

Manual: Corporate Policy and Procedure Document ID: 2.37

Section: Clinical Administration Internet location: Risk and Quality

1 PURPOSE AND SCOPE

a) Open Disclosure encourages health care workers to acknowledge that an adverse event has occurred and to provide an apology or expression of regret for what has occurred. This is not an admission of liability. However, there is a need to be aware of the risk of making an admission of liability during the open disclosure process. This policy provides guidance on what to say and what not to say to patients and their families when implementing open disclosure, and highlights related potential legal concerns.

- b) The objectives of the Open Disclosure policy are to:
 - 1. Establish a framework for communicating with patients and their family and carers, and other stakeholders after an incident.
 - 2. Ensure that communication with, and support for, affected patients and their family and carers, occurs in an empathetic and timely manner.
 - 3. Ensure that Healthe Care facilities have established consistent open disclosure processes.

2. TO WHOM DOES THIS POLICY APPLY?

All Healthe Care staff and Visiting Medical Officers

3. DISTRIBUTION OF POLICY

Prior to the implementation of the policy, all clinical staff and Visiting Medical Officers will be made aware of the policy at board, national and local staff meeting levels and the policy will be made available on the Healthe Care Intranet site.

4. POLICY

The Healthe Care policy on Open Disclosure:

- a) Supports a philosophy of open discussion with the patient, and with the patients consent, their nominated relative/carer of event/s that result in unintended, unplanned or unanticipated harm to a patient whilst receiving health care at any Healthe Care Hospital/Health Service.
- b) Purports the intent of the Australian Open Disclosure Framework Better communication, a better way to care: Australian Commission on Safety and Quality in Health Care, 2013.
- c) Ensures that Visiting Medical Officers (VMO's), consumers and staff function in accordance with the Healthe Care philosophy of open disclosure whilst taking into account the rights of all the parties concerned
- d) At all times complies with relevant legislation, statutory and Healthe Care's Insurance Policy obligations
- e) Open disclosure must not commence without prior discussion with Healthe Care's In-House Legal Counsel and the National Risk and Compliance Manager.

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5. PROCEDURE

5.1. KEY PRINCIPLES

All Healthe Care facilities practicing open disclosure will do so in accordance with the following Australian Open Disclosure Framework's eight guiding principles:

- Open and timely communication
- Acknowledgement
- Apology or expression of regret
- Supporting, and meeting the needs and expectations of patients, their family and carers
- Supporting, and meeting the needs and expectations of those providing health care
- Integrated clinical risk management and systems improvement
- Clinical governance
- Confidentiality

5.1.1. Open and timely communication

The patient, and with the patient's consent, their nominated relative/carer should be provided with information about what happened in a timely, open and honest manner. The open disclosure process is fluid and will often involve the provision of ongoing information.

5.1.2. Acknowledgement

All adverse events should be acknowledged to the patient, and with the patient's consent, their nominated relative/carer as soon as practicable.

5.1.3 Apology or expression of regret

A patient, and with the patient's consent, their nominated relative/carer should receive a sincere and unprompted apology or an expression of regret for any harm that they have suffered as a result of a clinical incident. An apology or expression of regret should include the words 'I am sorry' or 'we are sorry', but **must not** contain speculative statements, any admission of liability or fault *(we risk breaching our insurance policy and indemnity for any future claim)* or apportioning of blame.

5.1.4. Supporting, and meeting the needs and expectations of patients, their family and carers

- a) When a clinical incident has occurred, the patient is entitled to be treated with empathy, respect and compassion and to receive appropriate, ongoing support in a manner appropriate to their needs.
- b) The patient, their family and carers are to be given an opportunity to relate their experience.
- c) A patient, and with the patient's consent, their nominated relative/carer may reasonably expect to be fully informed of the known facts surrounding the clinical incident and its consequences in a way that ensures they understand the information, and considers any relevant information related earlier by the patient, family and carers, speculation should be avoided.
- d) The patient has a right to complain or comment about the quality of their care. The facility should provide appropriate information and assistance in relation to the complaint process as per

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Healthe Care's Complaint Management Policy (1.05). Where possible, a designated hospital/facility staff member should be assigned to assist and coordinate the provision of any ongoing support to the patient and his/her nominated relatives/carers.

e) Incompetent adults and minors support

- If a patient involved in a clinical incident is deemed to be incompetent, the patient's legal guardian should be fully informed of the facts surrounding the clinical incident and its consequences for the patient. If a guardian has not been appointed, efforts should be made to involve the patient's spouse/defacto partner, nearest living relative, or support person with a close relationship to the patient in the Open Disclosure Process if the matter is related to consent. Otherwise, legal advice should be sought (refer to Healthe Care's Claims Management (1.08) and Incident Management Protocols (2.04).
- If the patient involved in a clinical incident is a minor, the patient's parents should be involved in the Open Disclosure Process. If the patient was deemed to be a mature minor during the consent to treatment process, the patient should also be deemed to be a mature minor during the Open Disclosure Process. A mature minor is entitled to be fully informed of the facts surrounding the clinical incident and its consequences, and consent is required before the clinical incident is disclosed to their parents.

5.1.5. Supporting, and meeting the needs and expectations of those providing health care

Members of the clinical team are encouraged to report adverse events and should receive appropriate support from the Healthe Care hospital/facility when a clinical incident occurs. The clinical team should also receive appropriate training in communication and the principles of open disclosure, and supported through the open disclosure process.

5.1.6. Integrated clinical risk management and systems improvement

Thorough clinical review and investigation of adverse events and adverse outcomes should be conducted through processes that focus on the management of clinical risk and quality improvement. Findings of these reviews should focus on improving systems of care and be monitored and reviewed for their effectiveness. The information obtained about incidents from the open disclosure process should be incorporated into quality improvement activity.

Effective communication with staff is a vital step in ensuring that recommended changes are fully implemented and monitored. It will also increase awareness of patient safety and the value of open disclosure.

5.1.7. Clinical governance

Open disclosure is a key element of Healthe Care's Clinical Governance Framework. Facilities are required to establish appropriate accountability systems that integrate the Open Disclosure Process with other Healthe Care clinical governance processes, including clinical incident management and reporting processes, clinical risk management procedures and quality improvement processes. Through these systems, adverse events should be investigated and analysed to prevent them recurring and should include internal performance monitoring and reporting.

5.1.8. Confidentiality

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a) Due to the sensitive nature of the information collected during the investigation and analysis of a clinical incident, facilities and their staff are obligated to maintain the privacy and confidentiality of patient information. Facilities are to comply with Healthe Care's [Confidentiality (2.02) & Privacy Policy (2.01)] policies and procedures that take into account privacy and confidentiality for patients and staff, in compliance with relevant law.

b) Where an investigation (e.g. a Root Cause Analysis) was conducted under Statutory Privilege, there are restrictions on the information that can be disclosed (see Healthe Care's Incident Management Policy (2.04).

5.2 Fairness

- a) When a clinical incident occurs and the Open Disclosure Process is initiated, patients and health practitioners have the right to be treated fairly. Facilities will establish a process to communicate and support patients and health practitioners when a clinical incident occurs (refer to Healthe Care's Critical Debriefing Policy (4.06) and Employee Assistance Program Policy (4.08).
- b) Additionally, clinical incidents will be investigated in accordance with Healthe Care's incident and complaint management policies, and system failures corrected to improve patient safety. Health practitioners are entitled to procedural fairness (the right to a fair and unbiased hearing including the right to be informed of all relevant information and the right to respond to the information) in the investigation of a clinical incident.

5.3 Initial disclosure to the patient

- a) The Open Disclosure Process is part of ongoing communication between the facility and the patient. Consultation with the nominated relatives/carers of the patient may only take place with the **consent** of the patient.
- b) The initial disclosure to the patient should occur as soon as possible, ideally within 24 hours of the clinical incident occurring, even if all the facts are not yet known. However, the length of time required to conduct the Open Disclosure Process will be dependent on a number of factors, including:
 - the clinical condition, emotional and psychological state of the patient
 - the availability of reliable clinical information
 - the availability of key staff and of the patient's relatives/carers
 - patient preference and privacy.
- c) When preparing for the initial meeting, facility staff should take into account the following issues:
 - Identify whether the clinical incident needs to be disclosed (refer to 5.2.1).
 - Identify who will be responsible for leading the Open Disclosure Process with the patient.
 - Ensure that all team members maintain a consistent approach in any discussions with the patient and or their nominated relatives/carers.

5.3.1 Identify whether the clinical incident needs to be disclosed

a) As a matter of policy, patients must be informed of the probable or definite occurrence of a clinical incident that has resulted in, or is expected to result in, harm to the patient, including the following:

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- 1. A defined Sentinel Event that is reportable to the relevant state jurisdiction's Department of Health / Private Health Care Branch and the Healthe Care Broker (refer to Healthe Care's Incident Management Policy Reportable Incident Reports page 15).
- 2. A clinical incident that has or is expected to have a significant clinical effect on the patient and that is perceptible to either the patient or the health care team. For example, if a patient is mistakenly given a dose of frusemide (a diuretic that noticeably increases urine output), disclosure is required because a perceptible effect is expected to occur.
- 3. A clinical incident that necessitates a change in the patient's care. For example, a medication error that necessitates close observation, extra blood tests, extra hospital days, or follow-up visits that would otherwise not be required, or an error in a surgical procedure that necessitates additional/extra (corrective) surgery.
- 4. A clinical incident with a known risk of serious future health consequences, even if the likelihood of that risk is extremely small. For example, accidental exposure of a patient to an infection or toxin associated with a rare, but recognised serious long-term effect (e.g. HIV infection or increased incidence of cancer).
- 5. A clinical incident that requires facility staff to provide treatment or undertake a procedure without the patient's consent. For example, if a clinical incident occurs while a patient is under anaesthesia, necessitating a deviation from the procedure the patient expected, the clinical incident needs to be disclosed. Patients have a fundamental right to be informed about all aspects of their treatment.

5.3.2 Identify who will undertake the disclosure

- a) When a clinical incident occurs and requires disclosure, members of the treating team should determine who the most appropriate person is to speak to the patient. The person undertaking the Open Disclosure Process should:
 - ideally be known to the patient (however it may not always be practical for a health care practitioner, who is involved in a clinical incident, to lead the Open Disclosure Process);
 - · be familiar with the facts of the clinical incident and the care of the patient;
 - be familiar with HCA's Open Disclosure Policy and have received appropriate training in the Open Disclosure Process;
 - possess sound interpersonal communication skills;
 - be empathetic and able to offer reassurance and support to the patient;
 - be willing to maintain a medium to long-term relationship with the patient, as required.
- b) Ideally, the responsible Visiting Medical Officer (VMO) as the most senior member of the team will undertake the Open Disclosure Process. However, each facility may delegate this responsibility to an appropriate facility manager or another member of the treating team.
- c) A junior medical practitioner or a nurse will not perform the Open Disclosure Process.
- d) The facility staff member must refuse to undertake the delegated task if they do not consider they have sufficient skill or experience. Decisions made by a facility staff member, including a junior medical practitioner or a nurse in this regard, must be respected by the facility's executive management.

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5.3.3 Determine how the Open Disclosure Process will be conducted

a) The Open Disclosure Process is part of an ongoing communication process between the facility and the patient. Information should be prepared for the patient and their family and carers in an appropriate format. Assess whether there are any cultural considerations or special circumstances which may impact on the open disclosure meeting.

- b) At the first face-to-face discussion with the patient, the nominated leader of the open disclosure team should:
 - 1. Introduce all people attending the meeting, including their role.
 - 2. Explain the open disclosure process
 - 3. Acknowledge that a clinical incident has occurred
 - 4. Disclose all known facts and consequences, as documented in the patient's medical record, outlining the chronology of clinical and other events.
 - 5. Provide information of likely short-term and long-term effects if known (however this information may need to be deferred to a second or subsequent meeting).
 - 6. Offer an apology or provide an expression of regret for the event that has occurred (when making an expression of regret avoid admitting liability for what has happened).
 - 7. Listen to the patient's understanding of what happened and address any questions or concerns they may have.
 - 8. Review the care plan, outlining what will happen next (e.g. return to operating theatre, need for more investigations, and referral to another specialist) and the steps being taken to prevent recurrence.
 - 9. Offer support to the patient, as required.
 - 10. Provide the patient with contact details for the relevant health care practitioner (or an agreed substitute) to discuss further issues.
 - 11. Provide information to the patient about how to take the matter further, including any complaint processes available to them.
- b) Due to the length of time that may be required to undertake a thorough investigation of the clinical incident, not all of the facts may be known or available to facility staff at the time of the first meeting. If necessary, the nominated facility staff member should arrange further meetings with the patient. Facility staff must ensure that they only disclose the facts known at the time of each meeting.
- Facility staff must ensure that appropriate ongoing care and support is provided to the patient for as long as is required.

5.3.3a) Admissions of liability

When undertaking the Open Disclosure Process, facility staff must not make an admission of liability. An admission of liability may occur where a facility staff member states or agrees that:

- they are liable for the harm caused to the patient or that they were negligent
- another health care practitioner is liable for the harm caused to the patient or was negligent
- the facility is liable for the harm caused to the patient or was negligent.

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EXAMPLE: 1

The following example illustrates the difference between a statement of fact and an admission of liability:

Statement of fact: "You were told that you had breast cancer and a mastectomy was performed. Test results of the breast tissue show that there was no cancer in the breast that was removed".

Admission of liability: "I made a terrible mistake. I removed your breast but now we know that you didn't have breast cancer. It is all my fault".

5.3.3b) Expressing regret for what has happened

During the Open Disclosure Process, a facility may provide an apology for what has happened.

Protected apologies legislation varies greatly between states in respect of the degree of protection it provides and how it defines an apology, particularly whether it defines apology to include an admission of fault. See the table on the next page.

Apology provisions in Australian States and Territories

State/Territory	Fault included	Legislation
Australian Capital Territory	Yes	Civil Law (Wrongs) Act 2002
New South Wales	Yes	Civil Liability Act 2002
Northern Territory	No	Personal Injuries (Liabilities and Damages) Act 2003
Queensland	No	Civil Liability Act 2003
South Australia	No	Civil Liability Act 1936
Tasmania	No	Civil Liability Act 2002
Victoria	No •	Wrongs Act 1958
Western Australia	No	Civil Liability Act 2002

When expressing regret, the facility must ensure that it does not make any acknowledgement of fault/liability, otherwise the protection conferred by the *relevant state legislation and Healthe Care's Insurance policies* will be lost. Our Insurer/s are entitled to deny a claim or pay a reduced amount if statements made by our employees prejudice the Insurer's position.

Where an explanation involves the making of admissions of liability, no such explanation should be given to the patient without the prior written consent of **Healthe Care's In-House Legal Counsel, National Risk and Compliance Manager** or any other relevant insurer.

Further information is available in Appendix B: Open Disclosure Legal Information.

EXAMPLE 2:

The following example illustrates the difference between an apology and an acknowledgement of fault/admission of liability:

Apology: "I am sorry that a mastectomy was performed when you didn't have breast cancer".

Acknowledgement of fault/admission of liability: "I am sorry that I removed your breast when you didn't have breast cancer. I feel terrible. It's all my fault. We really messed things up"

5.4 When Formal Open Disclosure should be delayed or considered not appropriate

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The Chief Executive Officer or delegate is the decision maker when determining when Formal Open Disclosure will be delayed or not undertaken in the following circumstances:

- Patient and patient family/carer decline the offer to meet.
- The patient is incapacitated and has no family or next of kin.
- Relevant State Police Service, State Coroner or State Health Care Complaints Commission recommends a delay.

If open disclosure is deferred with the patient but is held with the patient's family, carers or other relevant persons, the process should recommence with the patient at a later date.

When a Formal Open Disclosure is not appropriate the following will occur:

- 1. Note the reason for the Open Disclosure not being actioned in RISKMAN.
- 2. Advise the Open Disclosure Team.
- 3. Documentation to be filed in accordance with Healthe Care's record management principles.

It should be noted as a journal entry in the RISKMAN incident notification that the patient or patient's family/carer in future may wish to re-engage with the hospital to discuss the adverse event.

5.5 Formal Open Disclosure – record management

All documentation relating to the Formal Open Disclosure process is the responsibility of the Chief Executive Officer of the Healthe Care facility.

The open disclosure process must be recorded in:

- The patient's health care record; and
- Riskman in accordance with the Healthe Care's Incident Management Policy (2.04). Depending
 upon the nature of the incident and as per the relevant state jurisdiction's private hospital
 licensing requirements, it may also be necessary for the Department of Health to be notified of
 the incident. NB: all patient incidents are reported to Healthe Care's insurer.

When a clinical incident occurs during treatment, it is possible that the clinical incident could be the subject of a future medical treatment liability claim. Therefore, all Healthe Care facilities and health practitioners must ensure that proper records are kept for any clinical incident.

Any records generated during the Open Disclosure Process are to be retained for a **minimum of seven years** by the Healthe Care facility in a central location, with restricted access for reasons of confidentiality. Refer to the relevant *State Records Act* and the *Patient Information Retention and Disposal Schedule and the Privacy Act (clth)* for further information.

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

The recording includes the **date and time** of each entry, what the patient was **told**, all **information** provided, and a summary of **plans proposed and agreed actions**. Confirmation that an **apology** was given must also be recorded. The recording should include only known facts, be objective and not apportion blame.

It is also important that a record is kept of the time, date and place of the disclosure discussion, the names and relationships of those present and the patient, family and carer contact details.

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5.6 Insurer Disclosure

Facility's Chief Executive Officer's responsibility to:

- Advise the Visiting Medical Officer that they should contact their Medical Defence Organisation before participating in the open disclosure process.
- Consult with Healthe Care's In-House Legal Counsel and National Risk & Compliance Manager prior to commencing the open disclosure process as per Healthe Care's Incident Management Policy (2.04), Incident Management Protocol (2.04a) and Claims Management Protocol (1.08)

6. EVALUATION OF POLICY AND PROCEDURE

This policy will be reviewed in three years. Special reviews will be undertaken when there are substantive changes to legislation or practice.

7. KEY PERFORMANCE INDICATORS

% notification of open disclosure in Riskman

% patient/family satisfaction rated through local audits and evaluation

% staff satisfaction rated through local audits and evaluation

8. EXPECTED OUTCOMES

Open disclosure information is open, honest and consistent Standardised open disclosure processes

9. REFERENCES

Australian Commission on Safety and Quality in Health Care, Australian Open Disclosure Framework, Better communication, a better way to care, 2013

Commonwealth of Australia. Health Insurance Act 1973. Consolidated Acts.

Healthe Care Complaint Management Policy (1.05)

Healthe Care Claims Management Protocol (1.08)

Privacy Policy (2.01)

Confidentiality (2.02)

Healthe Care Incident Management Policy (2.04)

Healthe Care Incident Management Protocol (2.04a)

Healthe Care's Critical Debriefing Policy (4.06)

Healthe Care's Employee Assistance Program Policy (4.08)

10. REVIEW / CONSULTATION

Executive General Manager Clinical Governance Chief Executive Officers, Healthe Care Australia In-House Legal Counsel All Directors of Clinical Services (however titled) All Quality Managers National Community Services Manager National Risk and Compliance Manager National Quality Managers

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11. VERSION CONTROL & CHANGE HISTORY REVISION TABLE

	REVISION HISTORY TABLE	
Date	Nature of Change	Issue / Section
19/03/2010 – April 2020	New policy	Original
April 2020	Review and update policy	Information updated consistent with the Australian Open Disclosure Framework.

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APPENDIX 1 - SAYING SORRY GUIDELINES

Here are some guidelines on how to say sorry.

Plan ahead

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

Provide the right information

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

Go slowly and genuinely

Have **ample time** to spend with the patient, family and carers.

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

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

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

Here are some key discussion areas and examples.

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

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"What would be the best way to contact you so we can keep you informed?"

APPENDIX B – Final Outcome Letter to Patient (Template)

(NB: Patient correspondence must be reviewed by Healthe Care In-House Legal Counsel and National Risk Manager prior to distribution)

Date [Facility Logo]

Patient name Patient address

Dear [insert name]

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

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

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

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

[Provide list of remedial actions]

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

Yours sincerely

Name Title

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