



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

**Review of the *Open Disclosure  
Standard***

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**▶ Outline**

- 1. Background**
- 2. Review of the Open Disclosure Standard**
- 3. Consultation & preliminary findings**
- 4. The role of indemnity insurers**



## ► Open disclosure: background

- Healthcare professionals often discussed unexpected care outcomes openly and directly with patients.
- 1980s, responses to patient harm, including open disclosure, began to be approached more systematically.
- Open disclosure championed as an integral aspect of ethical, transparent and patient-centred care seeking to restore patient trust and improve processes of care.
- Strategic response to rising legal costs → early models: \*
  - Lexington Veterans Affairs Medical centre (Kentucky)
  - University of Michigan Health Service
- Australia was an early national adopter: *Open Disclosure Standard* released in 2003.

\* Both implemented as part of broader clinical incident, and risk management programs.

## ► Open disclosure in Australia

**2003** *Open Disclosure Standard* (released by the Australian Council for Safety and Quality in Health Care)

**2006-07** **Open Disclosure Pilot** (Australian Commission on Safety and Quality in Health Care, ACSQHC)

**2006-08** **Evaluation of the Open Disclosure Pilot** (Consortium of Australian Universities headed up by UTS, funded by ACSQHC)

**2008** **Australian Health Ministers' Communiqué** (supporting adoption of open disclosure into policy)



## ► Open disclosure in Australia (cont)

**2008-10** **100 patient stories project** (UTS, funded by ACSQHC)

**2009-10** **Legal aspects of open disclosure project** (University of Melbourne, funded by ACSQHC)

2010 Australian Safety and Quality Framework for Health Care (ACSQHC)

*"If something goes wrong, my healthcare team look after me. I receive an apology and a full explanation of what happened"*



## ► Open disclosure in Australia (cont)

**2011-12** **Review of the *Open Disclosure Standard*** (ACSQHC)

**2013** **Open disclosure an accreditation requirement for health service organisations under NSQHS Standards** (ACSQHC)  
<http://www.safetyandquality.gov.au/our-work/accreditation/>



## ► Review of the *Open Disclosure Standard*

The Standard remains mostly relevant but could benefit from further refinement, which should:

- change the Standard consistent with findings and recommendations in the Review Report
- increase patient involvement in open disclosure
- encourage health professional preparation for open disclosure, including through awareness and training.



## ► Review findings

- Open disclosure is often conducted as a process of information provision, but patients prefer it as an open dialogue.
- Health professionals support disclosure but there remain barriers to its practice including:
  - Perceived medico-legal consequences of disclosure
  - Concerns about their preparedness for involvement in open disclosure
- Open disclosure is more effective as an ethical practice that prioritises organisational and individual learning from error than solely as an organisational risk management strategy.
- Open disclosure has been found to create larger benefits for the health system and patients by fostering cultures of openness and trust.
- There remains a 'gap' in open disclosure practice.

## ► Review findings: barriers to open disclosure

- Individual: includes fear of litigation, disciplinary, reputational and financial concerns
- Interpersonal: Sense of unpreparedness for communication; conflict avoidance
- Organisational or cultural: institutional support and leadership; 'club culture'
- Professional: misunderstanding of the needs and expectations of patients.

## ► Legal aspects

- The most powerful barrier to the effective implementation of open disclosure is not the law, but the **apprehensions held by providers** regarding medico-legal risks associated with openness around adverse events.
- Fears are compounded by the jurisdictional differences and confusion regarding relevant statutes.
- In terms of open disclosure fuelling litigation, there is:
  - No strong empirical evidence to suggest either an increase or decrease in litigation or claims
  - No Australian case law indicating that apology or expression of regret is used to determine liability
  - Some evidence suggesting that open disclosure, as part of a clinical incident management program, has a chilling effect on litigation.

## ► 'Apology' laws

State / Territory	Statute	The definition of apology expressly includes any admission of fault or liability	Apology IS an admission of fault or liability by the person making it	The apology IS relevant to a determination of fault or liability	Evidence of apology admissible in civil proceedings as evidence of fault or liability
NSW	Civil Liability Act 2002	√	x	x	x
Vic	Wrongs Act 1958	x	x	√	√
Qld	Civil Liability Act 2003	√	x	x	x
SA	Civil Liability Act 1936	√	x	√	√
WA	Civil Liability Act 2002	x	x	x	x
Tas	Civil Liability Act 2002	x	x	x	x
NT	Personal Injuries (Liabilities and Damages) Act 2003	x	√ *	√ *	x
ACT	Civil Law (Wrongs) Act 2002	√	x	x	x

s: section  
\* Implicit from the nature and purpose of related sections.

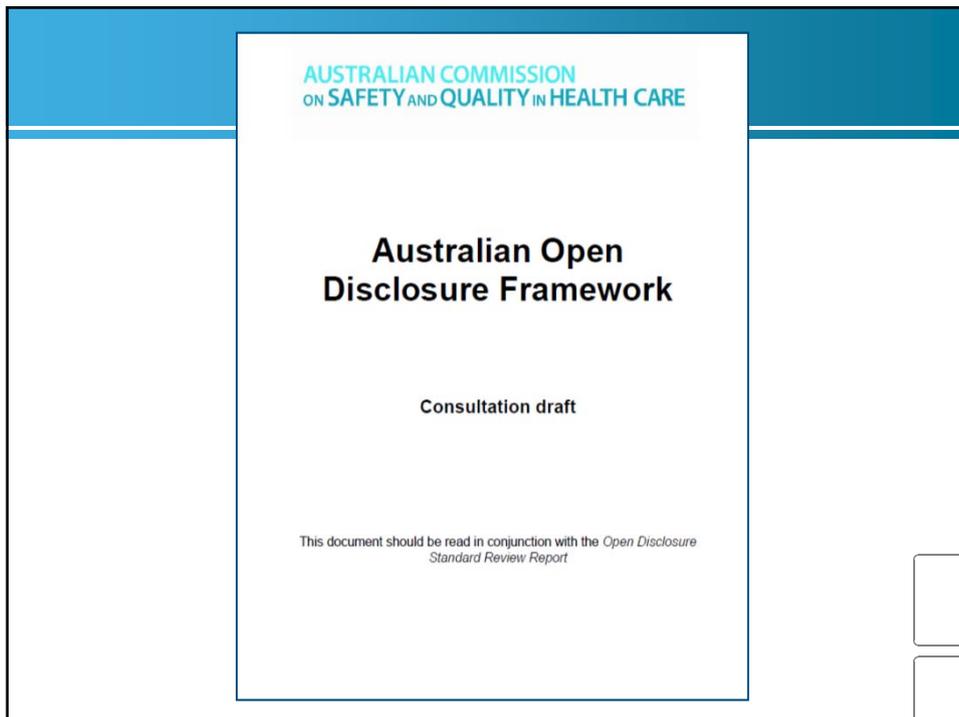
## ► Ramifications of not being open?

**No statutory duty to conduct open disclosure in Australia**

**Other levers: Accreditation, Code of Practice, AHMC directive...**

**However:**

- **“Errors do not necessarily constitute improper, negligent, or unethical behaviour, but failure to disclose them may.”**  
Ethics manual, fourth edition: disclosure. *Ann Int Med* 1998; 7: 576-94
- **even where the medical error was not negligent, “a breach of duty to disclose medical error can give rise to an independent cause of action... the patient may recover damages for the additional loss suffered as a result of not being told of the mistake.”**  
Madden B, Cockburn T. Bundaberg and beyond: Duty to disclose adverse events to patients. *Journal of Law and Medicine* 2007;14(2007):501–527
- **disciplinary consequences where failure to disclose is found to be deliberate or patients deliberately misled**



### ► Key changes between the Standard and the draft revised Standard

1. The words *I am* or *we are sorry* in an apology or expression of regret
2. Explicit instructions to avoid speculative statements
3. Emphasises key role of executive and management
4. Stresses importance of early management and response
5. Advises that open disclosure to be triggered by a variety of mechanisms (incl. patient perceptions/complaints)
6. Emphasis on continuous internal evaluation and improvement

## ► Definition of open disclosure

The open discussion of incidents that result in harm to a patient while receiving health care. The elements of open disclosure are:

### the Standard

- an expression of regret
- a factual explanation of what happened
- the potential consequences
- the steps being taken to manage the event and prevent recurrence.

### the draft revised Standard

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

## ► Consultation

**The consultation on a draft revised Standard consisted of three elements:**

1. consultation forums in each state (136 participants)
2. national online survey (n=149)
3. written submissions (34)

1 June – 31 August 2012

[www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-standard/consultation/](http://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-standard/consultation/)

### ▶ Preliminary findings

- Open disclosure is inherently complex, generating real and perceived barriers with regard to its implementation and uptake
- Open disclosure is:
  - a continuation of an episode of care
  - a core professional requirement (and institutional obligation)
  - a basic right of patients and healthcare consumers
  - an integral part of quality improvement, and a way of including information provided by patients, families and carers in the quality improvement cycle
- **The term 'open disclosure' is thought to harbor negative connotations but, equally, has strong brand/recognition value**

### ▶ Preliminary findings (cont)

- There is a need to manage broader community expectations of health care and its risks.
- Resource constraints must be recognised, however resources should support implementation and practice of open disclosure as a priority.
- The right culture of must be cultivated for open disclosure to thrive. Open disclosure training and development can feed into this culture change.
- **Requirements of all healthcare settings and sectors should be reflected in the revised Standard**

## ► Preliminary findings (cont)

### Training and development

- Training, development and education is seen as a key element for open disclosure implementation and uptake.
- There are broader benefits of training (e.g. participants learning about their personal strengths and weaknesses; communication skills)
- Open disclosure should be included in undergraduate and graduate curricula; there is a key role for universities, colleges, associations and other professional organisations.
- Ideally training should extend to insurers and legal professionals and non-clinical staff

## ► Where to now?

	Work	Complete
1	Review and analyse current open disclosure research, evidence and literature and report with recommendations: <i>Open Disclosure Standard Review Report</i> (Review Report)	Feb 2012
2	Develop draft revised <i>Open Disclosure Standard</i> (draft revised Standard) using recommendations from the Review Report	Apr 2012
3	Consult stakeholders on draft revised Standard	Aug 2012
4	Report on consultation process	Sept 2012
5	Finalise revised Standard based on consultation findings Develop resources to support implementation	Oct 2012
6	Submit revised Standard for endorsement	Nov 2012
7	Release revised Open Disclosure Standard and supporting resources	2013

▶ **Role of indemnity insurers**

- 1. Encourage openness and transparency about patient harm – opportunity to learn**
- 2. Be clear and consistent about open disclosure and clinical governance**
- 3. Educate and inform health professionals about their responsibilities**
- 4. Clarify concerns over medico-legal aspects**

▶ **Thank you**

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[www.safetyandquality.gov.au/our-work/open-disclosure/](http://www.safetyandquality.gov.au/our-work/open-disclosure/)