



Australian  
Commission on  
**Safety and Quality**  
in Health Care

# Australian Open Disclosure Framework

Better communication, for better care

The Australian Commission on Safety and Quality in Health Care pays respect to the Gadigal people as the Traditional Custodians of Country where the Commission's office is located. We extend that respect to all Aboriginal and Torres Strait Islander peoples, and their deep time connections to land, water and sky.

We recognise that knowledge about healthy Country, community and culture has been developed by Aboriginal and Torres Strait Islander peoples over tens of thousands of years and has been shared for generations. We are committed to partnering with and learning from Aboriginal and Torres Strait Islander peoples through the work that we do.

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Level 5, 255 Elizabeth Street, Sydney NSW 2000

Phone: (02) 9126 3600

Email: [mail@safetyandquality.gov.au](mailto:mail@safetyandquality.gov.au)

Website: [www.safetyandquality.gov.au](http://www.safetyandquality.gov.au)

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# Executive summary

# Executive summary

## Purpose

**The Australian Open Disclosure Framework (the Framework) provides a nationally consistent basis for effective communication following unexpected healthcare outcomes and harm.**

This document is a revision of the Open Disclosure Framework published in 2014. Open disclosure has become part of everyday practice in health service organisations in Australia. It aims to ensure that patients are treated respectfully after actual harm or potential harm (near miss) has occurred.

## What is open disclosure

Open disclosure is a principles-based approach to communicating openly and honestly with patients when things go wrong in health care. It involves timely, empathetic discussions that acknowledge what happened, offer an apology or expression of regret, listen to the patient's experience, and provide clear information about next steps and follow-up. The process aims to maintain trust, support understanding, and foster a culture of safety and accountability, while ensuring that lessons are learned to improve future care.

**The Commission uses the term patient or person to describe someone who is receiving or has received health care. When referring to a patient or person this also includes any support people such as family, partners, friends and paid or unpaid carers.**

## When should open disclosure be used

Open disclosure is expected whenever harm has occurred—whether physical, psychological, or social. It should also be considered when patients raise concerns about harm or may be initiated when an incident is identified through complaints, feedback, incident reporting systems, or surveillance programs. Even if no harm has occurred, open disclosure may still be appropriate. Listening to and acknowledging the patient's experience remains essential to maintaining trust and supporting a positive care relationship.

## Audience

The Framework is intended for use by Australian health service organisations and healthcare professionals across all healthcare settings and sectors.

## Use

The Framework is designed to enable all healthcare professionals working within Australian health service organisations to communicate openly with patients when health care does not go to plan. It can be used to modify existing or to inform new open disclosure policies.

This update has been considered in the context of current practice and describes the principles of open disclosure to support good practice and improvement. It recognises that there are differences between states and territories, and across health sectors in how open disclosure is managed.

Health service organisations should ensure open disclosure practices align with applicable state and territory policies, legislation and local requirements.

Open disclosure

# Open disclosure

Open disclosure principles such as respect, transparency, and empathy are applied daily through good clinical communication, helping to build trust, support patient understanding, and foster a culture of safety and accountability. Things can go wrong during health care for many reasons, including from human error or system failures. Open disclosure is a principles-based approach to honest, empathetic and timely discussions with a patient, when actual or potential harm occurs while that person is receiving health care.

**Open disclosure is the right thing to do when something goes wrong – for the patient, for the healthcare professionals involved, for the organisation and for the wider health system. It is an opportunity for healthcare professionals to meaningfully acknowledge, apologise for, remedy, reflect on and learn from incidents of actual or potential harm and to prevent the same thing from happening again.**

Internationally, open disclosure to patients has been recognised as an important ethical and patient safety concern for several decades.<sup>(1)</sup>

Open disclosure when done well is an extension of the mutual trust and respect that underpin good interpersonal relationships and the delivery of safe and high-quality health care. It relies on healthcare services and healthcare professionals to respond with honesty, compassion and empathy to human error or system failures when care did not go as intended.

## When should open disclosure be used

When an incident occurs that has resulted in harm or could have caused harm to a patient (if appropriate), healthcare professionals are expected to engage in open disclosure. Near miss and no-harm incidents are within the scope of open disclosure; however, the approach should be proportionate, guided by the circumstances of the event and responsive to the needs of the patient. Harm may be physical, social or psychological. Harm is defined as impairment of structure or function of the body and/or any effect arising therefrom, including disease, injury, suffering, disability and death. This broader meaning is important because the person's view on whether harm has occurred may differ from the healthcare professionals or health service organisation's view. Patient harm must be treated with the same seriousness as harm detected by clinical or organisational processes.

**Open disclosure can be initiated through several pathways, including an adverse event, clinical incident report, healthcare surveillance programs, healthcare professional identification, consumer identification, complaints or feedback.**

The right words used at the right time matter.<sup>(1)</sup> Creating space and time for these communications to occur is important. It is important to consider the patient's preference, in terms of when and where the open disclosure discussion(s) takes place and which healthcare professional leads the discussion.

**Processes for open disclosure should be culturally safe and provided in a way that a patient can understand.**

An '[Open disclosure: When and how to do it](#)' fact sheet can be found on the Commission [website](#).  
(2)

## Transparency

[The Australian Charter of Healthcare Rights](#) (the Charter) describes rights that consumers can expect when receiving health care. These rights apply to all people in all places where health care is provided in Australia.<sup>(3)</sup> The Charter right to partnership includes being able to ask questions and to receive open and honest communication, which are principles that underpin open disclosure. Healthcare professionals have the responsibility to be familiar with the Charter and to uphold its principles in practice, ensuring transparent, open communication and patient partnership are embedded in every interaction.

# Principles of person-centred open disclosure



# Principles of person-centred open disclosure

Open disclosure is a core part of safe, high-quality healthcare. It relies on clear, person-centred communication that supports transparency, accountability and continuous improvement in care.

**Person-centred care is health care that respects the patient, their family and carers, and responds to the person's preferences, needs and values. Person-centred care is equitable, culturally safe and free from racism and all other forms of discrimination. Patients, carers and consumers are treated with dignity, respect and kindness.**

These principles guide how open disclosure should be planned and delivered.

## Respectful and responsive communication

When something goes wrong in healthcare, it is essential that patients receive open, timely and accurate information about what has occurred. Communication should always be shaped around each person's preferences, needs and values, recognising that every individual experiences adverse events differently. Respectful and responsive communication helps maintain trust, supports emotional safety and promotes meaningful participation in decision making.

In practice, this includes:

- **Providing accurate, easy-to-understand and culturally safe information**  
Information should be factual, delivered in plain language and presented in a way that respects cultural beliefs, health literacy levels and communication styles.
- **Avoiding speculation and clearly explaining what is known and unknown**  
Patients should understand what information is available now, what cannot yet be confirmed, and what steps will be taken to obtain further clarity.
- **Ensuring communication remains accessible**  
This may involve using interpreters, Easy Read formats, plain language resources, visual supports, assistive technology or other communication aids tailored to the person's needs.
- **Allowing space for the person to share their experience**  
Patients must have the opportunity to describe what happened from their perspective, express concerns and ask questions without being rushed.
- **Checking understanding and clarifying information as needed**  
Healthcare professionals should regularly confirm that the patient understands what has been discussed, and offer clarification whenever required.
- **Enabling involvement of support people**  
Patients should be supported to include family members, carers, advocates or others of their choosing. Their involvement should be welcomed, not assumed, and respected when declined.

- **Making reasonable adjustments to support participation**  
Adjustments may relate to the physical environment, the timing of conversations, preferred formats for communication, or the use of communication aids or supports.
- **Communicating clearly and transparently to maintain trust**  
Honest and open communication reassures patients that their concerns are taken seriously and that the organisation is committed to learning from the event.
- **Ensuring healthcare professionals leading open disclosure are supported**  
Staff should have access to training, supervision, debriefing and organisational support to communicate effectively, compassionately and confidently during difficult conversations

Effective communication creates conditions for safe, meaningful and respectful discussions. It enables patients to feel heard, valued and involved, and forms the foundation of a thoughtful and person-centred open disclosure process.

## Compassionate acknowledgement and apology

A sincere apology or expression of regret using the words, “*I am sorry*” or “*we are sorry*”, is essential. Compassionate acknowledgement of the event and its impact supports healing and strengthens trust.

In practice, this includes:

- Offering early acknowledgement of harm or potential harm
- Delivering the apology with sensitivity to the person’s emotional state, communication needs, cultural context and preferences
- Validating the person’s experience and responding with empathy.

## Restorative process

A restorative approach enables open dialogue, emotional validation and shared accountability. It helps rebuild trust and supports healing for patients and healthcare professionals. By focusing on relationships, respect and learning, it strengthens both individual recovery and system-wide improvement.

## Cultural safety for Aboriginal and Torres Strait Islander peoples

For the open disclosure to be effective and meaningful for Aboriginal and Torres Strait Islander peoples it must be culturally safe.

### Cultural safety

The healthcare experiences of Aboriginal and Torres Strait Islander peoples occur within a broader context shaped by historical and ongoing racism, discrimination, and systemic power imbalances associated with Australia’s colonial history. These factors influence experiences of harm, trust and communication, and include the presence of inherent biases within healthcare services and interactions between healthcare professionals and Aboriginal and Torres Strait Islander peoples. This is particularly important in the context of open disclosure.

Health service organisations should engage Aboriginal and Torres Strait Islander health workers or liaison officers to support culturally safe communication and ensure respectful, inclusive disclosure processes.

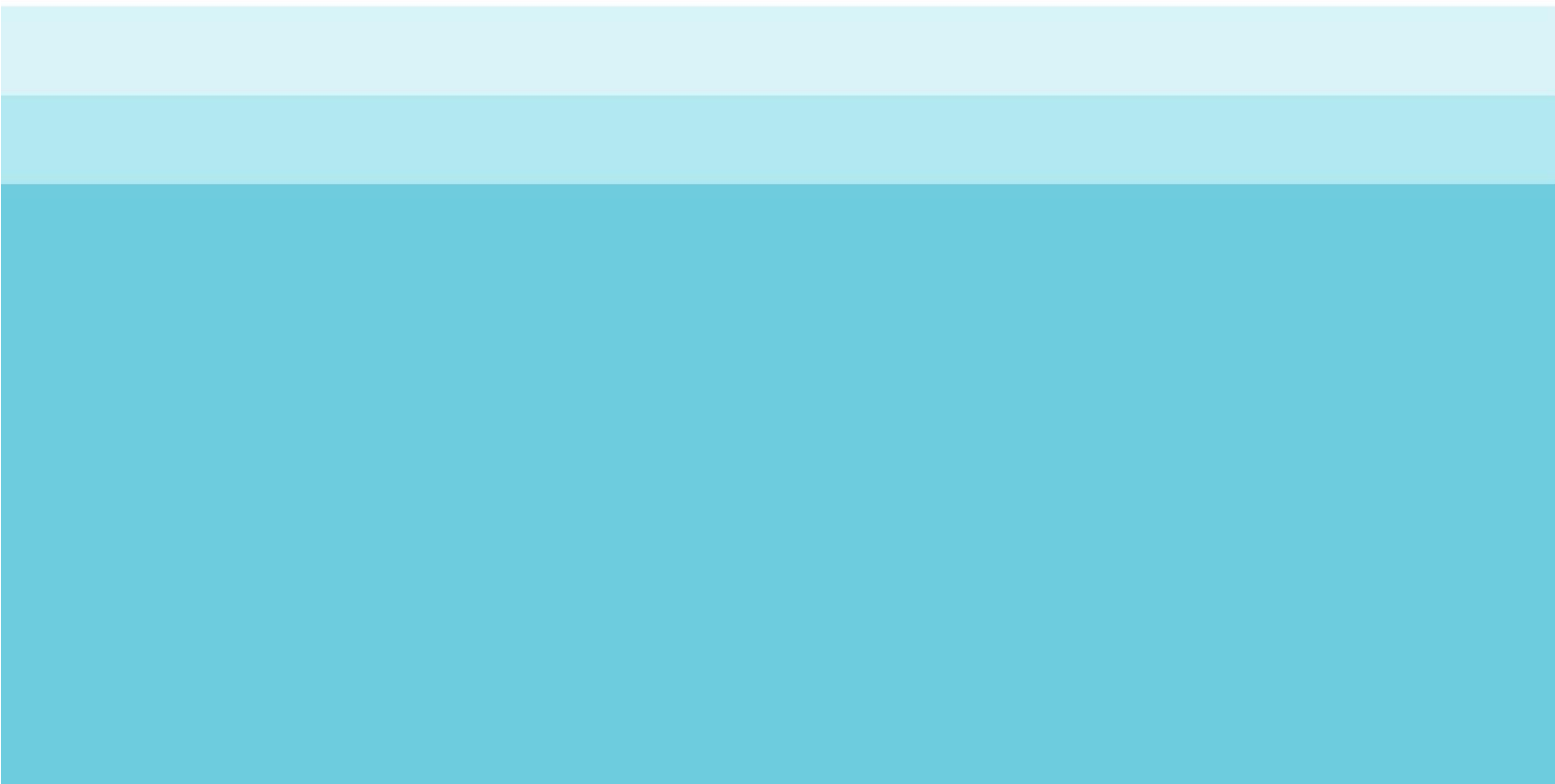
**Cultural safety is determined by Aboriginal and Torres Strait Islander individuals, families and communities. In health care culturally safe practise is the ongoing critical reflection of knowledge, skills, attitudes, practising behaviours and power differentials in delivering safe, accessible and responsive healthcare free of racism (Commission, adapted from Ahpra).**

## **Cultural competency**

Aboriginal and Torres Strait Islander peoples have diverse cultural beliefs, language groups, and experiences of healthcare. Healthcare services should actively improve the cultural safety of the care provided including by supporting capability development, embedding cultural protocols and working in partnership with Aboriginal and Torres Strait Islander communities, organisations and peoples.<sup>(4)</sup>

It is important to discuss whether the patient feels that the location for the open disclosure meeting is culturally safe. Hospitals and other healthcare settings, in some communities, are a place where people go to die and may not be the most appropriate environment to conduct these meetings.<sup>(4)</sup>

# The importance of an apology in open disclosure



# The importance of an apology in open disclosure

Apologising or expressing regret, in conjunction with saying sorry, is a key component of open disclosure. The principal aim of open disclosure is the fundamental right for a patient to know what happened to them. The process of open disclosure also helps to restore a patient's trust in healthcare professionals and the healthcare system. When a patient feels that their experience of harm has been acknowledged in a meaningful way, effective ongoing care and open communication post harm is more likely to occur. Healthcare professionals may also feel some relief and can learn from the experience by engaging with the patient to better understand their experience. <sup>(1)</sup>

## Using the words 'I am sorry' or 'we are sorry' is essential

A key element of achieving these aims is early acknowledgment of harm or potential for causing harm to the patient and an apology or expression of regret for the harm or near harm endured. Apologising and expressing regret should be done empathically and sincerely and must contain the word 'sorry'. Research supports this action as a very important step in the post-incident process for patients. <sup>(5)</sup>

While using the words 'I am sorry' or 'we are sorry' is essential, open disclosure is about more than the words alone, its overall success can often depend on how the apology or expression of regret is delivered. Three key points for those engaging in open disclosure are:

- **An apology or expressing regret is a natural human response after an unexpected event.** Patients who have been harmed and other persons affected by the incident, will often appreciate and benefit from a sincere apology. Equally, healthcare professionals can also benefit from this interaction. The conversation can be difficult but, according to evidence, may lead to a better outcome. <sup>(6)</sup> **Do not fear saying sorry.** Providing healthcare professionals don't engage in unwarranted speculation about the incident or apportion blame to individuals, entities or institutions, there are no medico-legal grounds for avoiding the word 'sorry'.
- **Consider your delivery.** Think about phrasing and non-verbal aspects of delivery. It is important to remember that what healthcare professionals say is not always what is heard, and that this can be influenced by non-verbal cues such as maintaining eye contact. Other aspects of delivery such as body language, tone, positioning, setting of the discussion and potential distractions can undermine the conversation and significantly influence how the apology and explanation are received.
- **Listen.** Apologising and expressing regret is also about listening and giving the patient an opportunity to tell how they feel, and how the incident has affected them, ask questions, and receive responses that are honest, respectful and clear. Practise, and engage in, active listening as it helps support healing, helps healthcare professionals understand the patient's experience and contributes to improved patient and healthcare professional relationships. Always give the patient the opportunity to respond.

## Legal aspects of apology and expressions of regret

Apologising or expressing regret is central to open disclosure. All Australian jurisdictions have enacted apology laws to protect statements of apology or regret made after incidents from subsequent use in certain legal settings. As previously stated, providing healthcare professionals

do not engage in unwarranted speculation about the patient safety incident or apportion blame to other individuals, teams or the health service organisation, there are no medico-legal grounds for avoiding the word 'sorry'.

The information provided in this resource is a guide only. Noting, each Australian jurisdiction has their own individual laws and regulatory requirements. Health service organisations and/or healthcare professionals should seek legal advice for any concerns and/or clarifying information they may need regarding individual cases.

# Stages of open disclosure



# Stages of open disclosure

There are different stages of open disclosure. Open disclosure may take place in a single conversation or as a series of discussions, which can include both initial exchanges and the more formal open disclosure process. Factors that determine whether more than one conversation is needed include the presence or severity of harm and the needs and expectations of the patient.

## Initial disclosure

An initial discussion should occur as soon as possible after recognising harm or potential harm, even if not all the facts are known. These may be applied daily through good clinical communication practices. There may be times when initial disclosure may need to be deferred due to the health of the patient and/or at the request of the patient.

The initial discussion should include:

- Acknowledging care did not go as expected and including known facts
- An apology or expression of regret
- An opportunity to listen to the patient experience
- The effect or potential consequences for the patient
- What the open disclosure process involves and the expected outcomes
- Steps being taken to manage the event and prevent recurrence
- Information about the open disclosure and incident management processes.
- Contact information to access independent support services

In cases where no significant harm has occurred to the patient and disclosure is still appropriate, listening to the patient's experience is very important. If the process ends after the initial discussion, it should still be documented appropriately.

## Formal open disclosure

Formal open disclosure is an organised process, led by a nominated open disclosure lead of the health service organisation, and may occur after initial disclosure. It should be considered following the unexpected death or significant injury to a patient, permanent or considerable lessening of body function following an incident or adverse event, major psychological or emotional distress, or where a patient requests a formal open disclosure process.<sup>(7)</sup> The timing, place and pace of formal open disclosure should be responsive to the needs and expectations of the patient.

The open disclosure process may take some time to finalise and may not follow a step-by-step process. This will be based on the needs of the patient and may be different from patient to patient. For instance, a patient may not want to discuss their experience until time has elapsed, or sufficient trust has been built which may take several meetings. If trust has been lost, the presence of an independent person from the health service organisation may be considered. Once there is agreement to proceed and to help prepare and plan for a formal open disclosure, consider the following options to support healthcare professionals:

- Selecting a designated open disclosure lead and determining who else will be involved
- Considering a multidisciplinary approach where appropriate, with participation tailored to the circumstances of the event

- Ensuring that team roles are clearly defined, as good teamwork is critical for effective open disclosure. Clear communication, mutual support, and a shared commitment to transparency, enable staff to respond consistently and compassionately when harm occurs
- Nominating, where possible, a staff member to support the open disclosure lead, ensuring both individuals have experience and/or training in open disclosure
- Anticipating and planning for more than one formal meeting, this may be required to support the open disclosure process.

Support the patient by:

- Identifying any specific needs of the patient to enable participation. This may include using communication aids or supports. Some people may prefer to defer to family members, guardians, advocates, community leaders, or community Elders in discussions. Some people may need interpreters, or a patient liaison officer to support participation
- Arranging the first formal meeting in consultation with the patient
- In situations where there is difficulty conducting open disclosure or finding an agreeable outcome, arrange for an independent facilitator to support ongoing discussions
- Asking the patient if they would like to nominate a contact person. A nominated contact person is the agreed individual who is formally identified as the recipient of information regarding the patient's care through any local and/or legal process associated requirements
- Ensure nominated contacts are by default entitled to receive information and participate in open disclosure unless otherwise instructed by the patient.

In cases where the adverse event spans more than one location or health service organisation, **all relevant healthcare services should be involved** and agreement made on who will lead the open disclosure process.

## When the patient does not want to participate in open disclosure

If a patient is unsure if they wish to participate in open disclosure:

- Respect the decision, and provide contact details for a nominated person should they wish to engage later
- Offer alternatives, such as a personal written apology and/or a written summary of the known facts to date
- Maintain openness by keeping the options available for future discussion and providing updates about system learning an improvement where appropriate.

Find out and discuss  
what happened

# Find out and discuss what happened

Discussing what happened openly and honestly helps maintain and, where needed, rebuild trust between patients and healthcare professionals. For the patient, this requires early acknowledgement of harm and an apology or expression of regret. However, over-promising or making statements that are subsequently retracted can undermine trust.

A factual explanation of what happened requires the facts to be established.

It is important that healthcare professionals avoid making speculative statements during initial or early open disclosure conversations.

**There should be no speculation on the causes of harm or near miss.**

**Blame or liability should not be apportioned to any individual, group or system.**

**The results of reviews and investigations should not be pre-empted.**

Discussion of the likely consequences of the harm that was caused is an important part of the factual explanation.

It is important not to speculate on what may happen but give an example of what the patient may need for future healthcare needs.

**Provide information** in a manner that supports the communication needs of the patient and avoid medical acronyms and jargon.

**Provide the patient with the opportunity to:**

- describe/share their experience
- listen, ask questions and seek clarification.

## Providing an opportunity for the patient to share their experience

Open disclosure should be a conversation where the patient can share their experiences. The patient should be able to seek clarification and access information and services such as social work, psychology and after-hours helplines.

**The patient should be encouraged to talk about the effect the harm has had upon their life. It is important for the patient that their views and concerns are heard, acknowledged and understood.**

Discuss what outcomes the patient wants to achieve and any questions they would like answered. A summary of the discussion should be documented and stored securely, with a copy provided to the patient.

**It is not always possible to cover everything in the first formal open disclosure meeting. A full explanation of why harm occurred may not be possible until investigations have been completed, and the causative factors are known.**

## Provide follow up

The patient may need reassurance that they will receive ongoing information and follow-up care. They should be able to request any additional details relevant to their circumstances. To maintain continuity, the healthcare professional leading the open disclosure process, or a nominated contact person, is responsible for coordinating and being involved in follow-up discussions. Follow-up should include:

- clear information about any further care or investigations
- updates on reviews, outcomes, and any actions taken to prevent recurrence
- contact details of a nominated position (the health service organisation contact person) who will be the primary contact for the patient

## Close: Document the process and outcomes by mutual agreement

The open disclosure process aims to conclude with mutual or shared agreement between the healthcare team and the patient.

**Each meeting discussion should be documented**, with copies provided to the patient, and to the healthcare team, and the record stored securely.

The health service organisation should document and communicate any recommendations or changes to systems, processes and practice resulting from an investigation.

### Closure of the process, potential deferral and other restrictions

In most cases, closure will occur after internal investigations are complete. Contact details of who the patient can reach out to in the future, should be provided.

When a review or investigation is complete, the patient should be provided with feedback through the agreed communication channels, and this communication should be documented. Further information about incident management can be found in the [Commission's Incident Management Guide](#).<sup>(8)</sup>

## Advocacy and support

People will often need additional help and support after experiencing harm. Support may be provided by family members, support people, social workers, religious representatives or trained patient or disability advocates.

Where more detailed long-term emotional support is required, the health service should ensure the patient is advised about how to access counselling or other services.

This may include:

- information (including contact details) about services provided by social workers, psychologists, after-hours helplines, religious representatives and trained patient advocates
- information about how to make a complaint when issues remain unresolved, including contact details for the relevant state or territory health complaints agency, and the patient's (and their nominated contact person's) right to access their healthcare record. Further information about [healthcare complaints can be found on the Commission's website](#).<sup>(9)</sup>

## Ongoing care: cost and other considerations

Open disclosure is most effective if it is coupled with restorative action. This may include a pledge of practical support for the patient to cope with the effects of harm. Those who have been harmed often indicate that bearing the cost of care and out-of-pocket expenses can be determining factors in initiating litigation. Out-of-pocket expenses may include, but not be limited to, transport, childcare, accommodation and meals.

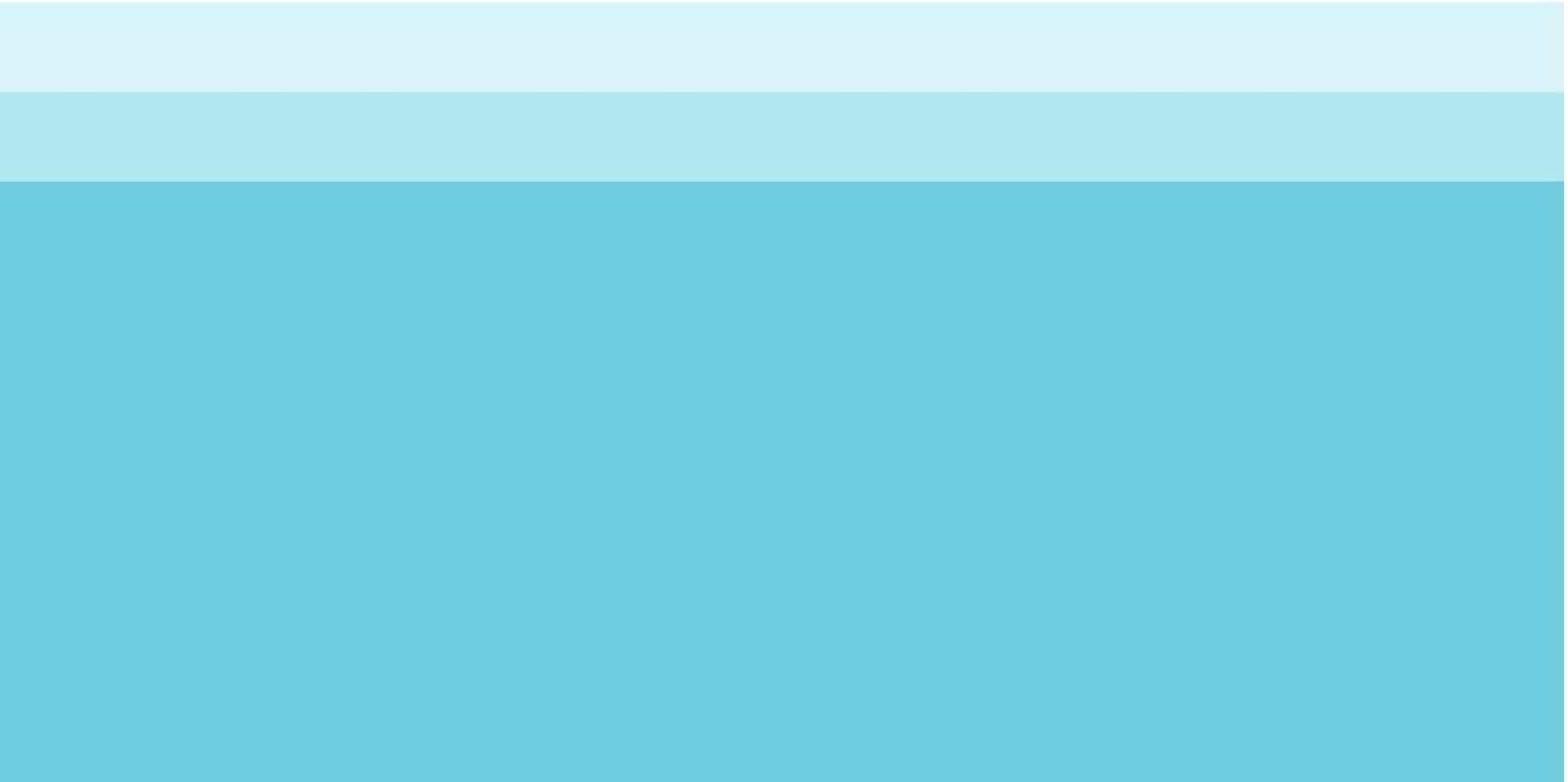
It is generally accepted that practical support made on a goodwill basis does not imply responsibility or liability. The context for financial reimbursement will vary between sectors and jurisdictions. Health service organisations and healthcare professionals should liaise with legal counsel, insurers and other stakeholders to develop guidelines for aiding patients that have been harmed when the preliminary investigation indicates that this would be appropriate.

Patients who have been harmed will often require ongoing treatment or care, which may be provided at the same health service organisation or another. Ongoing treatment costs need to be discussed openly and in a timely fashion, based on individual needs and circumstances. Agreeing on matters about ongoing treatment, such as billing and other costs (e.g. transport in rural areas), is important given the potential for disagreement to undermine an open disclosure process.

Health service organisations should engage in these discussions with the patient as soon as practicable after harm is identified.

Health service organisations and individual healthcare professionals should clarify any relevant restrictions and requirements around ongoing care with their indemnity insurer(s) prior to engaging in these discussions (particularly if the insurer is to meet the cost).

**Learn: Identify opportunities  
for system improvement and  
restorative practice**



# Learn: Identify opportunities for system improvement and restorative practice

Governance, risk management and quality improvement processes encourage health services to learn from harm events and strengthen systems through continuous monitoring and review. These processes support safe, high-quality care and form the foundation for organisation learning and accountability. Further information about [clinical governance can be found on the Commission's website](#).<sup>(10)</sup>

Thorough clinical review and investigation should be conducted using clinical risk management and quality improvement processes. Review findings should focus on strengthening systems of care, and information obtained from adverse events or open disclosure should be incorporated into ongoing system improvement activities.

In addition to system improvement, health services should consider adopting a restorative approach to open disclosure.

**Restorative processes focus on healing and rebuilding trust by acknowledging harm, validating the experiences of those affected, and involving patients and healthcare professionals in meaningful dialogue**

Information gathered during open disclosure and adverse event reviews can inform restorative practices, ensuring that learning is relational, person-centred and supports healing for all involved.<sup>(11)</sup>

## Review of open disclosure

Health service organisations should review open disclosure performance and integrate outcomes into quality improvement, clinical governance and performance monitoring.

Patients should be given the opportunity to provide feedback on the open disclosure process. Measurement may include a mixture of outcome evaluation and process evaluation. Consider linking with existing feedback mechanisms to make the process less burdensome to patients.

Staff involved in open disclosure should also be provided with the opportunity to provide feedback at the end of the open disclosure process. Sensitivity is needed when gathering this feedback, particularly when the incident has been distressing or involves significant harm.

# Supporting open disclosure in health services



# Supporting open disclosure in health services

When healthcare professionals are skilled and feel psychologically safe to conduct open disclosure conversations with patients, these conversations are less likely to be avoided, questions of responsibility are more likely to be addressed, and open disclosure is more likely to become embedded in ongoing clinical practice.<sup>(1)</sup>

## A just culture

A just culture within healthcare services means that healthcare professionals feel safe to report adverse events, including near misses so that accountability is shared and systems thinking can be applied to improvement.<sup>(12)</sup> Criticism and defamatory statements should be avoided. Involvement in adverse events should be considered in the context of system and human factors such as staffing, skill mix, workload and workflow.

To achieve a just culture, health service organisations should:

- acknowledge that health care involves inherent risk and that there is a need to reduce this risk wherever possible
- build a culture that encourages notification of, and open and honest communication about adverse events
- frame findings as learning opportunities and create processes for change management when it is required
- eliminate unnecessary punitive action against healthcare professionals involved in an adverse event, while ensuring appropriate professional accountability
- foster community awareness of the occurrence of adverse events.

Healthcare service organisations have an obligation to recognise the right of healthcare professionals to seek appropriate advice and guidance from their indemnifiers and other relevant advisers, and to act in accordance with such advice. Issues relating to competence or negligence of healthcare professionals should be managed by appropriate performance management processes and/or contact [Australian Health Practitioner Regulation Agency](#) (Ahpra).<sup>(13)</sup>

## Support for healthcare professionals

It is common for healthcare professionals to experience significant emotional distress following harm to a patient, including feelings of guilt, loss of confidence, anxiety, fatigue and burnout.<sup>(14)</sup> Healthcare professionals involved should be provided with support by the health service, this might include the opportunity to debrief and to access organisational Employee Assistance Programs (EAP) or external support services.

Open disclosure should be embedded into the organisational culture of health services. Health services need to foster a culture where people feel supported and are encouraged to identify and report adverse events so that opportunities for improvements can be identified and implemented. Health services should ensure that policies, protocols and practices regarding open disclosure focus on restoration, service recovery and improving quality and patient safety.

## Internal communication for healthcare professionals

Effective communication with healthcare professionals is a vital step in ensuring that recommended improvements are fully implemented and monitored. The process should be integrated into continuous improvement programs to support monitoring and evaluation of recommended system changes and to increase awareness and value of open disclosure. A process for evaluation of open disclosure events should be maintained by the health service organisation.

## Informed consent

The consent process is outside the scope of the Framework, but it is important in establishing the patient-healthcare professional relationship. Further information about [informed consent can be found on the Commission's website](#).<sup>(15)</sup>

## Leadership and senior management

Leadership and senior management have ultimate responsibility for ensuring open disclosure is implemented effectively in their organisations and in enabling and supporting healthcare professionals to perform open disclosure. This includes:

- Explicitly supporting open disclosure as:
  - A patient right
  - An organisational requirement
  - An integral part of healthcare provision
  - An opportunity to learn from adverse events and from patients
- Requesting regular reports on open disclosure practice
- Providing access to and participating in open disclosure training and open disclosure processes.

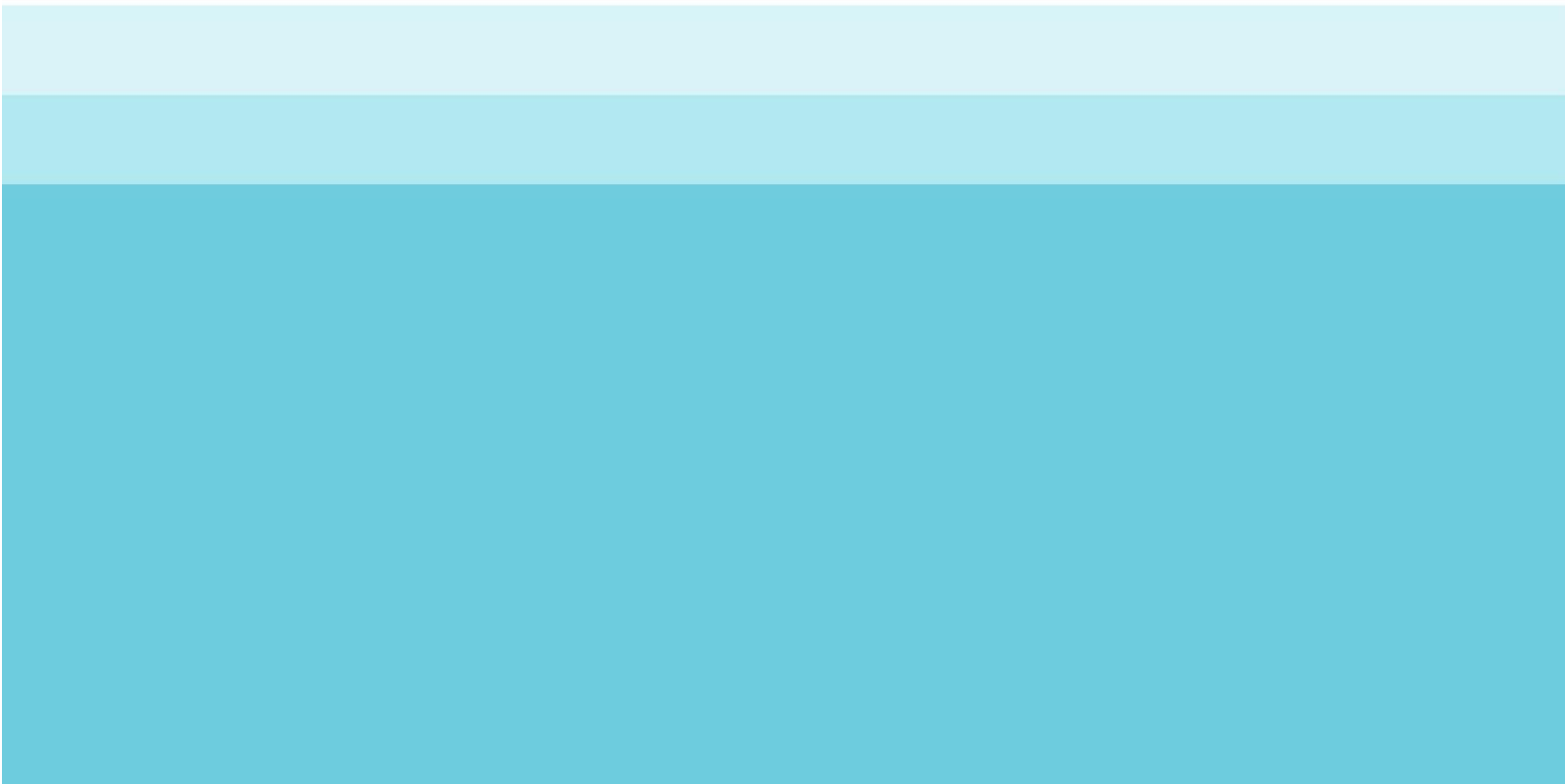
## Virtual care providers

The same open disclosure process and principles must be followed when harm occurs in a virtual care setting. Virtual care is considered to be any healthcare activity supported at a distance by information and communication technology services. Virtual care can be delivered by a range of modalities including telephone, video conferencing, remote patient monitoring or via a website and mobile applications. Virtual care can also be delivered not in real-time through a patient portal or mobile health application.

While open disclosure is recommended to occur in person, it is acknowledged that this may not be practical in all situations.

Open disclosure can involve complex communication (verbal and body language), and this should be considered when deciding whether open disclosure conversations should occur virtually or in person and decisions should be led by the preference of the patient. Open disclosure held virtually may have some advantages as it potentially allows more flexibility and may be easier for a patient if they are located far from the health service organisation. However, some challenges may include difficulty establishing rapport and trust which is an important part of open disclosure. It is recommended where possible; video calls should be used rather than audio-only to support verbal and body language cues.

# Other considerations



# Other considerations

## Breakdown in communication and relationships

Sometimes, despite the best efforts, the relationship between the patient and the health service organisation and individual healthcare professionals can break down. The patient may not accept the information provided or may not receive all the information that they have asked for following an adverse event or may not wish to participate in the open disclosure process. The following strategies may assist:

- Attempt to deal with the matter earlier rather than later
- Check if the patient feels that they have been heard
- Ensure the patient has access to support services
- Ensure the appropriate staff member (e.g. a senior healthcare professional) is aware of a potential relationship breakdown by communicating early warning signs (e.g. the patient communicates their concern to other members of the team)
- Assess whether sufficient weight has been given to the patient's version of events and whether reasonable efforts have been made to seek information that the patient has requested
- Offer the patient another health service contact person with whom they may feel more comfortable. This could be another member of the treating team or an independent person not directly involved in care
- Use a mediation or conflict resolution service to help identify the issues between the health service organisation and the patient and explore a mutually agreeable solution
- Involve the services of the local health complaints office if the patient wants to lodge a formal complaint
- Ensure the patient is provided with contact details of a nominated person to be able to contact at a later time if they wish to (re)commence the open disclosure process.

## Delayed detection of harm occurring elsewhere

In some cases, patient harm may not be detected as it may have occurred elsewhere during the patient's health care journey or become evident until after the care has ended. In this situation health services should:

- Establish whether the adverse event has already been recognised in the organisation in which it occurred and whether they have commenced an open disclosure process
- Notify the patient if they have not been previously notified
- Inform other healthcare providers, such as the patient's general practitioner or registered aged care provider or primary care provider
- Investigate any issues that relate to transitions of care between the services
- If the open disclosure process has not already commenced, the process should be initiated after consultation, and in collaboration with the other organisation.

The open disclosure process will need to be adapted in these situations to cater for the needs of the patient, as well as the healthcare professionals. While it is acknowledged that these circumstances can be complex, it is important that the patient's right to know is respected as per the [Australian Charter of Healthcare Rights](#).<sup>(3)</sup>

## Harm caused by therapeutic goods in Australia

Reporting adverse events or incidents associated with medicines, vaccines and medical devices helps the Therapeutic Goods Administration (TGA) identify previously unrecognised side effects and other safety concerns.<sup>(16)</sup>

Further information about how to report adverse events to the TGA, please refer to <https://www.tga.gov.au/safety/reporting-problems/reporting-adverse-events>.

Health service organisations incident reporting systems must ensure that harm caused by a medicine, vaccine and/or medical device are captured and trigger open disclosure.

### Mandatory reporting of adverse events involving medical devices

From March 2026, it is mandatory for healthcare facilities to report medical device adverse events, that have caused or could cause harm ('near-misses'), to the [TGA](#), in accordance with the Therapeutic Goods Act 1989 and Therapeutic Goods (Medical Devices) Regulations 2002.<sup>(17)</sup>

# Glossary

**Advocate.** A person who is independent from the health service and who supports a patient to participate in open disclosure and where appropriate represents the patient's views and rights in the process. The advocate might be a family member, friend or professional advocate. In some cases, the advocate will have legal authority to represent the patient in the process. This will be so if the person, legislation or a court or tribunal has given them that authority. Parents generally have authority to represent their children. Relevant legislation varies around Australia.

**Adverse event.** An incident that results, or could have resulted, in harm to a patient or consumer. A near miss is a type of adverse event.

**Apology.** An expression of sorrow, sympathy and (where applicable) remorse by an individual, group or institution for a harm or grievance. It should include the words 'I am sorry' or 'we are sorry'.

See also *Expression of regret*.

**Carer.** A person who provides personal care, support and assistance to another individual who needs it because they have a disability, medical condition (including a terminal or chronic illness) or mental illness, or they are frail or aged. An individual is not a carer merely because they are a spouse, de facto partner, parent, child, other relative or guardian of an individual, or live with an individual who requires care. A person is not considered a carer if they are paid, a volunteer for an organisation, or caring as part of a training or education program.

For Aboriginal and Torres Strait Islander people, there may be a collective approach to carer responsibilities. Confirming who is responsible for different aspects of care is important for ensuring that carer engagement is effective.

**Clinical governance.** Clinical governance is central to providing the best possible outcomes for patients. It is the combination of organisational culture, systems and structures that enables everyone in a health service to deliver care that is consistently high quality and improving. Effective clinical governance means that boards, executives, clinical leaders and the workforce are clearly accountable to patients and the community for providing high-quality care – care that is person-centred, safe, effective, accessible and integrated, provided in a way that is equitable, efficient and sustainable.

**Clinical risk.** The combination of the probability of occurrence of harm and the severity of that harm.

**Consumer.** A person who has used, or may potentially use, health services, or is a carer for a patient using health services. A consumer advocate or representative who is a person that provides a consumer perspective, contributes consumer experiences, advocates for the interests of current and potential health service users and takes part in decision-making processes.

**Contact person.** A nominated person who acts as an ongoing point of contact on behalf of the patient and is the recipient of information regarding the patient's care through any local legal process and associated requirements.

**Culturally Safe.** Providing an environment where individuals feel safe, respected and valued.

**Cultural Safety.** Determined by Aboriginal and Torres Strait Islander individuals, families and communities. In health care, culturally safe practice is the ongoing critical reflection of knowledge, skills, attitudes, practicing behaviours and power differentials in delivering safe, accessible and responsive healthcare free of racism. Essential features of cultural safety are individuals and organisations:

- Acknowledging colonisation and systemic racism, social, cultural, behavioural and economic factors which impact individual and community health

- Acknowledging and addressing individual racism, their own biases, assumptions, stereotypes and prejudices and provide care that is holistic, free of bias and racism
- Recognising the importance of self-determined decision-making, partnership and collaboration in healthcare which is driven by the individual, family and community
- Fostering a safe working environment through leadership to support the rights and dignity of Aboriginal and Torres Strait Islander people and colleagues.

**Disability.** The World Health Organization (WHO) International Classification of Functioning for Disability and Health (ICF) defines disability as the result of the interaction between a person's impairment and their environment. This is a biopsychosocial model of health and disability, combining both the medical and social models of disability. The ranges of disability encompass mild, moderate, severe and complete impairment.

**Error.** Failure to carry out a planned action as intended or application of an incorrect plan through either doing the wrong thing (commission) or failing to do the right thing (omission) at either the planning or execution phase of healthcare intervention.

**Expression of regret.** An expression of sorrow for a harm or grievance. It should include the words 'I am sorry' or 'we are sorry'. An expression of regret may be preferred over an apology in special circumstances (e.g. when harm is deemed unpreventable).

See also *Apology*

**Harm.** Impairment of structure or function of the body and/or any deleterious effect arising therefrom, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological.

**Health care.** The prevention, treatment and management of illness and injury, and the preservation of mental and physical wellbeing through the services offered by clinicians, such as medical, nursing and allied health professionals.

**Healthcare professional.** Refer to any individual who works in the healthcare sector and has professional qualifications. This includes

- Clinicians (A registered health practitioner. They include nurses, midwives, medical practitioners, allied health professionals, paramedics and other professionals who provide health care, and students who provide health care under supervision.) and
- Non-clinical professionals (e.g. health managers, practice managers, support staff).

**Healthcare record.** A record of the patient's medical history, treatment notes, observations, correspondence, investigations, test results, photographs, prescription records and medication charts for an episode of care. Information in a healthcare record can be sourced from multiple healthcare organisations

**Health service organisation.** Used to describe acute, primary and community healthcare services, as well as other services involved in the delivery of health care. Healthcare services are delivered in a wide range of settings and vary in size and organisational structure.

**Incident.** An event or circumstance that resulted, or could have resulted, in unintended or unnecessary harm to a patient or consumer; or a complaint, loss or damage. An incident may also be a near miss.

**Independent facilitator.** A neutral party who supports the process by guiding respectful, transparent, and inclusive communication between healthcare providers and patients and/or their support people. They are not directly involved in the clinical care of the patient.

**Liability.** The legal responsibility for an action.

**Multidisciplinary team.** A team including clinicians from multiple disciplines who work together to deliver comprehensive care that deals with as many of the patient's health and other needs as

possible. The team may operate under one organisational umbrella or may be from several organisations brought together as a unique team.

**Near miss.** An incident or potential incident that was averted and did not cause harm but had the potential to do so

**Open disclosure.** Open disclosure is a principles-based approach to honest, empathetic and timely discussions with a person, and/or their support people, when actual or potential harm occurs while that person is receiving healthcare. Open disclosure is an obligation for healthcare teams that enables them to meaningfully acknowledge, apologise for, remedy, reflect on and learn from incidents of actual or potential harm.

**Patient.** A person receiving health care.

**Person-centred care.** Person-centred care is health care that respects the patient, their family and carers, and responds to the person's preferences, needs and values. Person-centred care is equitable, culturally safe and free from racism and all other forms of discrimination. Patients, carers and consumers are treated with dignity, respect and kindness.

**Professional interpreter.** A qualified professional who enables communication between people who speak or sign a different language. Interpreters take a spoken or sign language and convert it accurately and objectively into another language to enable communication between two parties who do not share a common language. An interpreter should possess training in interpreting and a formal credential.

**Quality health care.** The degree to which health services increase the likelihood of desired outcomes and are consistent with current professional knowledge.

**Quality improvement.** The efforts of the healthcare professionals and others – including consumers, patients and their support people, researchers, planners and educators – to make changes that will lead to better patient outcomes (health), better system performance (care) and better professional development. Quality improvement activities may be undertaken in sequence, intermittently or continually.

**Reimbursement.** The act of paying for somebody's expenses without an admission of liability.

**Risk.** The chance of something happening that will have a negative impact. Risk is measured by the consequences of an event and its likelihood.

**Risk management.** The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the organisation.

**Safety culture.** A commitment to safety that permeates all levels of an organisation, from the workforce to executive management. Features commonly include acknowledgement of the high-risk, error-prone nature of an organisation's activities; a blame-free environment in which individuals can report errors or near misses without fear of reprimand or punishment; an expectation of collaboration across all areas and levels of an organisation to seek solutions to vulnerabilities; and a willingness of the organisation to direct resources to deal with safety concerns.

**Social Harm.** Negative impacts on a person, their family, or community arising from healthcare that diminish dignity, relationships, trust, or social participation, beyond physical or clinical outcomes.

**Support person/people.** An individual/group who has a relationship with the patient. References to 'support people' in this document can include:

- family members / next of kin
- support people
- friends, a partner or other person (paid or unpaid) who cares for the patient
- guardians or substitute decision makers
- social workers or religious representatives
- where available, trained consumer or disability advocates.

**System.** The resources, policies, processes and procedures that are organised, integrated, regulated and administered to accomplish a stated goal. A system:

- Brings together risk management, governance, and operational processes and procedures, including education, training and orientation
- Deploys an active implementation plan; feedback mechanisms include agreed protocols and guidelines, decision support tools and other resource materials
- Uses several incentives and sanctions to influence behaviour and encourage compliance with policy, protocol, regulation and procedures.

The workforce is both a resource in the system and involved in all elements of systems development, implementation, monitoring, improvement and evaluation.

**System failure.** A fault, breakdown or dysfunction within operational methods, processes or infrastructure.

**Treatment.** The way an illness or disability is managed by medicines, surgery, physiotherapy or other intervention to affect an improvement in, or cure of, the patient's condition.

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Australian  
Commission on  
**Safety and Quality**  
in Health Care

T. +61 2 9126 3600  
Level 5, 255 Elizabeth St  
Sydney NSW 2000 Australia

**[safetyandquality.gov.au](https://www.safetyandquality.gov.au)**

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