FORMAL OPEN DISCLOSURE
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:

1. 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.

1. **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.

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

   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 addressed.

Information provided should include:

- 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
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 Report’.

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.

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22. NSW Health Incident Management Policy PD2014_004 Section 2.9.2
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:


☐ 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.