AUSTRALIAN COMMISSION
ON **SAFETY** AND **QUALITY** IN **HEALTH CARE**

NSQHS STANDARDS

Australian Open Disclosure Framework

Supporting materials and resources

Open disclosure: Just-in-time information for clinicians

Disclaimer

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1. Introduction

Over the past two decades, open disclosure has been recognised as a practice that can benefit patients and clinicians when care does not go to plan.

Open disclosure can be complex, challenging and difficult for all participants. However, its systematic practice can assist clinicians[1] to manage adverse events compassionately and provide broader benefits through:

- re-establishing trust in patient and clinician relationships
- improving clinical communication
- centering health care on the person
- learning from error by improving care delivery systems and processes.

1.1 What is the purpose of this resource?

This resource is designed to provide 'just in time' information for clinicians who will participate in open disclosure and may not have much experience in doing so.

It should not be used as an alternative to training and development for open disclosure leaders. It is also not an alternative to using local 'experts' to lead open disclosure and support less experienced colleagues during open disclosure.

This is a resource to supplement other organisational and national open disclosure resources. It is based on the *Australian Open Disclosure Framework* (the Framework) and is part of a suite of resource materials including:

- Open disclosure evaluation surveys
- Open disclosure checklist
- Saying sorry: a guide to apologising and expressing regret in open disclosure
- Open disclosure planning

All of these can be accessed at www.safetyandquality.gov.au/opendisclosure

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This resource provides information about open disclosure including:
a. a definition
b. key aspects of open disclosure practice
c. what to expect from each step in the open disclosure process.

2. Open disclosure: the basics

Modern health care is complex, delivered in high-pressure environments and often involves multiple practitioners working in teams and across organisations. Excellent outcomes are most often the result. However there are significant risks and, at times, things don't go to plan.

Adverse events and patient harm can, and do, occur.

Open disclosure describes the way clinicians communicate with, and support, patients and/or their families, carers or other support persons (from here on referred

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[1] Clinician is defined as "a healthcare provider, trained as a health professional. Clinicians include registered and non-registered practitioners or a team of health professionals providing health care who spend the majority of their time providing direct clinical care".

to as 'the patient and their support persons') who have experienced harm during health care. Open disclosure is a patient right, is anchored in professional ethics, considered good clinical practice, and is part of the care continuum.

Over the past two decades, open disclosure has been recognised as a practice that can benefit patients and clinicians involved in adverse events. Being open about adverse events also helps organisations learn and provide safer and higher quality care.

Open disclosure is complex, and can be challenging and difficult for all participants. However, its systematic practice can assist health service organisations to manage adverse events compassionately and provide broader benefits through improved clinical communication and systems improvement.

2.1 Definition of open disclosure

Open disclosure is the open discussion of adverse events that result in harm to a patient while receiving health care with the patient and their support persons. The elements of open disclosure are:

- an apology or expression of regret, which should include the words 'I am sorry' or 'we are sorry'
- a factual explanation of what happened
- an opportunity for the patient and their support persons to relate their experience
- a discussion of the potential consequences of the adverse event
- an explanation of the steps being taken to manage the adverse event and prevent recurrence.

It is important to note that open disclosure is not a one-way provision of information, although providing information to the patient is important as is hearing their view of events. Open disclosure is a discussion between two parties that may take place in several meetings over a period of time.

2.2 What is patient 'harm' and an 'adverse event'

The Framework uses the World Health Organization definition of harm:

> '[i]mpairment 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' [2]

'Adverse event' means an incident in which a person receiving health care was harmed. In this document it will also be used in the same way that 'harmful incident' is sometimes used to link adverse events specifically to open disclosure and accommodate various interpretations of harm and related issues such as preventability, expected complication and error.

This broader meaning is important because the patient's view on whether harm has been suffered may differ from the clinician's or health service organisation's view.

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[2] World Health Organization. The International Classification for Patient Safety WHO, 2009

3. The open disclosure process

The open disclosure process is covered in detail in Part B of the *Australian Open Disclosure Framework* and other supporting resources. These are available at www.safetyandquality.gov.au/opendisclosure

3.1 Detecting and assessing incidents

Adverse events can be detected in a variety of ways. These include formal incident reporting, patient complaints, review of the patient record and informally, for example, by a colleague or even a visitor or student. Formal mechanisms are known to miss adverse events from time to time

All adverse event reports should be followed up. The patient's treating clinicians should be informed as soon as possible and prompt clinical care should be provided as required.

The treating clinicians should perform preliminary investigations into what has occurred. This will most often include a discussion with the patient and their support persons.

You may be asked to participate in determining the level of response. Generally, responses are graded as lower- or higher-level. When assessing an incident it is important to remember that an adverse event does not always result in *physical* harm. See Appendix 1 for incident examples and suggested responses.

If you have been involved in an incident, your employer has an obligation to provide you with support. You should openly discuss how you feel about what has happened.

If you are not involved, you should observe your colleagues who have been involved for signs of emotional distress.

Key points: Detecting and assessing incidents
- Detect incidents through a variety of mechanisms
- Provide prompt clinical care to the patient to prevent further harm
- Assess the incident for severity of harm and level of response
- Provide support for staff
- Initiate a response, ranging from lower to higher levels
- Notify relevant personnel and authorities
- Ensure privacy and confidentiality of patients and clinicians are observed

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3.2 Signalling the need for open disclosure

The fact that something has happened should be acknowledged to the patient and their support persons as soon as possible, even if you and your colleagues don't yet know the full story.

Discussing the incident with the patient to gather a better picture of what happened will acknowledge the incident and reassure the patient that it is being taken seriously. Open disclosure research shows a relationship between timeliness of the initial response and positive outcomes. Delaying acknowledgement can be counterproductive.

The acknowledgement should include, in most cases, an apology or expression of regret including the word 'sorry'. Only in cases where it is very unclear whether an incident has occurred should an apology not occur.

Apologising is *not* an admission of liability or fault, but an ethical and humane act. However, you should be careful:

- not to apportion blame to anyone including yourself
- not to speculate as to the causes and effects of the incident
- to be professional, empathic and courteous.[3]

Examples of appropriate phrases during an apology

- *'I am/we are sorry for what has occurred'*
- Factual statements explaining how the incident occurred '*this incident occurred because the wrong label was mistakenly placed on your specimen sample'*
- Explaining what is being done to ensure it does not happen again '*we are currently investigating exactly what caused this breakdown in the process and will inform you of the findings, and steps taken to try to prevent recurrence, as soon as we know'*

Examples of phrases to avoid during an apology

- *'It's all my/our/his/her fault… I am liable'*
- *'I was/we were negligent…'*
- Any speculative statements.

See also Appendix 2: Examples of useful phrases for open disclosure discussions.

Lower-level responses for minor incident can conclude at this stage. The conclusion should always be noted in the patient record and a written summary provided to the patient.

For higher-level responses, the acknowledgement conversation signals that a formal open disclosure meeting will be convened. The time and place, as well as attendees and participants in the meeting, should be negotiated.

A health service contact should be provided to the patient and their support. This will be an employee whom can call for further information.

Key points: Signalling the need for open disclosure

- Acknowledge the adverse event to the patient and support persons including an apology or expression of regret
- Signal the need for open disclosure if a higher-level response is required
- Negotiate arrangements for the open disclosure meeting
- Provide a health service organisation contact
- Avoid speculation and blame

3.3 Preparing for open disclosure

The importance of preparation cannot be overstated.

Open disclosure can be a highly charged and emotional process and it is essential that you and your colleagues are prepared. One or more team meetings should be held where:

- it is decided who will lead the discussions and who will participate (see below)

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[3] For more information see the resource titled *Saying sorry: a guide to apologising and expressing regret in open disclosure* available at www.safetyandquality.gov.au/opendisclosure

- all the necessary facts are established and information is gathered
- the immediate support needs for everyone involved are identified
- the patient record is updated
- potential areas of conflict or disagreement are identified
- a basic plan or agenda is agreed upon
- consideration and discussion is given to how the incident is conveyed to the patient and their support, ensuring that all team members maintain a consistent approach in any discussions with the patient and their support
- engaging patient support is considered, including the use of a facilitator or a patient advocate
- consideration is given to:
  - legal and insurance issues, both for the organisation and the clinicians
  - issues regarding ongoing care such as billing and other costs, which should be addressed at the earliest opportunity.

While careful scripting is not recommended, it is a good to have a basic idea of what will be said (and how) to avoid saying something that may later need to be retracted (remembering that summaries of open disclosure discussions should be entered into the patient record).

It may be appropriate to practice or even rehearse some aspects of the conversation, such as the apology or expression of regret with the team.

See Appendix 2 for some examples of useful phrases during open disclosure.

However, caution is urged. While it is very important to be prepared, patients may not feel that the discussion in sincere if it comes across as too scripted.

3.3.1   Timing, location and attendees

The timing and location of open disclosure meetings should be decided in consultation with the patient and their support. Bear in mind that it may not be appropriate to conduct the open disclosure where the harm occurred.

The patient and their support should be consulted about which health service professionals will participate in the open disclosure meeting and may need time to consider these matters.

If it becomes apparent that the patient would prefer to speak to a different clinician(s) than those designated to lead the open disclosure, the patient's wishes should be respected and, if possible, an acceptable substitute provided.

> **Key points: Preparing for open disclosure**
> - Hold a multi-disciplinary, inter-professional team discussion to prepare for open disclosure
> - Consider which clinicians will participate and location of the meeting
> - Appoint an individual to lead the open disclosure
> - Gather all the necessary information

3.4   Engaging in open disclosure discussions

Participating in open disclosure meetings require that you remain professional but not distant or cold. Sometime this can be challenging in an emotionally strained situation. However, and in general, patients and their support persons will appreciate a 'human face'.

It is important for patients and their support to be heard and be able to convey their thoughts as it is for you and your colleagues to convey your information and an apology or expression of regret.

Below is a checklist of open disclosure tasks, in some of which you will be involved.

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Table 1: Open disclosure task checklist

Beginning the meeting
☐ Find a suitable place to hold the meeting, in consultation with the patient
☐ Turn off mobile telephones, beepers (if possible)
☐ Be conscious of positioning and body language
☐ Everybody is introduced and attendees names and titles are provided in writing
☐ Describe the purpose of the conversation
Listen and empathise throughout
☐ Assess the patient's understanding of what happened
☐ Identify the patient's key concerns
☐ Actively listen (repeat back in your own words what the patient is saying)
☐ Acknowledge and validate the patient's feelings
Apology / expression of regret
☐ The lead will say they are sorry for the adverse event in a sincere manner early in the conversation, even if an apology was provided in an earlier discussion
Explain the facts
What happened and the role of team members?
☐ Identify the adverse event early in the discussion
☐ Explain what happened in plain language
☐ Explain what is known about why the adverse event happened; **do not speculate on causes, or blame others**
☐ Tell the patient what should have happened
☐ Explain your role in the incident and the role of other members of the clinical team
☐ Do not blame others or 'the system'
☐ Depending on the nature of the incident (e.g. preventability) consider using the word 'error' or 'mistake' with your colleagues
What are the consequences?
☐ Explain how the short-term consequences will be treated or managed
☐ Explain how the event is likely to impact the medium, and long-term health care and what will be done to care for the patient
☐ Explain how billing and other cost of consequent care will be managed (if applicable)
☐ Explain what will be done to ensure that a similar event doesn't happen to others.
Closing the discussion
☐ Discuss the next steps and plan for a follow-up conversation
☐ Ask the patient if they have any questions and provide responses
☐ Provide the details of the health service contact in writing
Following up
☐ Provide a written summary of the meeting to the patient
☐ File a copy of this summary in the appropriate place, such as the patient record

3.5 Providing follow-up

Higher-level response open disclosure is a process and not a single discussion. Follow-up is important and may occur over a considerable period of time, even after the patient has been discharged.

Follow-up will be done by a senior staff member but it may be delegated to more junior staff depending on the circumstances. It is important that follow-up is active and not reactive.

It is important to ensure patients and their support persons have an opportunity to ask further questions and request further information. It is also important that agreement is reached on providing, or monitoring, ongoing care related to the incident.

Importantly, follow-up is an opportunity for the health service organisation to provide information on changes that been implemented as a result of an adverse event, and how the changes are improving patient safety. Patients respond very positively to their misfortune resulting in improved safety and better outcomes for others.

The patient and their support persons should be offered an opportunity to discuss the process with another relevant professional such as a general practitioner, residential care facility or community care provider.

> **Key points: follow-up**
> - Ensure follow-up by senior clinicians or management, where appropriate
> - Agree on future care
> - Share the outcomes of investigations and the resulting practice changes
> - Offer the patient and support persons the opportunity to discuss the process with another clinician

3.6 Completing the process

The open disclosure process concludes with shared agreement between the patient and their support, and the healthcare team. In the majority of cases, this will occur after the adverse event review or investigation is completed.

When the relevant review or investigation is complete, the patient and their support persons should be provided with feedback through face-to-face interview or equivalent (e.g. videoconference) and in writing. The interview and document should include:

- details of the incident, including the clinical facts and other relevant facts
- the patient's concerns or complaints
- an apology or expression of regret (including the word 'sorry') for the harm suffered
- a summary of the factors contributing to the adverse event
- information about what has been and will be done to minimise the risk of recurrence of the adverse event, and how these improvements will be monitored.

If further issues are identified after the process is completed, the patient and their support should have the opportunity to re-contact the open disclosure clinician for a response to their questions.

3.6.1 Communication with primary care providers

When the patient is leaving the care of an acute health service organisation, they should be asked if they agree to a discharge letter being forwarded to their general practitioner, residential facility or community care provider.

Where possible these providers should also be telephoned.

3.6.2 Unable to reach agreement

Sometimes the relationship between the patient, and their support, and the healthcare team can break down. It is important that this not be seen as failure if all of the necessary steps and components of open disclosure are followed.

In these situations it is important to try to rebuild patient trust. The following strategies may assist:

- Deal with the problem earlier rather than later.
- With the patient's agreement, ensure that their family and support persons are involved in discussions from the beginning.
- Ensure the patient and support persons have access to support services.
- To ensure the appropriate staff member (e.g. a senior clinician) is aware of a potential relationship breakdown, communicate early warning signs.
- Offer the patient and support persons another health service contact with whom they may feel more comfortable. This could be another member of the treating team or personnel responsible for clinical risk.
- Use a mediation or conflict resolution service to help identify the issues between the health service organisation and the patient and support person and to look for a mutually agreeable solution.
- Involve the services of the local health complaints office if the patient and their support persons want to lodge a formal complaint.
- 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 their support persons.

Key points: Completing the process

- Reach an agreement on completing the process or provide an alternative course of action
- Provide the patient or support persons with final written and verbal communication including investigation findings
- Communicate the details of the adverse event and outcomes of the open disclosure process to other relevant clinicians

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3.7 Maintaining documentation

Documentation and evaluation of open disclosure are essential parts of the process. In terms of documenting open disclosure:

- patient record must be kept up to date
- a record of the open disclosure process must be maintained

- documents relating to the open disclosure process should be filed in the patient record
- the patient should be provided with documentation throughout the process.

Evaluation is important from a quality improvement and assurance point of view. Patients and their support should be offered an evaluation survey, which may need to be administered face-to-face.

Staff involved in open disclosure should complete a staff survey.

Information derived from the surveys will be aggregated and used to continually improve open disclosure processes at your organisation.

Key points: Maintaining documentation

- Keep the patient record up to date

- Maintain a record of the open disclosure process

- File documents relating to the open disclosure process in the patient record

- Provide the patient with documentation throughout the process

- Complete the evaluation surveys

Appendix 1: Lower and higher level open disclosure responses

Table A1: Criteria for determining the appropriate level of response

	Criteria
Lower-level response	1. Near misses and no-harm incidents 2. No permanent injury 3. No increased level of care (e.g. transfer to operating theatre or intensive care unit) required 4. No, or minor, psychological or emotional distress
Higher-level response	1. Death or major permanent loss of function 2. Permanent or considerable lessening of body function 3. Significant escalation of care or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care, or transfer to intensive care unit) 4. Major psychological or emotional distress 5. At the request of the patient

Table A2: Potential responses to various situations and incidents

Incident type	Response
1. Harm from natural progression of condition or disease process *e.g. a treatment for cancer was unsuccessful*	**Discuss and explain** *(lower-level)*
2. Complication or natural disease progression a. Anticipated by patient/family via education and consent process b. Not anticipated by patient/family via education and consent process (**go to 3**) *e.g. patient not adequately informed of the possibility of respiratory complications of general anaesthesia and feels that this would have altered their decision to proceed with treatment*	**a. Discuss and explain** *(lower-level)* **b. Open disclosure** *(higher or lower- level depending on severity)*
3. Patient harm/adverse event *e.g. Adverse drug event (wrong dose medication)*	**Open disclosure** *(higher or lower-level depending on severity and impact on patient)*
4. Clinical ('no harm') incident: reaches patient but no harm *e.g. Medication error (no/minimal effect on patient)*	**Generally disclose** *(lower-level)*
5. Clinical ('near miss') incident: does not reach patient *e.g. an intercepted wrong-patient biopsy*	**Team decision based on:** • context • circumstances • potential ramifications *(lower-level)*
6. Patient perception or report of harm *e.g. patient perception of delay in diagnosis resulting in poor patient outcome*	**Discuss and agree on appropriate form of disclosure** *(higher or lower- level)*

Appendix 2: Useful phrases for open disclosure discussions

The open disclosure process does not need to be a tightly scripted. However, it is important to practise the words you will use so you feel comfortable and natural with the language when the need arises, without appearing to be rehearsed, defensive or concealing,

The following text provides phrases to use with the patient in an open disclosure conversation.[4]

- *'Let me tell you what happened. There has been a significant lapse in quality and we failed to follow up with you and tell you about your diagnosis.'*

- *'Let me tell how sorry I am that this has happened.'*

- *'I want to discuss with you what this means for you, but first I'd like to apologise.'*

- *'I want to discuss with you what this means for your health.'*

- *'I'm sorry, this shouldn't have happened. Right now, I don't know exactly what happened, but I promise you we're going to find out and do everything we can to make sure it doesn't happen again.'*

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[4] Adapted from: RACGP. *Regaining trust after an adverse event. An education module on managing adverse events in general practice.* 2008, Melbourne

- *'I will get back to you as soon as we know what happened and we can talk about the steps we will take to prevent it happening again.'*

- *'Our organisation takes this very seriously and we will look into it to find out exactly what happened and what we can do to prevent it happening again.'*

- *'Do you have all the information you need? I'm here if you have any other questions.'*

- *'I know it's hard to take it all in so I'm happy to go over this again another time.'*

- *'Would you like us to contact you to set up another meeting to talk about what has happened and answer any questions you may have?'*