for a patient safety incident. Not all team members will be required to attend the discussion with the patient and/or their support person(s).

The composition of the team should be appropriate for the size and structure of the health care facility, and include multidisciplinary representation suitable for the type of patient safety incident.

Members are responsible for meeting to prepare for a formal open disclosure discussion with the patient and/or their support person.

The roles and responsibilities of the open disclosure coordinator, open disclosure advisor and the senior staff member leading the open disclosure discussion may overlap in smaller facilities or services.

The open disclosure coordinator will be able to advise on the composition of the team for each open disclosure discussion, taking into account the patient's preferences. Patients generally prefer to speak with a senior clinician who has been involved in their care. Wherever possible, appropriate arrangements should be in place to achieve this.

The open disclosure team may include:

- the patient's senior clinician
- other clinicians who have been involved in the care of the patient
- a senior manager for example the Director of Medical Services, Director of Nursing and Midwifery, General Manager or equivalent
- a representative of the local health district/specialty network
- the open disclosure coordinator
- if required, the Director of Clinical Governance or delegate.

To avoid any potential conflict of interest, it is recommended that any person involved in a Root Cause Analysis (RCA) investigation should not be part of the open disclosure team. In smaller facilities, this may not be practical, and a reminder of the confidentiality requirements of the RCA process may be necessary before confirming his/her role on the open disclosure team.

Open Disclosure team meeting to prepare for a formal open disclosure discussion with a patient and/or their support person

The open disclosure coordinator, open disclosure advisor, multidisciplinary team and other clinicians involved in the incident should meet as soon as possible after identification of the patient safety incident to plan and prepare for an appropriate response. The patient record must be current and a summary of the clinician disclosure discussion should be available before the team discussion takes place.

Points to be addressed at the team meeting include:

- establishing the basic facts clinical and other –
 using information gathered about the patient safety
 incident during previous discussions with patient
 and/or their support person(s), for example during
 clinician disclosure or incident investigation
- assessing the event to determine the appropriate response
- liaising with the patient and/or their support person(s) to ask who they would like to be present (or prefer not to be present) at the disclosure discussion, and what questions they wish to be addressed at the discussion
- identifying who will attend the formal open disclosure discussion and who will lead the discussion with the patient and/or their support person(s)
- offering the patient and/or their support person(s) the option of a patient advocate to accompany them throughout open disclosure
- identifying immediate support needs for everyone involved
- advising the patient and/or their support person of the potential for additional time commitments and costs associated with treatment required as a result of the incident
- maintaining a consistent approach in any discussions with the patient and/or their support person(s)

- considering risk management issues for the health service and its staff, including legal and insurance related issues, and notifying the relevant people in a timely way when needed
- considering how to attend to issues of ongoing care
- discussing offers to reimburse out-of-pocket expenses, which should be addressed at the earliest opportunity.

Stage 2: Engaging in a formal open disclosure discussion

A recommended approach to the formal open disclosure discussion with the patient and/or their support person(s) is set out below. The approach should be revised as required to meet local circumstances – for example, the patient and/or their support person(s) have expressed particular wishes about how the discussion should proceed, or if the patient and/or their support person(s) indicate that they prefer not to meet in person but to engage with the health service through mediation.

- Introduce all attendees at the formal open disclosure discussion and provide the patient and/or their support person(s) with the names and roles of all attendees, in person (as well as having provided the details in writing in advance of the discussion).
- 2. Acknowledge the patient safety incident and that the patient and/or their support person(s) have been affected by it. It is appropriate to acknowledge that people may be angry, shocked, distressed or unhappy with the outcome.
- 3. Offer a sincere apology for the harm that has occurred, including use of the words "I am sorry" or "we are sorry". For examples of ways to word an apology, please see Chapter 6 Apologising and saying sorry.
- 4. Explain the formal open disclosure process.

The person leading the discussion should outline the process and provide the patient and/or their support person(s) with the opportunity to speak about their expectations of open disclosure and to raise any questions they would like answered through the discussions.

Ascertaining the expectations of the patient and/or their support person(s) at the beginning of open disclosure, and establishing a framework with their involvement, is an important step in ensuring that patients and health care staff are prepared for what to expect of the process.

Information to be provided during the discussion may include:

- The known facts about the patient safety incident and the consequences (short term and long term) for the patient and/or their support person(s)
- Any restrictions on the information that is able to be provided and the reasons for the non-disclosure (see Chapter 10 Frequently asked legal and insurance questions for further detail)
- · What the open disclosure process does not cover
- The process for investigating the incident, including that:
 - the patient and/or their support person(s) will have the opportunity to meet with the investigators to speak about their experience of the incident
 - the investigations may cover a number of aspects to get as clear a picture as possible of what happened
 - new information may emerge as the investigation is undertaken
 - the patient and/or their support person(s) will be kept up-to-date with the progress of the investigation
- Anticipated timelines for the investigation and open disclosure processes, including that a series of discussions may be required (a 'timeline' on paper can be helpful)
- Steps for ongoing feedback and how and when the patient and/or their support person(s) will be kept informed and involved
- Who to contact for ongoing support, to address any concerns, or to make a complaint, and how to make contact
- A full explanation of how or why the incident occurred may be deferred until all the investigations have been completed. Facts which are known should be communicated, and it is appropriate to acknowledge what is currently not known.

 Provide an opportunity for the patient and/or their support person(s) to recount their experience.
 Encourage/invite the patient and/or their support

Encourage/invite the patient and/or their support person(s) to describe his/her understanding of what happened, the personal impact of the patient safety incident and to raise any ongoing concerns and questions.

It is important to be aware that the patient and/or their support person(s) may not know what questions to ask to address what concerns them the most. He or she may be fearful of asking 'silly' questions or may feel too intimidated by the health care team or the occasion itself, to ask questions.

Suggesting a few questions may help, for example, 'some people might want to know...'

Providing an opportunity for the patient and/or their support person(s) to tell of their experience and provide information only they know may change the analysis of the incident and influence the discussions which follow.

- 6. Listen and respond appropriately to the patient and/or their support person(s) so that they feel/see that their views and concerns are considered and understood. If the patient and/or their support person(s) have already received conflicting information, inform them that you will check it for them and attempt to clarify any confusion.
- 7. Provide a factually correct explanation of the patient safety incident and the patient's condition and the consequences for the patient (short and long term).

Use appropriate language and terminology when speaking with patients and/or their support person(s). For example, avoid medical jargon which is often meaningless to patients. It is important to try to strike a balance between information overload and over-simplification. If some of the information is not yet available or the cause/s has not yet been identified, inform the patient that the review of the incident is ongoing.

Use of health interpreters is recommended if the first language of the patient and/or their support person(s) is not English. Support tools for people with hearing or visual impairment may also be appropriate.

See Chapter 9 Open disclosure in specific circumstances

8. Provide the findings of any review or investigation which are able to be shared with the patient and/or their support person(s). For more information, please see Chapter 10 Frequently asked legal and insurance questions.

If the investigation has not been completed at the time of the formal open disclosure discussion, update the patient and/or their support person(s) as information becomes available.

- 9. Discuss and agree on a plan for care for the patient and/or their support person(s), which includes:
 - the provision of ongoing care and support (physical and/or psychological) which addresses the short and long term consequences of the incident
 - the names and contact details for the people and services who will be providing any ongoing care resulting from the patient safety incident
 - an offer to reimburse any out-of-pocket expenses, consistent with local processes. See Chapter 7 Practicalities of Open Disclosure – Financial Considerations
 - information on their right to continue their care elsewhere if they prefer
 - information on how to take the matter further, including any complaint or legal processes available to them

Provide the patient and/or their support person(s) and health care staff present with a written account of the open disclosure discussion and the plan for care.

10. Follow up discussions: Depending on the nature of the patient safety incident and the needs of the patient and/or their support person(s), follow up calls or discussions may be required, for example to provide updates on any investigations, including whether the results are delayed or uncertain.

To arrange any follow up discussions, the open disclosure coordinator should liaise with the patient and/or their support person(s), the senior clinician and the senior manager involved.

The patient and/or their support person(s) may also request further discussions with the open disclosure team to clarify information and to ask questions that may have arisen since the initial discussion.

Alternatively, the patient and/or their support person(s) may indicate that they are satisfied that open disclosure is complete after the formal open disclosure discussion. See Stage 4: Completing formal open disclosure.



Stage 3: Follow up with the open disclosure team

The open disclosure advisor should meet with the health care staff who were involved in the formal open disclosure discussion, as soon as possible after the discussion.

The purpose of this meeting is to review the outcomes of the discussion, which are then reported back to the open disclosure team and included with any documentation from the planning discussion.

Responses to any offers made to the patient and/or their support person(s) are recorded, along with any outstanding issues to be resolved, undertakings given that need to be followed through and recommendations to the team about further management of the patient safety incident.

The review discussion also provides an opportunity for clinicians to debrief with the open disclosure advisor, to identify any unresolved or new areas of concern for the clinicians as a result of the discussion, and to discuss how ongoing support for the clinicians (if required) will be delivered by the health service.

Stage 4: Completing formal open disclosure

The patient and/or their support person(s) may indicate that they are satisfied that open disclosure is complete and that no further discussions are needed. Completion should be noted in the patient's record.

Resolution may not be reached at the conclusion of a number of open disclosure discussions, despite all reasonable efforts to support the patient and/or their support person. If they have ongoing concerns, information should again be provided by the health service on alternative courses of action. For example, the internal complaints process or making a complaint to the Health Care Complaints Commission.

Final investigation report

When any investigations or reviews of the patient safety incident have been completed, information should be provided to the patient and/or their support person(s) in the form most acceptable to them. Ideally this should occur at a face to face discussion. This is especially important when a copy of the Root Cause Analysis (RCA) report is to be provided, to ensure that the often impersonal and clinical nature of the report can be explained, to enable discussion of the content and to allow for questions to be addressed²⁰.

Information provided should include²¹:

- details of the patient safety incident such as the sequence of clinical and other relevant facts
- details of the concerns or complaints raised by the patient and/or their support person(s)
- an apology (in similar terms to verbal apologies already made) for the harm suffered and shortcomings in the delivery of care
- a summary of the factors that contributed to the patient safety incident
- information on what has been done and will be done in future to avoid recurrence of the incident type, and how these improvements will be monitored.

Whenever a report is to be provided to the patient and/or their support person(s) in addition to a RCA report, or when a RCA has not been required, care should be taken to ensure that the language and communication style are appropriate to the patient and/or their support person(s).

The patient and/or their support person(s) may ask that provision of the final investigation report is deferred. They must be provided with the name and contact details for a liaison person at the health care facility, and informed that they may request to receive the final report at any time.

^{20.} NSW Health Incident Management Policy PD2014_004 Section 2.9.1

National Reporting and Learning Service, Being Open: Saying sorry when things go wrong, National Patient Safety Agency (2009)

In exceptional circumstances, clinicians caring for the patient and/or their support person(s) may consider that disclosure of information will adversely affect the health of patient and/or their support person(s). If information is not disclosed to a patient and/or their support person, the rationale must be clearly documented in the open disclosure file. Where possible, the decision should also be independently verified by a colleague who was not involved in the patient safety incident, the investigation process or the initial clinician disclosure discussion.

In some circumstances, disclosure may be deferred with the patient and held with their support person(s). The process should resume with the patient at a later date as appropriate.

Continuity of care

The patient and/or their support person(s) should be clearly informed about, and involved in planning for ongoing clinical management. This may include arrangements for rehabilitation, transition of care to their general practitioner or a community care provider.

Reassurance should be provided to the patient and/or their support person(s) that he/she will continue to be treated according to their clinical needs, even if they are in dispute with the health care team.

They should also be informed that they have the right to continue their treatment with another health care provider if they prefer.

Monitoring systems improvements

The clinical governance unit and/or the manager responsible for insurable risk should monitor and record the implementation of any changes recommended as a result of a review or investigation into the patient safety incident, and the effectiveness of those measures in preventing a recurrence.

Where possible, the patient and/or their support person(s) should be offered an update on implementation and effectiveness of any changes to practice that have been made as a result of the patient safety incident, within an agreed time frame.

Communicating lessons learned from a patient safety incident

Health services should have mechanisms in place to share with their staff the lessons that have been learned from a patient safety incident and any changes to clinical practice or facility management as a result. Effective communication of the outcomes of incident investigations is a vital step in ensuring that recommended changes are fully implemented and monitored. This process will also increase awareness of patient safety and the value of open disclosure. Existing opportunities to communicate these lessons may include morbidity and mortality meetings, clinical review discussions and patient safety grand rounds. It is important to note that the Incident Management Policy PD2014 004 requires that if an incident has been subject to a RCA investigation 'the information to be provided is limited to that which is included in the final RCA Report²².

Health care staff and patients and/or their support person(s) must be informed that the findings of the final investigation may be shared with others – although names and identifying information are removed.

The lessons learned from a particular patient safety incident may be used for teaching purposes locally and more widely. When a local teaching session is planned, it may be appropriate to notify the patient and/or their support person(s) and health care staff who were involved, to avoid unexpected exposure to discussion about the incident.

Evaluation of open disclosure

Health services should establish a system for recording and monitoring the performance and outcomes of open disclosure. Results of evaluation reports and other internal measures of open disclosure performance should be reported to the health service executive at regular intervals.

a) Evaluation by the patient and/or their support person(s):

When a patient and/or their support person(s) have agreed that open disclosure has been completed, they should be asked if they would like to participate in evaluating their experiences of open disclosure. Sensitivity is required and they should be able to choose which means is best suited to them. Options include a face to face discussion, a telephone interview and a standardised open disclosure evaluation survey.

When informing them about the evaluation process, important factors include:

- that they have a choice to participate
- their contribution would be valued and confidential
- the timeframes for involvement in evaluation
- a clear explanation of what is involved and the methods available.

If face to face or telephone contact is planned, it is important that the health service staff member who contacts the patient and/or their support person(s) is prepared for the possibility that aspects of, or related to, the patient safety incident may be revisited, and/or new information may be revealed during the discussion. This may occur particularly if the patient and/or their support person(s) perceive that the open disclosure process has not met their needs or expectations. In preparation, the open disclosure advisor or a colleague experienced in open disclosure may be able to advise on strategies to manage these situations should they arise.

b) Evaluation by clinicians and other health care facility staff involved in open disclosure:

Health care staff who participated in open disclosure discussions should also be offered the opportunity to evaluate their experience, and should be able to choose the method by which they would prefer to provide feedback.

Section 8.2.2 of the NSW Health Open Disclosure Policy includes some suggested measures to facilitate quality improvement, monitoring and reporting of open disclosure practice.

Tools for Formal Open Disclosure

Tools to assist Formal Open Disclosure are available to download and print from the Open Disclosure page of the CEC website: www.cec.health.nsw.gov.au

CHECKLIST B - PREPARATION FOR FORMAL

OPEN DISCLOSURE may assist with identifying the tasks to be competed or delegated when preparing for a formal open disclosure discussion with a patient and/or his or her support person(s).
CHECKLIST C – OPEN DISCLOSURE TEAM MEETING may assist in identifying tasks to be completed or delegated during a meeting of the open disclosure team in preparation for a formal open disclosure discussion.
CHECKLIST D – DURING THE FORMAL OPEN DISCLOSURE DISCUSSION may assist in identifying important points to be addressed during a formal open disclosure discussion with a patient and/or their support person(s).
CHECKLIST E – COMPLETION OF FORMAL OPEN DISCLOSURE may assist in identifying points to include when completing formal open disclosure.

See **Chapter 7** of this Handbook for practical considerations for open disclosure, such as privacy and confidentiality and establishing the right environment for clinician disclosure.

Offering a sincere apology to a patient who has been harmed by a patient safety incident and/or their support person(s) — saying sorry — is a key component of open disclosure.



APOLOGISING AND SAYING SORRY

It's OK to say sorry

A key component of open disclosure is offering a sincere apology – **saying sorry** – when a patient safety incident occurs.

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 matter²³. It should also acknowledge the consequences of the situation to the patient and/or their support person(s).

For many patients and/or their support person(s), it is the most valued part of open disclosure and essential to post-incident reconciliation and rebuilding of trust.

For many health care staff, apologising to a patient may also assist them in their recovery from patient safety incidents in which they have been involved.

Each open disclosure discussion with a patient and/or their support person(s) will be unique. The exact wording and phrasing of an apology will vary for each discussion and for each health care team member. Health care staff will find their own 'right words' to use when apologising, learning from their own experiences and those of respected and experienced colleagues.

Open disclosure in clinical settings is of such importance that NSW and all other Australian jurisdictions have enacted laws to protect statements of apology or regret made after a patient safety incident from subsequent use in civil proceedings²⁴. This protection is designed to encourage open disclosure, and to prevent any unwillingness on the part of health care staff to participate in open disclosure because of fear of legal ramifications for themselves or their local health district/specialty network.

The effect of an apology on liability in NSW

- (1) An apology made by or on behalf of a person in connection with any matter alleged to have been caused by the person:
 - (a) does not constitute an express or implied admission of fault or liability by the person in connection with that matter, and
 - (b) is not relevant to the determination of fault or liability in connection with a matter.
- (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.

Section 69 of the Civil Liability Act 2002 (NSW)

^{23.} NSW Civil Liability Act 2002

Australian Commission on Safety and Quality in Health Care (ACSQHC) Australian Open Disclosure Framework, Sydney, 2013

Key points

Open disclosure is much more than apologising, but its overall success can often depend on how the apology is delivered. In this regard, the key points for those engaging in open disclosure are:

> Do not fear saying sorry.

Providing you don't engage in unwarranted speculation about the patient safety incident or apportion blame to other individuals, teams or the health service, there are no medico-legal grounds for avoiding the word 'sorry'. Similarly, there is no reason to fear it from an interpersonal point of view. Remember that apologising is a natural human response after an unexpected event. Patients who have been harmed, their support person(s), families, carers and other persons affected by the incident, will appreciate and benefit from a sincere apology. Equally, you and your colleagues may also benefit from this interaction. The conversation can be difficult but, according to the available evidence, may lead to a better outcome.

Acknowledge that the incident has occurred and that the patient has suffered, or may suffer, harm as a result.

> Listen.

Apologising is also about listening and ensuring that the patient and/or their support person have an opportunity to tell you how they feel, and how the incident has affected them. Practise and engage in active listening and always ensure that the patient has an opportunity to respond.

- > Exhibit empathy with the patient and/or their support person(s).
- > Offer the opportunity to make amends.
- Consider your delivery.

Think about your phrasing and non-verbal aspects of your delivery. It is important to remember that what you say is not always what is heard, and that this can be influenced by non-verbal cues such as maintaining appropriate eye contact and the tone of your voice. Other aspects of delivery such as body language, positioning and potential distractions will influence the conversation. Rehearsing your words and delivery style with the open disclosure advisor or an experienced colleague may help you find the 'right words' for you.

What is empathy?

Empathy is "the ability to step into the shoes of another person, aiming to understand their feelings and perspectives and to use that understanding to guide our actions".

Roman Krznaric (2012)

To empathise is to understand how others feel, to see the situation as they do.

Empathy goes beyond sympathy and compassion because it involves an appreciation of each patient's story. You can be empathic for others even when you do not feel sympathetic toward them. For instance, you may not feel sympathy for the patient who as a drunk driver crashed his car resulting in the serious injury to a passenger, but you can be empathic when he develops depression as a result of guilt about the accident.

Empathic communication enhances the therapeutic effectiveness of the clinician – patient relationship. Appropriate use of empathy as a communication tool honours the patient, facilitates the clinical interview, and increases the efficiency of gathering information. An appropriate statement or gesture of empathy takes only a moment and can go a long way towards rebuilding relationships, re-establishing trust and enhancing rapport. Empathy enables a clinician to be with a patient and to identify more closely with how that patient and his/her family may be feeling.

Planning an apology

Plan ahead

Wherever possible, the health care staff directly involved in the patient safety incident should provide the apology. Before meeting with the patient and/or their support person(s), plan what you are going to cover in your apology.

When preparing for the clinician disclosure discussion when a patient safety incident has just occurred, the factors that may have contributed to or caused the incident may not be clear.

Chapter 4 Clinician Disclosure – An example of appropriate wording for clinician disclosure – STARS® offers more detail about including an apology at this early meeting.

Preparing for a discussion with a patient and/or their support person(s) also includes preparing yourself – being aware of your own feelings and emotions, including distress, guilt or anger, and the range of emotions and reactions that the patient and/or their support person(s) may have.

The open disclosure advisor and coordinator will be able to offer advice to assist you with preparing for an open disclosure discussion, including providing guidance on apologising in the particular circumstances of the patient safety incident.

Provide factual information

Patients who have been harmed whilst receiving health care and/or their support person(s) seek an honest, straightforward explanation about what happened and why. Harm should be acknowledged and an apology provided. The apology should make clear what is being apologised for and what is being done to address the situation. Only the known facts should be provided, without pre-empting the results of a review or investigation.

Go slowly and genuinely

The effectiveness of an apology depends on the way it is delivered, including the tone of voice, as well as non-verbal communication such as body language, gestures and facial expressions. The following tips will assist in communicating an apology appropriately:

- place yourself at the level of the patient e.g. sitting if the patient is seated or is in bed
- face the patient and maintain appropriate eye contact throughout
- > use plain, simple English avoid medical terminology
- take time go slowly. Speak in sentences rather than paragraphs
- allow time for the patient and/or their support person to think about what you have told them, and to comment or ask questions
- > don't overwhelm with information
- > listen actively to the patient and/or their support person as they recount their experience.



What to include in an apology

An Open Disclosure apology should include:

- using the patient's name and the name(s) of the support person(s) present, after checking that you have the correct patient and checking what name(s) they would prefer to be addressed by – for example, the patient's name may be Margaret but she is known as Peggy by her family and friends
- an acknowledgement that the patient safety incident occurred and its impact on the patient and/or their support person(s)
- > the words "I am sorry" or "we are sorry".

Examples of suitable wording for apologising

An apology needs to be suitable to the circumstances of the patient safety incident. Some examples of suitable wording follow:

- "I am/we are sorry for what has occurred".
- "This (the incident) means that you may/will... (feel some soreness around your wound), and we will... (check on you every X hours and ensure you receive appropriate pain relief)".
- "You have also told me about how this has affected you. Please let me or one of the team know if you have any further concerns, including if the pain doesn't settle down".
- "This incident occurred because the wrong label was mistakenly placed on your specimen sample".
- "We are currently investigating exactly what caused this breakdown in the process and will inform you of the findings and steps taken to fix it as soon as we know".

What NOT to include in an apology

When making an apology in the context of open disclosure, the following should be avoided:

- any admissions of liability which are specific about the fault of the health care staff or service, either as a verbal or written statement – for example, admitting that the health facility or a clinician breached their duty of care to a patient which led to the patient suffering harm or injury
- any speculation as to the cause of the patient safety incident – if you don't know, be truthful and explain the process which will take place to find out what happened and why
- any attribution of blame to the patient and/or their support person(s), a clinician or health care team, the health facility or the Local Health District/Specialty Network
- denying any responsibility before the facts about the patient safety incident are known
- providing conflicting information explain what will be done to verify the information about the patient safety incident
- any attempts to minimise or rationalise the severity of the patient safety incident – saying "it could have been worse" is not helpful to the patient and their support person(s)

Examples of what NOT to say

- 'It's all my/our/his/her fault...I am liable'
- 'I was/we were negligent...'
- 'We're sorry...but the mistake certainly didn't change the outcome..."
- 'I know for you this is unpleasant, awful... but believe me, for me it's shattering'
- Any speculative statements and apportioning of blame (to the patient, their family, individual clinicians or the health service), for example:
- 'I would say that the night shift staff probably forgot to write down that you were given this medication...'
- So-called apologies that are vague, passive or conditional:
 - 'I apologise for whatever it is that happened'
 'Mistakes were made'
 - 'These things happen to the best of people...'
 - 'If I did anything wrong, I'm sorry'
 - 'It could have been worse'

Key discussion areas and examples of an apology as part of open disclosure

Discussion areas	Examples of usage
Acknowledge	"Mr/s X, there has been a problem with your medication. I understand that you are disappointed with what has happened and probably worried about what effect it might have"
Apology	"I am very sorry that this has happened" "I realise it has caused great pain/distress/anxiety/worry"
Known facts	"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" "We have been able to determine that" "This occurred because the wrong label was mistakenly placed on your specimen sample"
Tell me about it – Patient story Answer questions	"I'd really like to hear about things from your point of view. What do you know about what's happened?" "Mr [patient's name], can I just summarise what you have told me?"
·	"You may have a few questions you would like to ask, and I will try to answer them as best I can." "Is there anything you think we should do to move forward from here?"
Respond – Plan for care	"I have reviewed what has occurred and this is what I suggest we need to do next. Would you agree?"
Investigation	"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"
	"We will be investigating what happened to you to find out how this incident occurred. We would like to hear from you and/or your family members who have been with you. We will also be speaking with our staff members and others who may be able to contribute to the investigation."
	"We will keep you informed throughout the investigation process, if that is OK with you."
	"We will be taking steps to learn what happened so that we can prevent this from happening to someone else"
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?"
	"Should we contact another person on your behalf?"



PRACTICALITIES OF OPEN DISCLOSURE

Arranging open disclosure discussions

A face-to-face discussion is preferred wherever possible. The patient and/or their support person(s) should be consulted about who they would like to be present or prefer not to be present. This includes the option of having their own support person(s) in addition to those provided by the health service. It is important to be aware that the number of health care staff attending the formal open disclosure discussion does not overwhelm the patient and/or their support person.

If a patient and/or their support person prefer, or circumstances determine that open disclosure is by telephone, it is important to check that appropriate support is available to them during and after the discussion. It may be possible to enlist the assistance of a local health care professional with appropriate skills.



Open disclosure discussions should be held, wherever possible:

- in person
- at a location and time that is suitable, convenient and easily accessible for the patient and/or their support person(s)
- in a quiet, private area to maintain confidentiality and provide privacy for the patient and/or their support person(s), especially if they are distressed
- away from the clinical area, in a space that is free from interruptions – for example, ask colleagues to cover your pager and turn off your mobile phone
- with sufficient time to apologise, explain the known facts of the incident, listen to the patient and/or their support person(s) and address any questions they may have
- in a manner that empowers the patient and/or their support person(s) and avoids the barriers or demonstrations of rank that may intimidate or discourage them from speaking openly and asking any questions for example, a round table creates an equal space for all participants in an open disclosure discussion.

If a patient does not have the physical or mental ability ('capacity') to participate in the disclosure discussion, their support person(s)* must be notified and involved until the patient is able to fully participate and make decisions on their own behalf. If the patient has died (as a result of the patient safety incident or otherwise), the support person is the lead contact for open disclosure about the incident.

*See Chapter 11 Key Definitions and References

The importance of open and effective communication

It is the responsibility of the health care facility and health care staff to:

- > create an environment that supports open and effective communication
- work with the patient and/or the patient's family, carers and other support persons (as well as people who understand the patient's communication needs, if necessary) to determine the best way to communicate.

Information about a patient safety incident should be provided to a patient and/or their support person verbally and in writing, and in a language or communication style that they understand.

Chapter 9 *Open Disclosure in Specific Circumstances* provides information about open disclosure in circumstances when the patient and/or their support person may have specific communication needs.

Tips for good communication in open disclosure discussions

- Be aware of and sensitive to cultural, language and communication needs of the patient.
- Convey an open and sincere approach with body language and the words that you use: empathic communication is essential.
- Structure the disclosure discussion around the expectations and needs of the patient and/or their support person(s).
- Ensure the style of the disclosure discussion is appropriate to the kind of patient safety incident that has occurred – for example a minor problem may require a short conversation and a simple apology, while a serious incident may require a series of discussions over many months, with long term support.
- Use words that are likely to be understood by the patient and/or their support person(s) – avoid or explain medical terminology and jargon.
- Present the facts using a simple description of what happened and what is known of the outcome at that point. Use visual prompts where possible.
- Carefully pace the delivery of information, allowing pauses and time for you and the patient and/or their support person(s) to process the information and ask any questions at that point.
- Active listening helps with understanding the patient's experiences and needs. This means reflecting back what you have heard to the person you are communicating with.
- Ensure enough time for the disclosure discussion, including ample time for the patient and/or their support person(s) to tell his/her story and ask any questions.
- Ensure that the discussion is not interrupted turn off phones and pagers (or ask a colleague to look after them for you).
- Check and clarify that the information that you provide is understood by the patient. Ask them to feed back to you their understanding of what has been said. Avoid using the words 'Do you understand?', which tends to elicit a positive response even where uncertainty exists.

The open disclosure advisor will be able to offer assistance with preparation and communication skills.

Documenting open disclosure

Following a patient safety incident, essential documentation includes **notifying the incident** via the incident management system (IMS) and recording the reference number in the patient's health record. This includes incidents notified to the Ministry of Health using a Reportable Incident Brief (RIB)²⁵.

a) Recording clinician disclosure

Managers are responsible for noting in the **patient's current health record** (electronic or paper-based) that a clinician disclosure discussion with the patient and/or their support person(s) has occurred, if not already recorded by the clinician. Key points and outcomes from the discussion may also be recorded. The IMS identification number must be noted in the patient's health record. The manager may also enter brief notes into the Clinical Notes screen (or similar) in the IMS.

Documentation should be clear, concise and legible, and include only facts relevant to the incident. The record should be objective, not apportion blame, and should include:

- the date and time discussions were held
- who was present: patient and/or support person(s), health service staff by their position (not name)

** health care staff names are not to be entered into the IMS**

- agreed actions and next steps
- any documentation provided to the patient and/or their support person(s).

The following may be helpful as an example of what to record in the patient's health record for clinician disclosure, and/or to enter into the IMS in the progress report on the Manager Tab:

The senior registrar and the NUM met with the patient and her daughter on 13/9/2013 at 1400hrs, shortly after the patient safety incident (IMS number) was identified. The patient received an apology. They discussed what happened, the treatment that the patient will require and what the ward staff will do to prevent this happening again. The patient has been provided with the contact details for the NUM should she have any further concerns or questions.

For the most serious patient safety incidents, a RIB is submitted to the Ministry of Health which requires the recording on the RIB form of whether an initial open disclosure discussion has occurred. If initial disclosure has not yet occurred, a free text box allows for an explanatory statement.

b) Recording formal open disclosure

Initiation of formal open disclosure should be recorded:

- in the incident management system (IMS)
- in the patient's health record noting the IMS reference number

Managers may also record that formal open disclosure has occurred in the clinical notes section of the incident management system (IMS) or in the progress report on the Manager tab in the IMS. The sample paragraph below provides a guide for recording a summary of formal open disclosure discussions.

Documentation relating to open disclosure discussions should be kept as part of the health service's clinical governance records. It should not be filed with the patient's health record. The file may include open disclosure checklist/s, minutes of open disclosure discussions, any summaries of formal open disclosure discussions, the incident report and evidence of the ongoing monitoring of outcomes.

A reference to the existence and location of these records relating to open disclosure, for example, an open disclosure file, should be included in the patient's health record and the incident management system.

Information about open disclosure discussions which is kept in the clinical governance records may include:

- > time, date and place of the disclosure discussion and the names and relationships of those present
- > confirmation that an apology was given
- plan for providing further information to the patient and/or their support person(s)
- > offers of support and the responses received
- questions asked by the patient and/or their support person(s)
- plans for follow-up as discussed with the patient and/or their support person(s) and responses that were provided
- progress notes relating to the clinical situation and accurate summaries of all points explained to the patient and/or their support person(s)
- > copies of letters sent to the patient and/or their support person(s) and their general practitioner and other relevant health professionals.

A contact person at the health care facility, for example the open disclosure coordinator or manager responsible for insurable risk, should be available to advise clinicians and health care facility staff about processes for documentation and sharing of information.

Financial considerations

When a patient has been affected by a patient safety incident, actual or potential financial impacts should be discussed unless circumstances dictate otherwise. This includes advising the patient and/or their support person(s) of the potential for additional time commitments and costs associated with treatment required as a result of the incident.

Billing and costs

Ensure that consideration is given to waiving the costs to a patient associated with billing for investigations and treatment that are required as a result of the patient safety incident – for example blood tests, x-rays, extended hospital stay, and/or further surgery. Explain to the patient and/or their support person(s) that if they do receive any bills, to contact their open disclosure liaison person for assistance.

Reimbursement of out of pocket expenses²⁶

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. Practical support offered through reimbursement does not imply responsibility or liability. Out-of-pocket expenses may include, but are not limited to, meals, travel, accommodation and childcare.

Offers of reimbursement are made at the discretion of the local health district/specialty network (LHD/SN) and on a case-by-case basis. Reimbursement of any out-of-pocket expenses must be documented in the open disclosure records. It may be preferable that detailed discussions about financial considerations with the patient and/or their support person(s) are arranged separately to open disclosure discussions.

Each LHD/SN should have processes in place to enable reimbursement of the immediate and/or ongoing out of pocket expenses of a patient and/or their support person(s). The Finance Branch at the NSW Ministry of Health supports each LHD/SN developing clear local processes to facilitate early offers of reimbursement as a gesture of goodwill.

Points to consider for local processes include:

- Nominating key contact people in each LHD/SN who are able to advise on and facilitate the reimbursement process
- Linking the reimbursement process to the patient's identification number/incident identification number
- > Requiring any request for reimbursement to be accompanied by a receipt or statutory declaration
- > Establishing clear lines of delegation/responsibility at site level in relation to authorising reimbursement of out of pocket expenses
- > Facilitating the tracking of expenses by providing a Purchasing card (P Card)²⁷ or debit card with a pre-set limit. (A policy is in development for the use of a new Health Credit card called the Purchase Card (P card))
- > Ensuring local staff are aware of the processes in place for reimbursement, through education and training.

If the amount requested is likely to exceed \$5,000 and/or the LHD/SN intends to seek reimbursement from Treasury Managed Funds (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 reimbursement is requested for a significant amount, for example, to assist with funeral expenses, the 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.

Expenses incurred as a result of the incident but not related to the disclosure process

Patients and/or their support person(s) may ask about expenses that are not related to out of pocket expenses, such as funeral costs, long term placement, continuing care expenses or expenses not covered by an insurance program. Health services should anticipate these types of questions and be prepared to respond with appropriate information.

Privacy and confidentiality

Health care staff: Health services are required by legislation to protect the privacy of patients, health care staff and others when conducting investigations, creating reports and making any disclosures during open disclosure.

Health services should ensure that staff participating in open disclosure are aware of and adhere to the relevant privacy principles and other obligations of confidentiality during open disclosure. As part of open disclosure discussions, health care staff are encouraged to inform patients and/or their support person(s) of these requirements and to explain the reason/s that some information is not able to be provided.

Open disclosure advisors can advise on how to provide information without breaching privacy and confidentiality obligations in the context of a particular patient safety incident and the open disclosure process.

Patients have a right to expect that their personal health information will be given to another person only if this is important for their health care or can be otherwise legally and ethically justified²⁸. The safest way to ensure that there is not a breach of privacy or confidentiality is to obtain the consent of the patient (or their parent/guardian) to disclose specified information to a person or people that they nominate. In circumstances where the patient is able to make decisions (i.e. the patient has capacity), only the patient (or their parent/guardian) can determine who this person or people will be.

The discussion about patient's consent to release of information to support person(s) should have been held at the time of admission to the health care facility.

The following points should have been included in the discussion with the patient:

- > the names of the person or people who can provide assistance and support to the patient
- the names of the person or people to whom the patient has agreed that information about their health care can be given
- the names of the person or people who can make decisions on behalf of the patient should he/she be incapable of making decisions about their health care

^{27.} NSW Treasury Circular 11/15 13 December 2011

^{28.} PD2005 593 NSW Health Privacy Manual version 2 Section 3.4

- > The Health Records and Information Privacy Act 2002 (HRIP Act) does not give the patient's next of kin any authority to receive information about or make decisions on behalf of the patient. The health service should check whether the next of kin has been nominated by the patient.
- > any special restrictions on openness that the patient would like the health care team to respect.

After a patient has been involved in a patient safety incident, he/she may decide that a person or people different to whom he/she had previously agreed should now receive information about his/her care.

When a patient does not have capacity to decide for themselves who can receive information about their health care, and if they have not nominated a contact person on admission, an "authorised representative" can decide on their behalf who the person (or people) is to receive information and make decisions about the patient's health care.

The HRIP Act sets out the list of people who can be an authorised representative²⁹.

An authorised representative is appointed by the patient before they lose capacity. Once the patient has lost capacity, it is too late to make such an appointment. The appointment is usually made by Power of Attorney or Enduring Power of Attorney and will state when it is to come into effect. By way of example, it may say that it is to come into effect when the patient ceases to have capacity or if the patient is in a coma or unconscious.

If the patient is deceased the authorised representative is the Executor/Executrix or Administrator/Administratrix of their Estate. An Executor/Executrix is appointed by a valid Will. If there is no valid Will a person is said to die intestate and the Administrator/Administratrix is appointed by the Court. Advice can be obtained from the NSW Trustee and Guardian if there is uncertainty as to who can look after the affairs of the Deceased.

Open disclosure on compassionate grounds:

When considering open disclosure without explicit consent on compassionate grounds³⁰, such as in emergency situations or when a patient has died without nominating a contact person, the following restrictions must be considered:

- > the individual must be incapable of giving consent
- disclosure must be limited to "what is reasonably necessary" in the circumstances
- disclosure must not be contrary to any wish the patient has expressed and not withdrawn, or any wish that the health care facility is aware of, or could reasonably make itself aware of.



^{29.} ibid Section 5.6

^{30.} PD2005_593 NSW Health Privacy Manual version 2 Section 11.2.9

Information about a patient safety incident should be provided to a patient and/or their support person verbally and in writing, and in a language and communication style that they understand.



SUPPORT FOR STAFF

[Adapted with permission from the Irish Health Service Executive and State Claims Agency³¹]

Open disclosure plays an important role in how well health care staff who are involved in the patient safety incident – sometimes referred to as the second victims – manage following the incident. Disclosure and apology can help staff to heal and recover from a patient safety incident and also preserve the relationship between health care staff and the affected patient and/or their support person³².

Some staff may fear that reporting a patient safety incident may result in litigation or disciplinary action, and consequently may not report incidents. Effective open disclosure requires an environment which seeks to balance the need to learn from patient safety incidents and the need to take disciplinary action – a "just culture" 33 – where clinicians, managers, patients and their support people feel supported. A "just culture" fosters an honest and transparent approach in which lessons learned from patient safety incidents are shared not only with the patient and/or their support person(s), but with health care staff, the health service and the wider health community.

Benefits for health care staff from participating in open disclosure

Health care staff who have been involved in open disclosure have reported that it

- > encourages a culture of honesty and openness
- helps to create an environment where staff are more willing to learn from patient safety incidents
- enhances the relationships between health management staff and clinicians
- enhances the communication between health care staff about clinical outcomes
- improves communication and relationships with patients and/or their support person(s)
- improves staff recovery from patient safety incidents.

Concerns about participating in open disclosure

Health care staff have identified a number of concerns about conducting open disclosure following a patient safety incident, including:

- fear of litigation especially about perceived liability and making an apology
- a lack of knowledge about how, what and how much information to disclose about a patient safety incident
- a need for more training to assist health care staff when disclosing patient safety incidents
- > concerns about the effect on professional reputation and career
- > lack of peer support and support from management.

The open disclosure advisor or a senior colleague experienced in open disclosure will be able to provide guidance about measures to mitigate these concerns. Please see Chapter 10 Frequently asked legal and insurance questions.

^{31.} Health Service Executive and State Claims Agency of Ireland National Guidelines Communicating with service users and their families following adverse events in healthcare, Naas, 2013

^{32.} Canadian Patient Safety Institute Canadian disclosure guidelines: being open and honest with patients and families, Edmonton, 2011

^{33.} World Health Organization The Conceptual Framework for the International Classification for Patient Safety, Version 1.1 Final Technical Report Technical Annex 2, WHO, Geneva, 2009

Actions for health service managers to support staff involved in a patient safety incident

Following a patient safety incident, managers should ensure that the following actions are taken:

- All staff involved have access to immediate practical and social support during and immediately after the incident. This may include acknowledging what has happened, organising transport home, contacting a family member, organising time out, listening to their concerns.
- Information is provided to staff involved about the Employee Assistance Program (EAP), Staff Counselling Services or similar service available to them and they are supported to attend at their request.
- > Factual information is provided and people's reactions are normalised.
- Proactive problem solving is promoted encouraging staff to take an active role may help them to feel more in control of the situation
- Checking in with staff regularly to identify people who may be at risk – at the time of the incident, immediately after, during any leave from work, on return to work and throughout the investigation and open disclosure process – and referring them to appropriate services if required.
- > Rapid access is provided to early intervention for people who report ongoing distress.
- Appropriate organisational liaison and feedback occurs, linking support services, the staff involved and management.

Health care staff debriefing

Debriefing following a patient safety incident may be of benefit and staff should be encouraged to attend. They should be advised of the benefits, but attendance should not be mandatory.

Debriefing may be undertaken at different levels – informal, formal or a combination of both. The level will be dependent on the nature of the patient safety incident, the staff involved in the incident and the consequences of the incident for those involved.

The purpose of health care staff debriefing is to:

- evaluate the emotional and physical impact on all individuals involved
- > provide support to reduce the isolation of staff
- > relieve stress at an early stage
- > reinforce team spirit
- decrease isolation at a time when staff may want to withdraw from social contact
- > reduce dysfunctional reactions or health consequences over time
- identify the need for and provide counselling or support for all individuals, in relation to any trauma which may have resulted or emerged from the incident.

The debriefing process must maintain the confidentiality and privacy of the individuals involved. Debrief records are not noted on any personal or personnel files. Any feedback to management is only what is agreed with the member(s) of staff involved in the debriefing.



The impact of patient safety incidents on health care staff

The impact of patient safety incidents on health care staff will vary depending on the nature of the incident and the individual's response to the incident. The symptoms and stages of responding to a patient safety incident are detailed below.

Symptoms health care staff may experience after a patient safety incident

A significant number of health care staff may experience degrees of stress as a result of exposure to a patient safety incident where a patient was harmed, or from participating in the open disclosure discussions and being exposed to the distress of the patient and/or their support person(s), or a colleague. Individual responses range from common uncomplicated stress-related reactions to the more complex post-traumatic stress disorder³⁴. Being aware of their own vulnerability may help health care staff to enhance their insight and compassion towards each other and to their patients.

A patient and/or their support person(s) may also experience similar symptoms following a patient safety incident.

Feelings and behaviours experienced by those involved in the patient safety incident, particularly if it was harmful to the patient, may include:

- > feelings of incompetence and isolation
- denial and avoidance of responsibility, discounting of the importance of the event and the impact on themselves and others
- > emotional distancing
- > guilt, particularly if open disclosure has not occurred
- overwhelming guilt in relation to the incident itself and the impact on the patient and/or their support person(s)
- > poor insight
- > panic resulting in a 'fight or flight' reaction
- > feelings of abandonment

- a desire to disclose to the patient and/or their support person(s) with uncertainty about how to proceed
- > improved recovery following open disclosure.

Health services must continue to support health care staff to minimise any residual emotional and professional harm.

Health care staff who think that they, or a friend or colleague, may be experiencing stress-related symptoms after a patient safety incident, are strongly encouraged to seek advice and support from the staff support services, including the Employee Assistance Program (EAP) or similar service offered by each Local Health District/Specialty Network on a confidential basis.

Health care staff members who have been harmed through being involved in a patient safety incident, and/or the open disclosure discussions with the patient and/or their support person(s), may require the ongoing support provided through local management in consultation with Work Health and Safety and the risk management team.



^{34.} Canadian Patient Safety Institute Canadian disclosure guidelines: being open and honest with patients and families, Edmonton, 2011

Stages associated with health care staff reaction following a patient safety incident

Scott et al³⁵ have identified six stages associated with health care staff reactions following a patient safety incident or other traumatic event.

Stage Name	Characteristics of this Stage
1. Chaos	 Error realised and recognised Tell someone, get help Care for the patient Questioning how and why did it happen Distracted
2. Intrusive reflections	 Re-evaluation of the event Haunted re-enactments of the event Self-isolation Feelings of internal inadequacy
3. Restoring personal integrity	Need to manage gossipQuestioning trustFear
4. Enduring the inquisition	 Realisation of seriousness Reiterating the scenario Wonder about repercussions Who can I talk to? Physical and psychosocial symptoms
5. Obtaining emotional first aid	Seeking personal and professional support Where can I turn to for help?
6. Moving on:	
6.1 Dropping Out	Changing professional roleLeaving professionGoing to a new practice location
6.2 Surviving	Coping Continuing to be plagued by the event but performing at the expected level
6.3 Thriving	 Gains insight and perspective into the error Learns from the incident – identifies opportunities for further training Not focussed solely on the error

^{35.} Scott SD, Hirschinger LE, Cox KR, McCoig M, Brandt J, Hall LW. The natural history of recovery for the healthcare provider "second victim" after adverse patient events. Qual Saf Health Care. 2009;18(5):325-330

Symptoms of Post-Traumatic Stress Disorder (PTSD):

A patient safety incident can be traumatic for the patient and health care staff.

Post-traumatic stress disorder (PTSD) develops differently from person to person. While the symptoms of PTSD most commonly develop in the hours or days following the traumatic event, it can sometimes take weeks, months, or even years before they appear.

While individuals experience PTSD differently, there are three main types of symptoms:

- > re-experiencing the traumatic event
- > avoiding reminders of the trauma
- > increased anxiety and emotional arousal.

Following a traumatic event some people might experience some symptoms of PTSD. These are normal reactions to abnormal events. For most people, however, these symptoms are short-lived. They may last for several days or even weeks, but they gradually lift. With PTSD, the symptoms don't decrease, and people may start to feel worse over time.

For more information on how to access help: www.helpguide.org/mental/post_traumatic_stress_ disorder_symptoms_treatment.htm





OPEN DISCLOSURE IN SPECIFIC CIRCUMSTANCES

The approach to open disclosure can vary depending on the particular circumstances of the incident. Some of these are described below.

Death of a patient as a result of a patient safety incident, a known error or suspected suicide

When a patient dies as a result of a patient safety incident

When a patient safety incident has resulted in a patient's death, it is crucial that communication with people who were close to the patient is sensitive, empathic and open.

The health service's policies and practices should ensure that support persons receive information on the processes that will be followed to identify what happened, and on what care and support is available to them. Establishing open channels of communication enables people to indicate when it is appropriate to discuss what happened, and if counselling or other assistance is needed.

When a patient's death is to be investigated by the coroner

Open disclosure should not be delayed by waiting for completion of the coroner's investigation or inquiry. Where the coronial investigation has been initiated by the health facility, in addition to the usual open disclosure steps, the patient's support person(s) should be informed that the coroner's process has been initiated. They should be provided with contact details for the Coroner's office, who will liaise with the support person about the coronial process.

If a patient dies as a result of suspected suicide when they have received care for a mental illness

Although the full circumstances surrounding the person's death may not be known until after further investigation, the ensuing investigation process should not delay open disclosure.

Clinician disclosure should occur with the patient's nominated support person(s) as soon as possible.

According to the NSW Health Privacy Manual (Version 2)³⁶, a health service may disclose personal health information to an immediate family member for compassionate reasons. The following restrictions apply:

- disclosure must be limited to what is "reasonably necessary"
- disclosure must not be contrary to any wish the individual has expressed that the health care facility is aware of or could reasonably make itself aware of.

Where liaison with police is required to locate the support person(s), clinician disclosure should occur generally within 24 hours of the health care facility being notified of the name and contact details of that person.

Children and young people, people with a mental health condition, patients with cognitive impairment

Infants, children and young people

When a patient safety incident results in harm to an infant, child or young person (the child), the clinical team and the child's parents or guardian need to make informed and complex assessments of what the child should be told, with the child's best interests in mind.

The clinical team should assess the involvement of children and young people in open disclosure on a case-by-case basis, taking into account whether the child or young person is mature enough to receive the information and the wishes of the child or young person and his/her parents or guardian where appropriate.

When a young person has legal competence, the considerations are comparable to those for consent for treatment involving the young person. PD2005_406 Consent to Medical Treatment – Patient Information may be able to provide further guidance³⁷.

The clinical team will need to assess the young person's maturity and ability to understand the patient safety incident and deal with its physical and psychological impacts.

^{36.} PD2005_593 NSW Health Privacy Manual version 2 Section 11.2.9

^{37.} PD2005 406 NSW Health Consent to Medical Treatment – Patient Information Section 25 p19

Advice and guidance from specialist paediatric health professionals should be sought when caring for children and young people who have been involved in a patient safety incident and who may be involved in formal open disclosure. The open disclosure advisor may also be able to provide advice.

Patients with a mental health condition

The principles of disclosing information relating to treatment, including open disclosure of a patient safety incident, apply equally to patients with a mental health condition, irrespective of whether the patient is subject to mental health legislation, or whether the mental health condition was related to the reason the patient was being treated.

The timing of the disclosure discussion is informed by documented advice from the clinical team on how this information may affect the patient's health and his or her ability to understand what they are being told.

If the patient has not nominated a support person, it would be inappropriate to discuss patient safety incident information with a partner, carer or relative. In an emergency situation, the NSW Privacy Manual (Version 2) Section 11.2.9 allows for restricted disclosure to an immediate family member on compassionate grounds. The restrictions are as follows:

- > the individual must be incapable of giving consent
- disclosure must be limited to what is "reasonably necessary"
- disclosure must not be contrary to any wish the individual has expressed that the health care facility is aware of or could reasonably make itself aware of.

If an open disclosure discussion is not able to be held with the patient, or is delayed or commenced with the patient's support person(s), the rationale must be clearly documented in the patient record and the IMS. Where possible, the decision should be independently verified by a colleague who was not involved in the incident and be documented in the patient record.

Patients with cognitive impairment

Patients with a temporary or permanent cognitive impairment who have been involved in a patient safety incident should be involved directly in communications about what has happened to them. The health care facility has a responsibility to work with the clinical team and relevant support people to determine the most accessible type and format of communication for the patient. A patient's capacity to understand what is being communicated to them may depend on whether the information is provided in a way that is appropriate to their abilities and usual methods of understanding³⁸.

Where the patient has a guardian or a carer with a power of attorney, the scope to which they can make decisions on behalf of the patient to decide whether or not they should be involved in open disclosure should be checked. Sometimes, a guardian may only have the power to make financial decisions for a patient and should therefore not be part of the open disclosure discussion, unless the patient wants them to be there.

Patients with complex care requirements and language or cultural diversity

Patients with complex care requirements involving multiple health care teams, wards and facilities

When a patient has been involved in a patient safety incident whilst receiving health care from multiple teams or health facilities, open disclosure requires consistent and coordinated communication:

- > with the patient and/or their support person
- > with each of the teams involved and
- > between the teams/health facilities involved.

Patients and/or their support person(s) should receive unambiguous information, preferably from a single point of contact. Appointing a person to ensure that communications are timely and coordinated is recommended – for example, the open disclosure coordinator, complaints officer or patient safety manager. This person may also work with the clinical teams involved to ensure that the patient's complex care requirements are met in a timely and coordinated way.

A senior clinician from the primary treating team, or a senior manager should be nominated to lead the formal open disclosure discussions, with representation from other treating teams and other facilities if appropriate. When several teams or facilities are involved and wish to be represented at the formal open disclosure discussion, it is important to be aware of the potential for the number of health care staff to overwhelm the patient and/or their support person(s). It is important to liaise with the patient and/or their support person(s) about the people whom they would like to be present or prefer not to be present at the disclosure discussion.

Language and/or cultural diversity considerations

Ensuring appropriate and effective communication which conveys empathy and respect is an important consideration, especially when patients and/or their support person(s) come from a linguistic or cultural background different to that of the clinician. Clinicians and managers should seek assistance from appropriate services when planning open disclosure, especially formal open disclosure.

If a patient safety incident occurs, the physical and emotional impact of the patient safety incident may affect the patient's ability to communicate in English. Some patients who are proficient in English may have difficulty in understanding medical terms.

Awareness and consideration of special cultural needs must be taken into account when planning to discuss patient safety incidents – for example patients from cultures where it is difficult for a woman to speak with a man about intimate issues. If unsure about culturally appropriate communication with a patient, advice should be sought from a patient advocate or interpreter on the most sensitive way to discuss the information.

Interactions with the health system for people from culturally and linguistically diverse backgrounds, in particular Aboriginal people and refugees, may be influenced by previous personal or family experiences of racism, discrimination and mistrust.

Aboriginal people include a diversity of cultural and linguistic groups. Barriers to communication with clinicians for some Aboriginal people include language differences and differences in principles and beliefs regarding health and other matters. If available, an Aboriginal liaison officer should be involved from the outset to ensure open disclosure occurs in a culturally appropriate manner.

Professional health care interpreters are available for health care staff and patients in public hospitals and community health services. Most community languages are catered for. The service is free of charge and operates on an appointment basis. For further information, contact your nearest Health Care Interpreter Service. Avoid using 'unofficial translators' and/or the patient's family or friends as clarity of communication and the information being conveyed is essential during open disclosure discussions.

Every effort needs to be made to ensure that the appropriate people (in the context of the patient and/or their support person(s) and with their agreement) are included in discussions regarding patient safety incidents and their investigation and management.

A breakdown in the relationship between the patient and the health care team

Sometimes, despite the best efforts, the relationship between the patient, their support person(s) and the health care team can break down. The patient and/or their support person(s) may not accept the information provided or may not wish to participate in open disclosure.

The following actions may assist to rebuild the trust between the patient and/or their support person(s) and the health care team:

- > address an issue/problem as soon as it arises
- > do what you say you are going to do, and keep to timeframes wherever possible
- with the patient's agreement, ensure that their support person(s) and other relevant people are involved in discussions from the time when a patient safety incident is first identified
- ensure access to appropriate support services for the patient and/or their support person(s)
- > ensure the appropriate staff member (most often the senior clinician) is aware of a potential relationship breakdown by notifying them of early warning signs such as a patient and/or their support person(s) expressing concern to members of the team.

- offer the patient and/or their support person(s) another health care facility contact with whom they may feel more comfortable. This could be another member of the clinical team or the health service's manager responsible for insurable risk
- use a mediation or conflict resolution service to help identify the issues between the health service and the patient and/or their support person(s), and to look for a mutually agreeable solution
- > provide information about the local health care complaints office if the patient and/or their support person(s) wishes to lodge a formal complaint with the Local Health District/Specialty Network or with the Health Care Complaints Commission (HCCC)
- assess whether sufficient weight has been given to the patient's version of events and whether reasonable efforts have been made to seek information from all key witnesses, including witnesses identified by the patient and/or their support person(s).

When the patient doesn't want to meet with the clinician or other member of staff

Where the patient and/or their support person(s) express a preference for the health care staff involved in the patient safety incident not to be present, the health care staff may wish to provide a personal written apology that can be given to the patient and/or their support person(s) during the discussion.

When the clinician doesn't want to meet with the patient and/or their support person

There may be occasions following a patient safety incident when a key clinician who was involved in the incident is unable or unwilling to meet with the patient and/or their support person. It is important for the health service to ascertain the reasons and address them wherever possible, including asking the open disclosure advisor to speak with the clinician, referring him/her to their professional indemnity insurers for further advice and/or referring him/her to the appropriate support services.

If the clinician is unable or unwilling to attend, his/her department head, a senior manager or an open disclosure advisor should be available to attend the open disclosure discussion on his/her behalf.

The patient and/or their support person(s) should be informed that the clinician is unable to attend, provided with an explanation as to why he/she can't be there, and that the health service is able to offer a senior clinician to attend in his/her place, to enable them to make a decision about whether to proceed with the discussion.

Patient safety incidents occurring elsewhere or involving transfer of the patient

Patient safety incidents occurring elsewhere

A patient safety incident may have occurred in a different facility or health service from where the incident is identified. The person who first identified the incident should notify the patient safety manager in their health care facility.

The patient safety manager should establish whether:

- the patient safety incident has already been recognised in the health care facility in which it occurred
- > open disclosure has already commenced in that health care facility
- > reviews or investigations are underway in that health care facility
- > the incident has been reported to Treasury Managed Funds (TMF).

If open disclosure has not already commenced, it should occur after consultation and collaboration with the other health service, and without undue delay. Respect for the patient's right to know about a patient safety incident that involves them is paramount.

A thorough clinical review and investigation of the patient safety incident should occur in the health care facility where the incident took place.

Transfer of the patient to another facility or Local Health District/Specialty Network with their support person(s) accompanying them

A patient safety incident may necessitate transfer of the patient who has been harmed to another health care facility in order to receive the care that they require. Clinician disclosure should occur before the patient is transferred, depending on the patient's condition and the availability of their support person(s).

It may be appropriate for the clinicians involved from both settings to be present and conduct the formal open disclosure discussions together.

Delayed detection of a recent patient safety incident

In any situation when there has been delayed detection of a patient safety incident, for example after a patient has been discharged, health services should:

- notify the patient and/or their support person(s) (clinician disclosure)
- with the agreement of the patient and/or their support person(s), notify other health care teams who have responsibility for ongoing care of the patient – for example, their general practitioner or community care provider
- > commence an investigation of the incident
- proceed with formal open disclosure if indicated by the particular circumstances.

The needs of the patient and/or their support person(s), as well as the health care staff involved in the incident, may require flexibility with the location or delivery of the open disclosure discussion(s). Video or internet based conferencing may be an option to offer to the patient and/or their support person(s).

Incident identification following a death audit

When a serious patient safety incident is identified during a retrospective death audit, open disclosure may not have been initiated. In these situations, it may be preferable to undertake an incident investigation prior to initiating open disclosure. If the incident investigation confirms a patient safety incident has occurred, then open disclosure should be commenced.

Issues of accountability or suspected intentional unsafe acts

If during the investigation of the patient safety incident a performance issue relating to an individual member of health care staff is identified, the course of action is redirected to the health service'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.

Privacy legislation prevents the sharing of information about investigations into the performance of individual clinicians, unless that clinician provides consent. The patient and/or their support person(s) can be informed that incident review processes routinely consider whether or not further investigations into

individual performance are needed. Further assessment may be made at the local level or through referral to the Health Care Complaints Commission (HCCC) or the Australian Health Practitioners Regulation Agency (AHPRA). It is important to emphasise that performance assessment processes are confidential to enable proper and fair processes to be followed. The hospital is legally unable to provide a copy of the investigation report or any specific details of the investigation to the patient and/or their support person(s). However, where a person made a complaint to the HCCC or AHPRA, he/she will be advised of the outcomes directly by these bodies.

Criminal or intentional unsafe acts

Patient safety incidents are almost always unintentional. If, at any stage following an incident, it is determined that harm may have been the result of a criminal or intentional unsafe act, the health service chief executive and the manager responsible for insurable risk should be notified immediately. This applies to any person working in any capacity within a NSW Health facility, including contractors, students and volunteers.

The person who is the subject of the process should not be involved in the open disclosure discussion.

Health service management should follow the pathway outlined in the Complaint or Concern about a Clinician – Management Guidelines GL2006_002, which includes referring the matter to the appropriate authority.

Obligation to report to Police

All suspected criminal acts (whether instigated by a staff member or a patient) must be reported to the NSW Police Service as soon as they are identified. Investigations by the health service must be conducted in accordance with the NSW Health Policy Directive concerning the allegation of criminal and child related conduct PD2006_026 Criminal Allegations, Charges and Convictions against Employees. Examples of criminal acts include suspected homicide, and sexual or physical assault.

In these situations, open disclosure will be modified to accommodate the context and particular circumstances. The Police Service will advise on what information is able to be provided to the patient and/or their support person(s). At a minimum, the health service should disclose that there are concerns about a patient safety incident, that police have been informed and then provide the contact details for the police officer in charge.

Exceptions to the timeframes for initial clinician disclosure discussion

After a patient safety incident is identified, the initial clinician disclosure discussion should occur at a time which meets the needs of the patient and/or their support person(s), and be generally within 24 hours of the incident.

In some settings such as mental health patients in the community or patients of Justice Health and Forensic Mental Heatlh, conditions or events surrounding a patient safety incident may delay the initial clinician disclosure discussion.

The rationale for any delay must be clearly documented in the patient record and the IMS.

Deferring open disclosure

Occasionally open disclosure may need to be deferred – for example on the advice of the treating clinician that the patient is not able to participate due to the state of their physical or mental health.

The decision and rationale for delaying open disclosure must be clearly documented in the patient record and the incident management system (IMS). Where possible, the decision should be independently verified by a colleague who was not involved in the patient safety incident and documented in the patient record.

The patient and/or their support person(s) may also request deferral. They must be provided with the name and contact details for a liaison person at the health care facility and informed that at any time, they can request that open disclosure proceeds.

Open disclosure may be deferred with the patient and held with their support person(s) either instead or as a temporary measure. Where possible, the process should recommence with the patient at a later date.

Large scale open disclosure

When there is potential for a number of people to be harmed by a common patient safety incident or series of incidents, each situation should be assessed promptly with legal counsel and public relations departments.

The NSW Health Lookback Policy PD2007_075 provides guidance to ensure a consistent, coordinated and timely approach for notification and management of potentially/affected patients when necessary. Initial communication should be direct, either face-to-face or via telephone, where the patient must be given the opportunity to ask questions. Where appropriate, the timing of the disclosure to individuals who may have been affected needs to be considered so that a person is contacted (where possible), before learning about the event from other sources e.g. media. Affected patients are offered a written apology by the health service.

All information should be given in accordance with the Open Disclosure Policy PD2014_028 and privacy principles detailed within the NSW Health PD2005_593 Privacy Manual (Version 2). Clinicians are responsible for applying open disclosure principles when communicating with patients and/or their support person(s).

Proactive disclosure is recommended. This may include a public announcement (e.g. a press conference) and description of what has occurred using various media; an apology for distress that the announcement may cause, details of the investigation underway and what would happen if it is identified that a person has been affected, and details of a dedicated toll-free contact number staffed by clinical members of the team and an email address³⁹.

Aldrich R, Finlayson P, Hill K, Sullivan M (2012). Look back and talk openly: responding to and communicating about the risk of large-scale error in pathology diagnoses. International Journal for Quality in Health Care 2012;24(2)135-143

Disclosure and apology can help staff to heal and recover from a patient safety incident, and also preserve the relationship between health care staff and the patient and/or their support person.

10. FREQUENTLY ASKED LEGAL AND INSURANCE QUESTIONS



FREQUENTLY ASKED LEGAL AND INSURANCE QUESTIONS

What is the difference between an admission of liability and an apology?

An admission of liability is an acceptance or acknowledgement that as a result of some negligent act or omission you are subject to pay damages to an injured party. Admissions of liability have no place in open disclosure.

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 express or implied admission of fault or liability and is not admissible in any civil proceedings as evidence of fault or liability

Are there any restrictions on release of information during open disclosure?

The following restrictions prevent the release of information to the patient and their support person(s), in some circumstances:

Special Privilege under Section 23 of the Health Administration Act 1982

Clinical Reportable Incident Briefs (RIBs) 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.

Statutory Privilege under Division 6C of the Health Administration Act 1982

Although a Root Cause Analysis (RCA) team's final report can and is routinely provided to interested parties, sometimes as part of the open disclosure process other working documents relating to an RCA investigation are privileged and cannot be disclosed. During the RCA process, the team will generate many documents including preliminary notes, records of interviews with staff/clinicians, minutes of discussions and records of discussions with various people either involved in the incident or with fundamental knowledge about the incident or processes involved. All of this material is privileged.

Statutory privilege does not cover documents that were not created for the purposes of the RCA, such as clinical incident summaries, medical records or other records created on providing general care of patients or management of the health service. The privilege does not cover the incident management system's advanced classification of the RCA reportable incident. See Incident Management Policy PD2014 004.

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 or receiving legal advice in relation to the incident or for use in legal proceedings and which remain confidential, will be subject to client legal privilege. This might include Coronial investigations and inquest hearings, Health Care Complaints Commission investigations, civil claims for compensation, and prosecutions before a disciplinary body.

Do documents created during open disclosure have any special status?

The answer to this is generally "no". However, this is subject to a claim for statutory privilege or client legal privilege. Save for any privileged communications, documents created during open disclosure 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 Health policy.

Documents relating to open disclosure may be provided to patients on request, produced under Government Information (Public Access) Act 2009, 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. As with clinical records, health care staff should take care when creating documents to ensure that they are accurate and do not contain inappropriate language. As far as is possible, only verified facts should be contained in documents. Documents should not:

- attribute blame to any health care team member or the health service
- contain information that is not fully informed, or statements that are emotive or emotional, ambiguous, unnecessary or which contain gratuitous or speculative comment
- contain statements which are likely to be defamatory (see below).

Although open disclosure documents will not be covered by client legal privilege, notifications of incidents to Treasury Managed Funds (TMF), professional indemnity insurers (Pl Insurers), and medical defence organisations (MDOs) may be privileged and should not be provided to patients without first seeking legal advice.

In addition, documents created by a Root Cause Analysis (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, health care staff or the general public. As noted above, the RCA Final Report can be provided to the patient and/or their support person(s).

What is a defamatory statement?

A defamatory statement is a communication (whether to one other person or to many) 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 is reasonably required for the purposes of open disclosure.

What is the Treasury Managed Fund?

The Treasury Managed Fund (TMF) is a NSW Government scheme used in place of regular insurance for most government entities, including NSW Health.

The NSW Self Insurance Corporation (SICorp) is the government division that operates the TMF.

TMF Health liability claims are managed by GIO, under contract to SICorp and on behalf of the Ministry of Health.

Does SICorp/TMF support the NSW Health Open Disclosure Policy?

SICorp/TMF recognises that open disclosure is an integral part of incident management in NSW Health, and is a key element of early response and investigation of serious patient safety incidents. SICorp/TMF supports the planned and coordinated approach to open disclosure as outlined in NSW Health's Open Disclosure Policy and this Handbook.

When a formal open disclosure response is being considered, the patient safety incident should be notified to GIO in accordance with TMF incident notification procedures.

What does TMF cover?

- Health liability claims, including awards, legal fees and associated expenses in the defence or settlement of claims for compensation made against a Local Health District/Specialty Network
- b. Visiting Medical Officers (VMO), Honorary Medical Officers (HMO) and Staff Specialists exercising rights of private practice are provided with cover as a separate self-contained arrangement within the TMF, including cover for legal liabilities arising from health care claims made in the treatment of public and private patients in public hospitals. TMF coverage is detailed in the TMF Statement of Cover⁴⁰.

The TMF does not cover legal advice for participating in open disclosure unless a claim has been formalised.

^{40.} NSW Treasury Self Insurance Corporation https://riskinsite.nsw.gov.au/portal/server.pt/community/Publications/272

TMF cover is not provided for:

- > Legal representation, legal and other costs or penalties arising out of disciplinary proceedings, criminal proceedings and any other similar actions or inquiries against an individual clinician such as those taken by the Medical Board, Health Care Complaints Commission and other disciplinary tribunals
- Legal representation or legal advice for Coronial inquests except for those matters where a claim is likely
- > VMO legal representation or legal advice for Coronial inquests

Legal and insurance queries should be coordinated through the LHD/SN's manager responsible for insurable risk.

Whom should I contact for assistance?

If you are a clinician with private insurance cover, you should contact your professional indemnity insurer, medical defence organisation (MDO) or Treasury Managed Funds (TMF), for assistance with insurance or legal issues.

If you are a manager responsible for insurable risk, a Senior Manager or Director of Clinical Governance in a health service, you can contact the following:

- Insurance issues: NSW Ministry of Health Finance Branch/Treasury Managed Funds.
- > Legal issues: NSW Ministry of Health Legal Branch.

Medical Defence Organisations provide an advisory service which can be accessed by members requiring assistance with participating in open disclosure processes.

The Clinical Excellence Commission is committed to providing support for clinicians and managers in relation to open disclosure. Locally, practical advice may also be available from the open disclosure advisors.

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

I am a privately insured clinician. When should I notify my MDO, professional indemnity insurer and the TMF?

Your insurance policy or Contract of Liability Cover will set out when you must notify your MDO/PI insurer and the TMF of an incident. If the incident is a notifiable incident under your insurance policy and/or Contract of Liability Cover, you should notify your insurer and/or the TMF as soon as possible after the incident.

I am a privately insured clinician. How can I ensure I do not jeopardise my insurance coverage and/or indemnity under a contract of liability cover by participating in open disclosure?

Early telephone contact with your MDO/PI insurer is the best way to obtain reassurance about how you can participate without jeopardising your insurance cover for the incident.

Generally, professional indemnity insurers, TMF and MDOs are supportive of open disclosure. However, care should be taken not to admit liability (and such an admission has no place in the open disclosure process) as this may fall within an exclusion clause of your insurance policy or contract. Such an admission may potentially have a negative impact on your insurer's decision to indemnify you or provide you with legal representation or assistance in relation to any Court or other proceedings arising from the incident. Any decision about admitting breach of duty of care or liability should be left to your professional indemnity insurer, TMF and MDO in the context of a claim for compensation by the patient.

How should open disclosure be managed when more than one indemnity provider (i.e. TMF and a MDO) is involved?

If necessary, representatives from professional indemnity organisations e.g. a MDO and TMF will liaise to ensure that the information provided to the patient and/or their support person(s) as part of open disclosure does not jeopardise the insurance cover of any of the clinicians involved in the incident.

What if an insurance claim is lodged during the open disclosure process?

Open disclosure must be managed to completion irrespective of other circumstances occurring at the same time. It is recommended that insurers are notified that open disclosure has occurred and whether any issues were raised during that process that may impact on any real or potential insurance claim. In the public health setting, this would often be the responsibility of the manager responsible for insurable risk, who would send the information to the Treasury Managed Fund (TMF) on behalf of the clinician(s).

Communicating with patients and/or their support people

What are we able to say to the patient and/or their support person(s) when an individual health care team member is being investigated as a result of the incident?

As part of the formal open disclosure discussion, the patient and/or their support person(s) should be informed that the health service is conducting a full review into the circumstances of the patient safety incident.

This review may cover a number of aspects and may include a Root Cause Analysis (RCA) investigation. An RCA will focus on any systems issues that contributed to the incident. The investigation of an individual's performance or competence is not within the scope of the RCA investigation team. The Report from the RCA can be provided to the patient and/or their family.

The patient and/or their support person can be informed that one aspect of any incident review is to consider whether or not further investigations into an individual clinician's performance are indicated. The management of complaints or concerns about an individual clinician is a formal process managed locally. It is important to emphasise that the performance assessment process is confidential to enable proper and fair processes to be followed.

Only after the completion of local processes can it be determined whether there is a need for the Local Health District/Specialty Network to make a formal complaint to the Health Care Complaints Commission (HCCC) or a notification to the Australian Health Practitioners Regulation Agency (AHPRA) into the performance, conduct or competence of a clinician. The hospital is legally unable to provide a copy of any report on an investigation into an individual clinician's performance nor any specific details of the investigation or its outcome without the consent of the clinician/s involved.

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 open disclosure.

Health services and all health care staff also have an obligation to respect the privacy of both staff and patients during open disclosure. Open disclosure discussions should be conducted in accordance with the Health Records and Information Privacy Act 2002 and the NSW Health Privacy Manual (Version2).

Section 22 of the Health Administration Act 1982 and Section 289 of the Mental Health Act 1990 create offences for wrongful disclosure of confidential information.

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 support person, that is acceptable wherever feasible. Common sense should prevail with regards to the actual number of support people. If a conflict arises between the support people as to how open disclosure will progress, this should be managed using strategies such as repeat discussion, mediation, and counselling.

What about young people?

Whilst young people may elect to have a parent(s) as a support person(s), if they are competent to make medical decisions (as well as decisions in relation to open disclosure) for themselves, the consent or participation of the young person's parent is not legally required. If there are any concerns regarding consent see Section 26 of Consent to Medical Treatment – Patient Information PD2005 406 for further information.

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

Sometimes a patient may have a legal guardian or 'person responsible', but does not elect to engage that person in the open disclosure process. In these cases, open disclosure should take place with the involvement of the support person(s), however, discussions relating to further treatment must involve the person who has the legal capacity to make treatment decisions on behalf of the patient.

What if a patient and/or their support person(s) want to record the discussion?

Patients and/or their support person may wish to record the discussion for a range of reasons. Recording of the discussion is not common practice because of concerns that it may impede the free flow of information. Open disclosure depends on the flow of open discussion for its success.

Many organisations have established alternative practices, including offering to provide the patient and/or their support person with a copy of the record of the open disclosure discussion for them to review and comment on. This may be helpful in allaying concerns about the accuracy of what was discussed and agreed upon.

If the patient and/or their support person continue to request that the discussion be recorded, inform them that everyone involved has to agree to the recording first and without that consent, the open disclosure discussion is not able to proceed.

Where the patient or support persons insist on recording the discussions, the senior team member should assess and manage the associated risks, including personal, organisational and reputation risks, as best as possible.

What to notify to the Professional Indemnity Organisations

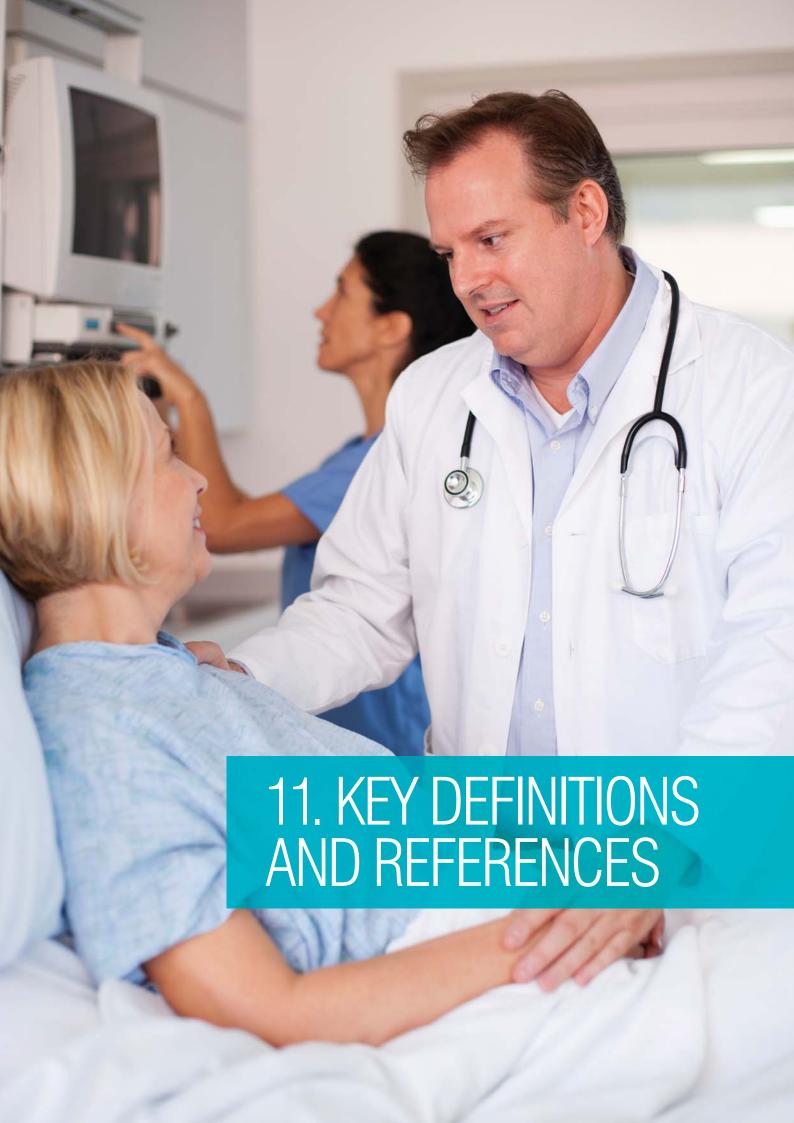
This section has been provided as consolidated generic information from participating professional indemnity organisations. Irrespective of the degree of harm caused to the patient, clinician disclosure with the patient and/or their support person(s) should commence as soon as possible, and at the latest generally within 24 hours of identification of the patient safety incident by the health service.

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

Without limiting the scope of the general guidance above, incidents that definitely require notification to your professional indemnity organisation include:

- Inappropriate or incorrect medication or dosage leading to a serious 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 for example breast cancer, other cancer, meningitis, acute abdomen, fracture, myocardial infarction, subarachnoid haemorrhage, obviously missed pathological or radiological diagnosis such as foetal 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 foetal 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
- > A patient safety incident 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 health care facility staff
- > Patient complaint relating to a serious incident

Indemnity organisations appreciate that clinician disclosure – the initial explanation and apology for a patient safety incident – often occurs 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 planned formal open disclosure is to be undertaken.



KEY DEFINITIONS AND REFERENCES

KEY DEFINITIONS

Apology	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. It should also acknowledge the consequences of the situation to the recipient. It must include the words "I am sorry" or "we are sorry". Under Section 69 of the NSW Civil Liability Act 2002, the effect of an apology on liability: (1) An apology made by or on behalf of a person in connection with any matter alleged to have been caused by the person: (a) does not constitute an express or implied admission of fault or liability by the person in connection with that matter, and (b) is not relevant to the determination of fault or liability in connection with a matter. (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.
Clinician	A health care provider who is trained as a health professional, and who provides direct patient care.
Clinician Disclosure	An informal process where the treating clinician discusses with a patient and their support person(s) the occurrence of a patient safety incident, actively seeks input and feedback from, and listens to, the patient and their support person(s), and provides an apology for the occurrence of the event. 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.
Formal Open Disclosure	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. 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).
Harm	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.
Health care facility	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.
Health Services	For the purposes of this policy, the term "Health Services" refers to Public Health Organisations and NSW Ambulance.

Open Disclosure	Open disclosure is defined in the <i>Australian Open Disclosure Framework</i> 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: an apology a factual explanation of what happened an opportunity for the patient to relate their experience, be listened to and ask questions a discussion of the potential consequences an explanation of the steps being taken to manage the event and prevent recurrence.
	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."
Open Disclosure Advisor	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.
Open Disclosure Coordinator	A staff member who has responsibility for coordinating and supporting clinician and formal open disclosure in a health facility or service.
Open Disclosure Team	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.
Patient	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'.
Patient safety incident	Any unplanned or unintended event or circumstance which could have resulted, or did result in harm to a patient. 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.
	Harmful incident: 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').
	No harm incident: a patient safety incident which reached a patient but no discernible harm resulted.
	Near miss: a patient safety incident that did not reach the patient, and/or in which a potential for harm from ongoing risk may result.

Public Health Organisations (PHO)	This term refers to a Local Health District/Specialty Network, a statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services as defined in the Health Services Act 1997.
Staff	Any person working in any capacity within NSW Health, including contractors, students and volunteers.
Support person	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. 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.
	Where a patient does not have capacity to decide for themselves or is deceased an "authorised representative" can decide on their behalf who can receive information (see s5.6 of the NSW Health Privacy Manual v2). A nominated next of kin is not necessarily an authorised representative.

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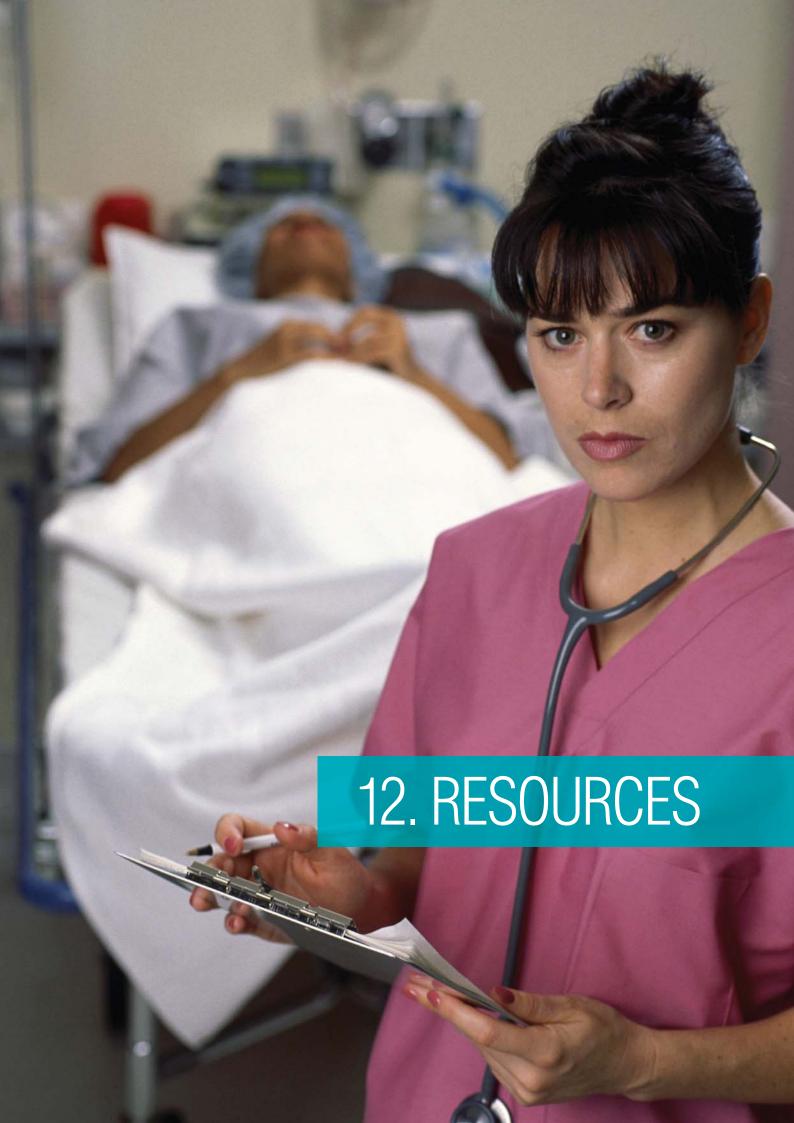
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Open disclosure is 'an open discussion with a patient (and/or their support person) about a patient safety incident which could have resulted, or did result, in harm to that patient while they were receiving health care'.



RESOURCES

EXAMPLES OF WORDING

Signalling formal open disclosure

Following on from the clinician disclosure discussion when the patient has suffered serious harm – for example a significant complication during surgery, an adverse drug reaction, a fall which results in a serious fracture, an incident of self-harm to a mental health inpatient, a post-partum bleed from retained placenta:

"Mr Chan, what has happened to your wife has resulted in serious harm to her. I would like to explain what happens now. If you would prefer that I come back at another time, please let me know. We have already covered quite a lot of information and this situation is very distressing".

An example of appropriate wording if the patient and/or their support person(s) agree to continue:

"Mr Chan, what happens from now on is that we will provide Mrs Chan with all the care that she requires. We will provide you with as much support as we can.

Because we want to find out how this terrible event occurred, we will be investigating the incident in detail. This is a formal process supervised by a group of experienced clinicians and managers. The investigation will start shortly and can take several months.

Part of this process involves formal meetings with you and other people that you may wish to be with you to offer support, for example family members or a close friend.

Do you have any questions about what I have said so far?

At these meetings we will keep you informed about the progress of the investigation. You can ask any questions that you may have over time, as you think about what we have told you and your experiences of the incident.

We would also welcome **anything that you are able to share with us** about your understanding of what happened to Mrs Chan. This will help us with finding the causes of what happened.

As the doctor in charge of Mrs Chan's care, I would usually be at these meetings along with the nurse in charge and one of the hospital managers. Would you prefer someone else to be present at the meeting?

Mr Chan I'm aware that I have just provided a lot of information, and that it is not easy to take all this in at this time. We have some written information for you that covers what I have just explained – you can keep this and read it when you wish.

We will contact you to update you on the progress of the investigation and to find a date to have a formal meeting at which we can discuss your concerns, and our findings of what happened and what needs to be done in the future.

When you have any questions or concerns, **please contact me**, the nurse manager, or my colleague the patient representative. I will leave our names and phone numbers with you, and please feel free to ask the staff as well.

Thank you Mr Chan and may I say again how sorry I am that this has happened to your wife Mrs Chan".

Apologies in different circumstances

These examples are provided as a guide only. The apology should be relevant to the circumstances of the patient safety incident, the harm caused to the patient and the responses of the patient and/or their support person(s) to both the incident and open disclosure.

An apology during the initial clinician disclosure discussion:

- "Mr Nguyen, I'm sorry that I've not been able to take a blood sample although I've had several attempts. I have not been able to access a vein. Is there anything that you can tell me about when you've had blood tests taken before? You may have some bruising and soreness around the site – we will keep a close eye on it. Please let us know if the soreness doesn't settle or gets worse. I will ask my colleague to take your blood sample so that there is no delay in getting the results."
- "Mrs Patel, when I was removing the tape over your wound dressing, some of the skin around the dressing was damaged. I'm really sorry that this happened. Can you tell me if you've had any skin sensitivity with the tape used for this dressing or others? We will apply a protective film to your skin, and change the tape that we use to one that is more suitable for sensitive skin. We'll monitor the response closely to ensure that this doesn't happen again."
- "Mr Kelly, you didn't receive your medication when it was due as you were off the ward having an x-ray, and we didn't remember to give it to you when you returned. I'm very sorry. Please tell us if this has caused you any concern or if there is something that we may have missed. We will need to keep a close eye on your blood sugar levels for the next few hours, and we may need to give you some extra medication this afternoon. Please let us know if you are feeling unwell or 'not quite right'."
- > Young child: "Ms Tan, your daughter Julie didn't receive her medication when it was due as she was off the ward having an x-ray. We didn't remember to give it to her when she returned. I'm very sorry. We will need to keep a close eye on Julie for the next few hours. Please let us know if there is something that we have missed, or if you or Julie's other family members notice anything or have any concerns about Julie's condition while you are here."

An apology during clinician disclosure when it is likely that formal open disclosure will be required and the facts may not be known yet:

- "Mr Suzuki, we are very sorry that this has happened. It is clear that something went wrong and we are investigating it right now. We will give you information as it comes to hand. It is very important for us to understand what happened from your point of view. We can go through this now if you like, or we can wait until you are ready to talk about it."
- "Mr Brown, there has been a problem with your medication and you have told me that the pain has been quite bad. I'm very sorry that this has happened and that your pain has not been controlled well. Please tell me about what happened from where you stand? We are not exactly sure what happened at present, but we will investigate to find out and will give you more information as it becomes available. For now, we have adjusted your medications and will ensure that you receive them when you need them. Please let us know if your pain increases or if you notice that anything else is not right."
- "Mr Malouf, shortly after your wife Mrs Malouf was given a medication through her IV drip, the nurse noticed that she experienced trouble breathing and developed a red rash over her body. The nurse called the senior nurse for help. The senior nurse made an emergency call and while she was doing this, Mrs Malouf stopped breathing. We resuscitated her and she is resting comfortably and being monitored closely. Something serious appears to have happened and we are investigating it now. I am sincerely sorry that this has happened. To help us find out what caused the incident, it would be helpful if you could tell us what you saw or perceived. We can go through this when you are ready to talk about it."

> 15 year old patient: "Hello Sarah. We need to speak with you about the plaster cast on your right wrist. Is it OK with you if we include your parents in this discussion?"

(If Sarah agrees): "Sarah, when we were checking the x-ray of your right wrist after applying the plaster cast, we noticed that the cast had been applied to the wrong wrist. As you know it is your left wrist that you broke after falling off your skateboard. I'm so sorry about this. We're not sure how this happened and are trying to find out now. Is there anything that you or your parents noticed and can tell us that may help us to understand what happened?

We'll shortly apply the plaster cast to your left wrist and remove the cast from your right wrist. There should be no long term consequences and you should be able to go home in the next few hours. We'll continue your pain relief. Please let me know if you have any concerns or questions. After we've investigated how this happened, we'd like to meet with you and your parents again to discuss the results of the investigation. Once again, I'm very sorry that this has happened."

An apology when a patient has died as a result of a patient safety incident:

Initial clinician disclosure discussion – acute care setting

"Ms Lim, I am very sorry about the death of your father Neil. At this stage we are not sure exactly what happened that has resulted in his death. What we do know is that after his fall yesterday he was assessed by the medical and nursing staff and showed no apparent signs of injury.

Last evening he ate all his dinner and was talking to the other men in his room.

However, when the nursing staff went to wake him this morning for his breakfast, he did not respond to them. Despite urgent medical attention, he did not improve and died not long after you arrived. I am so sorry.

We will be investigating the matter extensively and will of course keep you informed throughout.

Is there anything that we should know about your father's condition over the past day – anything that you've noticed or were not sure about?

You may have some questions you would like to ask and I will try to answer them as best I can. If you would prefer to wait for your family or to meet later today please let me know. Here is my telephone number, or you can ask the nurse in charge to contact me."

Initial clinician disclosure discussion – Mental Health in-patient:

"I am so sorry Mr Napier about the death of your daughter Leanne. At this stage we are not sure exactly what happened that has resulted in her death. As you know, she has been receiving treatment for severe depression for several months. Over the last few weeks Leanne had seemed to improve.

This afternoon she didn't come to her appointment with me. When we looked for her, one of the nurses found her in the TV room. Leanne had a number of deep cuts to her arms and had lost a lot of blood. The nurses gave her emergency treatment and she was transferred by Ambulance to the teaching hospital.

Sadly, Leanne did not respond to the treatment and died shortly after arriving at Hospital X.

I am so very sorry.

We will be investigating the matter extensively and of course will keep you informed throughout.

Is there anything that we should know about your daughter's condition over the past few days – anything that you noticed or were not sure about? You may have some questions you would like to ask and I will try to answer them as best I can. If you would prefer to wait for your family or to meet later today please let me know. Here is my telephone number, or you can ask the nurse in charge to contact me."

Formal open disclosure – follow up discussion after the investigation has been completed:

"Ms Oakley, your husband, John, was given an injection of penicillin shortly before his death. We found notes in his medical records that he was allergic to penicillin, but the person who gave the injection did not see the notes. I am so sorry that this happened. I cannot imagine the distress that this has caused to you and your family. If you are able, I'd appreciate it if you could tell me about things from your point of view.

We have spoken several times since John's death. Now that we have the results of the investigation we can go through the findings if you wish, and you may have questions you would like to ask. I will try to answer them as best I can.

As a result of the investigation and the recommendations, our hospital is reviewing the ways in which we signal that a patient has an allergy. We are examining how leading hospitals from across Australia and internationally highlight allergies that a patient may have. If you wish, we will keep you and your family informed about our progress and the changes that result to our system so that this terrible incident does not happen to anyone else.

We understand that this does not bring your husband back. The changes to our system will serve to prevent this from happening to any patients in the future."

GENERAL PRINCIPLES AND REQUIREMENTS FOR OPEN DISCLOSURE

The NSW Health Open Disclosure Policy PD2014_028 determines that the roles and responsibilities of all clinicians include:

- > completing education about open disclosure
- ensuring that the patient is safeguarded from further harm following a patient safety incident
- apologising to a patient and/or their support person(s) 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 and associated open disclosure is recorded in the patient's health care record and the incident management system.

The Policy also sets out the specific responsibilities of senior clinicians, directors of clinical governance, managers with operational responsibility at facility/service level, department heads, open disclosure coordinators and open disclosure advisors.

The mandatory requirements outlined in the NSW Health Open Disclosure Policy are derived from the Australian Open Disclosure Framework⁴¹ 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, for as long as required, to appropriately support the patient and their support person(s) and health care staff involved in the patient safety 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 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 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 one of the following⁴²:

- 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 respects and is responsive to 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 health care team where feasible.
- 5. Providing support to health care staff when they have been involved in a patient safety incident which respects and is responsive to their needs and expectations, in an environment in which all staff are:
 - encouraged and able to recognise and report patient safety incidents
 - prepared through training and education to participate in open disclosure

⁴¹ Australian Commission on Safety and Quality in Health Care (ACSQHC) Australian Open Disclosure Framework, Sydney, 2013

^{42.} NSW Ombudsman Apologies – A practical guide 2nd edition, Sydney, 2009

- 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 health care is provided by multidisciplinary teams.
- 8. Compliance with legal and ethical requirements for privacy and confidentiality for the patient and/or their support person(s), and health care facility staff.

CHECKLISTS AND OTHER RESOURCES

CLINICAL EXCELLENCE COMMISSION

The following Checklists to support open disclosure practice are included in this section and can be downloaded from the Open Disclosure page on the CEC website: www.cec.health.nsw.gov.au

- > CHECKLIST A: CLINICIAN DISCLOSURE this checklist may be useful for identifying the steps to be completed for the initial clinician disclosure discussion with a patient and/or his/her support person(s).
- > CHECKLIST B: PREPARATION FOR FORMAL OPEN DISCLOSURE this checklist may be helpful for identifying tasks to be completed or delegated when preparing for a formal open disclosure discussion with a patient and/or his or her support person(s).
- > CHECKLIST C: THE OPEN DISCLOSURE
 TEAM MEETING this checklist may be useful
 for identifying tasks to be completed or delegated
 during a meeting of the open disclosure team in
 preparation for a formal open disclosure discussion.
- > CHECKLIST D: FORMAL OPEN DISCLOSURE DURING THE DISCUSSION this checklist may be useful for identifying important points to address in a formal open disclosure discussion with the patient and/or his or her support person(s).
- CHECKLIST E: FORMAL OPEN DISCLOSURE COMPLETION – this checklist may be useful for identifying important points to consider when completing formal open disclosure.

Additional resources available from the Open Disclosure page on the CEC website include:

- > CHECKLIST: ORGANISATIONAL READINESS FOR OPEN DISCLOSURE
- > GUIDE TO OPEN DISCLOSURE FOR MANAGERS RESPONSIBLE FOR INSURABLE RISK
- OPEN DISCLOSURE POLICY PD2014-028 DIFFERENCES BETWEEN FORMER AND CURRENT POLICIES

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE (ACSQHC)

www.safetyandquality.gov.au/our-work/open-disclosure/

To support the Australian Open Disclosure Framework, the ACSQHC has developed a range of resources for clinicians and health care providers, health service organisations and consumers.

CLINICIAN DISCLOSURE CHECKLIST 'A' – STEPS FOR THE INITIAL DISCUSSION

This checklist may be useful for identifying the steps to be completed for the initial clinician disclosure discussion with a patient and/or his or her support person(s).

Health professional (s) to speak with the patient and/or their support person as soon as possible, at the latest within 24 hours of the patient safety incident	
Assess the need for and arrange support for the patient and/or their support person e.g. social worker, patient safety representative, health care interpreter	
Hold the initial discussion with the patient and/or their support person(s) SORRY • Acknowledge what happened, explain known facts of the incident	
 Applogise for the incident "I'm sorry that this has happened" Acknowledge the consequences for the patient and/or their support person 	
TELL ME ABOUT IT: encourage the patient and/or their support person to relate their experience of the patient safety incident, its impact and what is needed from their perspective. Listen and respond appropriately.	
ANSWER QUESTIONS: honestly, without speculation or blame	
RESPONSE: Discuss what happens next with the patient and/or their support person • The plan for ongoing care (if required) • Follow up (if required)	
 Lessons learned – how the incident will be investigated and managed, to prevent recurrences 	
SUMMARISE: the key points of the discussion and the next steps	
Provide the patient and/or their support person with the relevant person's name and contact details should they have any concerns or questions	
Document in the patient's health record that clinician disclosure has occurred, including	
 a confirmation that an apology was provided a brief outline of the information provided to the patient and/or their support person future steps to be taken (if required) 	
Record that clinician disclosure has occurred in the incident management system	
Notify insurers, if appropriate, via managers responsible for insurable risk (e.g. TMF, professional indemnity insurers)	
Assess whether a formal open disclosure response is required	
Provide the patient and/or their support person with information about how to provide feedback or make a complaint should they wish	
If required, provide the patient and/or their support person with further information about the formal open disclosure process	
If required, document activation of formal open disclosure in the incident management system and the patient's health record	

For more detailed information please refer to the Clinician Disclosure section of the CEC Open Disclosure Handbook www.cec.health.nsw.gov.au

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FORMAL OPEN DISCLOSURE CHECKLIST 'B' – PREPARATION

This checklist may be useful for identifying tasks to be completed or delegated when preparing for a formal open disclosure discussion with the patient and/or his or her support person(s)

Notify all relevant people about the patient safety incident: health care staff involved in the patient safety incident, Clinical Governance Unit, Senior Executive
Consider legal and insurance issues for the organisation and the clinicians – notify the relevant people
Appoint an open disclosure coordinator
Contact an open disclosure advisor
Establish a formal open disclosure team – multidisciplinary: senior clinicians and executive, open disclosure advisor. Determine who will lead the discussion with the patient and/or support person
Hold the team discussion: consider using Checklist C to guide preparation for the team meeting
Be aware of your emotions and those of other health care staff participating in the discussion – seek support or advice from the open disclosure advisor/experienced colleagues if necessary
Anticipate the patient's and/or their support person's concerns and questions about the formal open disclosure discussion, and prepare appropriate responses
Liaise with patient and/or their support person to arrange: ☐ the date, time and location for discussion ☐ who they would like to be present ☐ any additional support required e.g. interpreter, aboriginal liaison officer, social worker, spiritual support
Follow local processes for early reimbursement of out of pocket expenses to the patient and/or support person
Review the clinician disclosure discussion
If possible, establish the patient's and/or support person's understanding of the incident before the formal open disclosure discussion
Check if the patient (if able) has consented/agreed to sharing information with their support person(s), family members, others
Locate a quiet , private area to hold the discussion, free from interruptions
Prepare any information for the patient and/or their support person in an appropriate format
Establish whether there has been any involvement of the media, and if so, what actions are required
Document activation of formal open disclosure in the patient's health record and the incident management system

For more detailed information please refer to the Formal Open Disclosure section of the CEC Open Disclosure Handbook www.cec.health.nsw.gov.au

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FORMAL OPEN DISCLOSURE CHECKLIST 'C' – OPEN DISCLOSURE TEAM MEETING

This checklist may be useful for identifying tasks to be completed or delegated during a meeting of the open disclosure team to prepare for a formal open disclosure discussion with the patient and/or support person(s)

Please notify the Clinical Governance Unit when planning a formal open disclosure discussion.	
	All relevant health care staff involved in the patient safety incident have been notified/consulted
	Notify and invite the open disclosure advisor to the disclosure team meeting
	Identify the person(s) responsible for the disclosure conversation with the patient and/or their support person(s). Where possible, this person will: • be known to the patient • be familiar with the incident and care of the patient • have good interpersonal and communication skills • be willing to offer an apology to the patient and/or support person(s) • be willing to maintain a close relationship with the patient • have received open disclosure training
	Team discussion to include: Which team members will attend the discussion with the patient and/or support person Determining who will be the liaison/contact person for the patient/support person(s) Establishing and agreeing on known facts and sequence of events: avoid opinion, speculation or blame The known impact/s for the patient and/or support person(s) Steps being taken to manage the impact and consequences of the incident What to include in the apology and who will provide it Encouraging/inviting the patient and/or support person to give their perspective of the incident An early offer of reimbursement of out of pocket expenses, and who will raise this with the patient/support person Anticipating potential questions from the patient and/or support person and considering answers What key messages need to be conveyed to the patient and/or support person(s) and health care staff involved in the incident and/or the formal open disclosure discussion
	☐ Advice to provide on complaints process or legal action if indicated

For more detailed information please refer to the Formal Open Disclosure section of the CEC Open Disclosure Handbook www.cec.health.nsw.gov.au





FORMAL OPEN DISCLOSURE CHECKLIST 'D' – DURING THE DISCUSSION

This checklist may be useful for identifying important points to address in a formal open disclosure discussion with the patient and/or support person(s). If there is more than one discussion, not all steps may be required for follow up.

Please notify the Clinical Governance Unit when planning a formal open disclosure discussion.	
	Use language and terminology that is appropriate for the patient – avoid jargon. If using this checklist during the discussion, explain the reason to the patient/support person
	Assess the need for and as required, arrange support for the patient and/or their support person e.g. social worker, patient safety representative, health care interpreter
	Introduce the participants to the patient and/or their support person(s), their roles and reasons for attending
	Acknowledge and apologise: Acknowledge what happened – known facts Apologise for the patient safety incident "I am/we are sorry that this has happened" Acknowledge the consequences for the patient and/or their support person
	Explain the formal open disclosure process, including: The process for investigating the incident and timelines The patient and/or support person will be able to contribute to the investigation How the patient and/or support person will be kept informed What the formal open disclosure process does not include Any restrictions on information that is able to be provided and the reasons
	Invite the patient and/or support person to tell of his/her experience of the incident, its impact and what is needed from their perspective.
	Listen and respond appropriately
	Describe the facts of the patient safety incident and any outcomes known at the time
	Provide the findings of any review or investigation that are able to be shared
	Discuss and agree on a plan for care for the patient and/or his/her support person: Ongoing care and support (if required) addressing short and long term consequences Names and contact details for people/services who will be providing care Information on the patient's right to continue his/her care elsewhere if preferred Information on how to take the matter further, including complaint or legal processes available to him/her Offers of practical and emotional support as needed An offer to reimburse out of pocket expenses
	Review with the patient and/or support person(s) and health care staff present what was discussed and any decisions made
	Provide the patient and/or support person(s), and health care staff involved in the incident and/or the open disclosure discussion, with a written record of the discussion and outcomes, including the plan for care
	Offer to arrange follow up discussions as required
	Provide the patient and/or their support person with the relevant name and contact details should they have any concerns or questions
	Document in the patient's health record that formal open disclosure has occurred and the date

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FORMAL OPEN DISCLOSURE CHECKLIST 'E' – COMPLETION

This checklist may be useful for identifying important points to consider when completing formal open disclosure.

The open disclosure team meet to review the formal open disclosure discussion with the patient and/or support person(s).
Prepare a summary of the formal open disclosure discussion. Consider the following points for inclusion: Date and location of the discussion Name of the patient and any support person/people present Members of the open disclosure team present: names and role Whether an apology was offered Response to the apology by the patient and/or support person(s) Information about the patient safety incident provided, including the investigation/review process Questions asked by the patient/support person and responses and explanations provided Offers of practical and emotional support and response from the patient/support person Offer to reimburse out of pocket expenses and response from patient/support person Information provided about how to take the matter further, including complaint or legal processes available Relevant person's name and contact details for the patient and/or support person should they have any concerns or questions Outstanding issues to be resolved Undertakings given that need to be followed through by the open disclosure team, such as Follow up discussions Providing a written record of the discussion to the patient and/or support person, and to health care staff who were present and/or involved in the incident Other issues raised that need addressing Final recommendations to the open disclosure team about further management of this incident
If resolution for the patient and/or support person has not been reached, provide information on alternative courses of action e.g. making a complaint via internal processes or HCCC
Notify the manager responsible for insurable risk if an offer has been made to the patient/support person to reimburse out of pocket expenses and the response from the patient/support person
Offer clinicians and others involved in the incident and/or the formal open disclosure discussion the opportunity to debrief with the open disclosure advisor or other support services
Offer to provide the patient /support person with a copy of the report of any investigation or review and to discuss/explain the findings
Offer patients, support people and clinicians/managers involved in open disclosure the opportunity to evaluate their experience of the process
Complete any documentation about the incident and open disclosure, in the incident management system, the patient's health record and the open disclosure records in the Clinical Governance Unit
Monitor and record the implementation of any changes recommended as a result of the review of the patient safety incident, and the effectiveness of those measures
Share any lessons learned from investigation of the patient safety incident at appropriate forums e.g. clinical grand rounds, morbidity and mortality meetings, executive and board meetings

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