

Open Disclosure Standard

Review Report • June 2012



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

Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology/expressions of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps taken to manage the event and prevent recurrence.

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Australian Commission on Safety and Quality in Health Care

GPO Box 5480 Sydney NSW 2001 | Level 7, 1 Oxford Street, Darlinghurst NSW 2010
Phone: (02) 9126 3598 or (02) 9126 3613
www.safetyandquality.gov.au

Editing and design: Biotext, Canberra and Melbourne

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Glossary

Accreditation	A status that is conferred on a health service organisation or individual when assessed as having met particular standards, relating to quality of care and patient safety.
Admission of liability	A statement by a person that admits, or tends to admit, a person's or organisation's liability in negligence for harm or damage caused to another.
Adverse event	An incident in which harm resulted to a person receiving health care. See definition of <i>Harm</i> below. See also <i>Harmful incident</i> below.
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>I am</i> or <i>we are sorry</i> . Apology may also include an acknowledgment of responsibility, which is not an admission of liability. See also <i>Admission of Liability</i> and <i>Expression of regret</i>
Clinical microsystem	A group of healthcare professionals and support staff working together with a shared clinical purpose to provide care for a population of patients. ¹
Clinical risk	The combination of the probability of occurrence of harm and the severity of that harm. ²
Clinical risk management	See <i>Risk management</i>
Clinical workforce	The nursing, medical and allied health staff who provide patient care and students who provide patient care under supervision. This may also include laboratory scientists.
Commission, the	The Australian Commission on Safety and Quality in Health Care
Complication	A detrimental patient condition that arises during the process of providing health care. ²
Consumer (healthcare)	Patients and potential patients, carers, and organisations representing consumers' interests.
Corporate risk	Potential liabilities, exposures and dangers faced by an organisation or corporation. These can be financial or reputational.
Corporate risk management	See <i>Risk management</i>
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. ²
Ex gratia	'Out of good will', usually referring to financial reimbursement or recovery payments. By definition, ex gratia payments are not an admission of liability.

Expression of regret	An expression of sorrow for a harm or grievance. It should include the words <i>I am</i> or <i>we are sorry</i> . An expression of regret may be preferred over apology in special circumstances (e.g. when harm was unpreventable). See also <i>Apology</i>
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological. ² Examples of social and psychological harm include: not having dignity, autonomy or beliefs respected being demeaned or insulted.
Harmful incident	A clinical incident that led to patient harm. Note: This term means <i>Adverse event</i> when used in this report.
Healthcare professionals	This term refers to clinical workforce and relevant non-clinical workforce who have a role or participate in open disclosure.
Non-clinical workforce	The workforce in a health service organisation who do not provide direct clinical care but support the business of health service delivery through administration, corporate record management, management support or volunteering.
NSQHS	National Safety and Quality Healthcare Service
Open disclosure	An open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology/expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.
Outcome	The effect upon a patient, which is wholly or partially attributable to an incident. The status of an individual, a group of people or a population which is wholly or partially attributable to an action, agent (one who/which acts to produce a change) or circumstance, i.e. all factors connected with influencing an event, agent or person(s).
Patient	A person receiving health care. Synonyms for patient include consumer and client. In this report, patients can also refer to family members, nominated support persons, loved ones, partners, carers or guardians.
Patient safety	The reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of current knowledge, resources available and the context in which care was delivered and weighed against the risk of non-treatment or other treatment. ²
Quality	The degree to which health services increase the likelihood of desired outcomes and are consistent with current professional knowledge. ²

Quality improvement	The continuous study and adaptation of a healthcare organisation's functions and processes to increase the probability of achieving desired outcomes and to better meet the needs of patients and other users of services.
Reimbursement	The act of paying another party for incurred expenses.
Risk management	<p>The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the institution.</p> <p>Clinical risk management: Clinical, administrative and manufacturing activities that organisations undertake to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organisation itself.²</p> <p>Corporate risk management: Activities of an organisation or corporation to identify and reduce potential financial or reputational liabilities, exposures and dangers.</p>
Sentinel event	An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase 'or the risk thereof' includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called 'sentinel' because they signal the need for immediate investigation and response. ³
Service recovery	The process used to 'recover' dissatisfied individuals or patients by identifying and fixing the problem or making amends for the failure in customer or clinical services. ⁴
Staff	Anyone working within a hospital, including self-employed professionals such as visiting medical officers.

References

1. Mohr J, Batalden P, Barach P. Integrating patient safety into the clinical microsystem. *Quality and Safety in Health Care* 2004;13(suppl 2):ii34–ii38.
2. WHO (World Health Organization). *The international classification for patient safety*. Geneva: WHO, 2009.
3. Joint Commission. Sentinel event policy and procedures 2011. (Accessed November 2011, at http://www.jointcommission.org/Sentinel_Event_Policy_and_Procedures)
4. Conway J, Federico F, Stewart K, Campbell M. *Respectful management of serious clinical adverse events* (2nd ed.). Cambridge, Massachusetts: Institute for Healthcare Improvement, 2011.

Executive summary

Open disclosure is an individual and health service-level response to incidents of patient harm. It is a process in which healthcare providers communicate with, and support, patients who have been harmed as a result of health care. It is considered an important element of good clinical practice and professional ethics, and is part of effective clinical communication.

The *Open Disclosure Standard* (the Standard) specifies that the open disclosure process should entail, at a minimum, an expression of regret, explanation of what has occurred, and description of the action being taken to manage the incident and prevent recurrence.

Since the 2003 release of the Standard, there has been much research and inquiry into disclosure. The Australian Commission on Safety and Quality in Health Care (the Commission) has funded independent research into open disclosure including evaluation of the *National Open Disclosure Standard Pilot*, investigation of patients and healthcare professional disclosure experiences, and opinions on legal aspects of open disclosure in Australia.

It is now nearly ten years since the Standard was developed and endorsed. The Commission has undertaken a review of the Standard to ensure it continues to meet the needs of patients, health professionals and health services.

Purpose

This report has been prepared by the Commission to present findings from the review of the Standard. It is intended for the people and organisations that have a role to play, and an interest, in open disclosure and aims to:

- present findings from a review of the Standard drawing on current research and evidence of, and experience with, disclosure
- identify where the Standard does and does not reflect current evidence and practice
- recommend changes to the Standard.

The report explores current evidence and practice for each of the eight principles contained in the Standard. Implications for a revised Standard are discussed at the end of each chapter and recommendations made.

Findings

The review found that the Standard remains mostly relevant but could benefit from further refinement. Further refinement should:

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

In addition, the revised Standard should be supported by implementation resources to enable open disclosure uptake and sustainability.

There are four main review findings:

- 1 Open disclosure is often conducted as a process of information provision from the service to the patient but patients prefer it as an open dialogue.
- 2 Health professionals support disclosure but barriers remain to its practice including:
 - perceived medico-legal consequences of disclosure
 - concerns about preparedness for involvement in open disclosure
 - difficulty with communicating openly in the context of risk management.
- 3 Overseas evidence and Australian experience suggest disclosure is more effective as an ethical practice that prioritises organisational and individual learning from error than solely as an organisational risk management strategy.
- 4 Open disclosure has been found to create larger benefits for the health system and patients by fostering cultures of openness and trust.

Recommendations

The report recommendations are compiled below and are also found in the report under the Standard's eight principles, plus an additional recommendation related to implementation.

Principles 1 and 2: Openness and timely acknowledgment

Recommendation 1.1: The revised Standard should emphasise that the open disclosure process is a two-way exchange of valuable information and an ongoing dialogue that can:

- redress harm and repair damaged relationships
- contribute towards health system improvement.

Recommendation 1.2: The revised Standard should emphasise that early management of an incident, especially the way communication is undertaken with patients, has been found to have a powerful effect on:

- patient perceptions of the incident itself
- levels of patient trust
- medico-legal implications and results
- eventual outcomes and residual harm.

Recommendation 1.3: The revised Standard should:

- promote support for open disclosure implementation, particularly health professional education on managing post-incident communication and interaction with patients
- emphasise that all aspects of disclosure are to take place in a fair manner, without bias and in keeping with the ethos of patient-centeredness
- stress the importance of supporting providers throughout the process.

Recommendation 1.4: The revised Standard should:

- stress early intervention and communication

- provide guidance on which part of the post-incident communication spectrum applies in specific situations.

Recommendation 1.5: The revised Standard should describe an inter-disciplinary, inter-professional and multi-sector approach to disclosure based on the same principles of openness and transparency described in the current Standard.

Recommendation 1.6: The revised Standard should:

- explicitly address the tension between immediately providing patients with information and taking preliminary advice from insurers and, where applicable, employers
- recognise insurer and, where applicable, employer roles and responsibilities in overall open disclosure policy development as well as in individual cases.

Principle 3: Expression of regret

Recommendation 2.1: The revised Standard should change the name of Principle 3 to *Saying sorry*.

Recommendation 2.2: The revised Standard should:

- specify the need for saying sorry within either an apology or an expression of regret in open disclosure as appropriate
- outline how saying sorry (as part of an apology or expression of regret) is beneficial for patients and providers
- describe the basic principles and components of an apology or expression of regret (including the words *I am* or *we are sorry*) in the context of patient harm, but not be too prescriptive due to
 - the complexity and uniqueness of individual incidents and consequent disclosure process
 - variations in legislative context between jurisdictions.
- stress that the need for an expression of regret versus an apology may change over time as new information comes to hand during the open disclosure process.

Recommendation 2.3: The revised Standard should:

- state explicitly that an apology or expression of regret may interact with jurisdictional law
- highlight the importance of avoiding speculative statements during the initial disclosure and delivery of an apology or expression of regret (illustrating with examples based on jurisdictional laws)
- recommend professional development and training aimed specifically at building understanding, knowledge and skills to approach apologising and expressing regret confidently during open disclosure.

Principle 4: Recognition of the reasonable expectations of patients

Recommendation 3.1: The revised Standard should:

- recommend that patient perception of harm be considered when deciding whether open disclosure is necessary

- recommend a holistic approach to the assessment of harm and impact on a patient using the patient's experience of their care as well as biomedical factors.

Recommendation 3.2: The revised Standard should recognise that:

- the needs and preferences of patients should be a principal driver of open disclosure policy and procedures
- patient and provider views and expectations may differ on what should be disclosed and how
- there is a need for modulated communication and a nuanced way in which information is exchanged.

Recommendation 3.3: The revised Standard should:

- recommend that the need for disclosure be triggered by a range of mechanisms including patient reports of their experience, and formal and informal complaints
- promote the involvement of patients, families and carers in incident investigation and quality improvement
- highlight the importance and effect of the consent process on incident management and on open disclosure.

Recommendation 3.4: The revised Standard should be supported by materials and resources to assist implementation, and address the gaps in the current Standard with regard to the management of patient expectations throughout the entire episode of care.

Principle 5: Staff support

Recommendation 4.1: The revised Standard should encourage healthcare organisations to institute a 'best practice' approach, including the requirement and description of a formal staff support process following a harmful incident and during the open disclosure process.

Recommendation 4.2: The revised Standard should be complemented by a suite of implementation resources in a variety of formats.

Recommendation 4.3: The revised Standard should strongly advocate for open disclosure training and education of healthcare professionals as an integral part of progressing and embedding cultural change, with the aim of:

- encouraging open acknowledgment of harmful incidents as
 - an existent aspect of modern health care
 - a potential driver of quality improvement and systems learning
- making explicit the organisational values conducive to supporting staff and patients following harmful incidents
- encouraging senior staff to act as role models and mentors for less experienced staff
- viewing incidents as learning opportunities
- recognising the clinical and corporate risk management and quality improvement dimensions of communicating with patients in an empathic manner
- optimising the processes for managing harmful incidents.

Principles 6 and 7: Integrated risk management, systems improvement and good governance

Recommendation 5.1: The revised Standard should continue to emphasise the key role of executive leadership, ownership and engagement in implementing open disclosure.

Recommendation 5.2: The revised Standard should:

- advise on how open disclosure can be integrated into, and enhance, existing risk management and clinical governance frameworks
- assume the existence of clinical governance frameworks and protocols for the conduct of investigations, rather than describing their development.

Recommendation 5.3: The revised Standard should:

- emphasise the value of open dialogue with patients in satisfying the needs of the patient
- recognise that open dialogue with patients is a key component of healthcare quality improvement, systems learning and clinical risk management.

Recommendation 5.4: The revised Standard should highlight the importance of data and information management processes to ensure:

- systems learning and quality improvement
- executive oversight and leadership of open disclosure
- intra-organisational accountability
- organisational accountability to external authorities.

Recommendation 5.5: The revised Standard should be accompanied by implementation resources to enable health services to implement and sustain open disclosure. These may include:

- staff safety culture survey templates
- risk management guidelines
- sets of standardised open disclosure outcome and process measures
- templates for executive reporting.

Recommendation 5.6: The revised Standard should be made relevant to a wider spectrum of healthcare services, including non-acute and primary care setting.

Principle 8: Confidentiality

Recommendation 6.1: The revised Standard should outline the importance of formally seeking support person nominations early in the episode of care in case of subsequent open disclosure and incident management.

Recommendation 6.2: The revised Standard should advocate for best practice open disclosure that openly and transparently provides all available information to patients and support persons.

Recommendation 6.3: The revised Standard should address the need to balance patients' need for information with protecting the personal information about healthcare professionals involved in a harmful incident (information that is not related to the incident or the ensuing open disclosure).

Recommendation 6.4: The revised Standard should outline documentation requirements that provide patients and providers with consistent and complete information during the open disclosure process.

Open disclosure implementation

Recommendation 7.1: The revised Standard should recommend implementing systems to monitor, evaluate and improve the quality of open disclosure processes including:

- internal process measures
- data collected from patients and staff to measure and inform open disclosure improvements
- feedback to clinical staff about open disclosure performance and improvement activities.

Next steps for review of the *Open Disclosure Standard*

The *Open Disclosure Standard* review is occurring in the following stages:

Table 1 Open Disclosure Standard review stages

Stage	Work	Complete
1	Review and analyse current open disclosure research, evidence and literature and report with recommendations	February 2012
2	Develop revised Open Disclosure Standard using recommendations from the Open Disclosure Standard Review Report	April 2012
3	Consult stakeholders on revised Open Disclosure Standard	August 2012
4	Finalise revised Open Disclosure Standard based on consultation findings	September 2012
5	Develop revised Open Disclosure Standard implementation resources	October 2012
6	Report on review project and submit revised Open Disclosure Standard for endorsement	November 2012

This report has completed Stage 1 of the review process.

Future consultation will be based on a revised Standard developed from the findings and recommendations in this report.

The consultation process will consist of three elements:

- consultation forums in each jurisdiction
- a national online survey
- written submissions.

Further information on the *Open Disclosure Standard* review is available from the Commission's website: www.safetyandquality.gov.au/our-work/open-disclosure.



Introduction

Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology, expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

1 Introduction

Every day across Australia, many thousands of healthcare interventions are made. These interventions are often complex, delivered in high-pressure environments using highly advanced equipment, and involve multiple practitioners working together in teams and across organisations. Such interventions usually result in excellent clinical outcomes, but modern health care also carries significant risks. Sometimes unintended incidents occur and some result in patient harm.⁵⁻⁹

Open disclosure is a response to incidents of patient harm by both the individual healthcare practitioner and the organisation involved. It includes a frank and open discussion with the patient and their carer, as well as individual and organisational management of, and response to, the patient harm. A national open disclosure standard has been available to Australian healthcare services since 2003 when Australian health ministers endorsed the national *Open Disclosure Standard* (the Standard), which defines open disclosure as the 'open discussion of incidents that result in harm to a patient while receiving health care.' Its elements include 'an expression of regret, a factual explanation of what happened, the potential consequences and the steps taken to manage the event and prevent recurrence.'^{10(p1)}

The Australian Commission on Safety and Quality in Health Care (the Commission) is responsible for maintaining the Standard and for reducing national barriers to its implementation. The Commission is advised on conduct of its Open Disclosure Program by the Open Disclosure Advisory Group. The group includes clinicians, public and private hospital representatives, academics, consumers, and professional indemnity and institutional insurers.

At its meeting of 29 November 2010, the Open Disclosure Advisory Group supported the proposed *Open Disclosure Standard* review process of developing a discussion paper to generate interest and responses and subsequently to create a model with which stakeholders could engage. The Commission and its Inter-Jurisdictional, Private Hospital and Primary Care Committees have been informed of, and support, the review of the Standard.

1.1 Purpose of this report

The purpose of this report is to present the findings of the review and suggest changes to the Standard. The report discusses:

- the background to open disclosure
- Australian and overseas experience, latest research, literature and best practice in open disclosure
- gaps and limitations in the current Standard in light of the latest evidence
- barriers and enablers of open disclosure implementation
- benefits and opportunities that open disclosure delivers to Australian patients, healthcare professionals, health services and the broader community
- recommended changes to the Standard that will encourage implementation.

1.2 Structure of this report

Following a background to open disclosure (Chapter 2), this report explores current evidence in practice within each of the eight principles expressed in the current Standard:¹⁰

- 1 Openness and timeliness of communication (Chapter 3)
- 2 Acknowledgment (Chapter 3)
- 3 Expression of regret (Chapter 4)
- 4 Recognition of the reasonable expectations of patients and their support person(s) (Chapter 5)
- 5 Staff support (Chapter 6)
- 6 Integrated risk management and systems improvement (Chapter 7)
- 7 Good governance (Chapter 7)
- 8 Confidentiality (Chapter 8).

Note that principles 1 and 2 and principles 6 and 7 are considered together.

Each section discusses how the Standard might be revised in light of current thinking, evidence and practice. Implementation barriers, enablers and benefits of open disclosure are then discussed (Chapter 9). This includes a section on the economics of open disclosure. The Appendix outlines examples of successful open disclosure programs.

1.2.1 Quotes

Quotes from Australian patients, family members and health practitioners reflecting their experience of open disclosure have been included throughout the report. These are taken from independent, ethics-approved research (funded by the Commission) involving interviews with over one hundred patients, family members, carers, and healthcare providers. Data and knowledge generated by this research have been published in several peer-reviewed journals.

1.3 Evidence

Medical science relies on scientific method to inform practice. Evidence gathered through meta-analyses of randomised controlled trials is considered the gold standard of scientific enquiry. However, applying such methods in the quality improvement context is inherently difficult because the effect of interventions depends on a multitude of organisational, cultural and demographic factors as well as on the quality of implementation.^{15, 16} In addition, programs that span entire healthcare organisations cannot be re-created in a laboratory environment. This is especially true in an area as complex and unpredictable as open disclosure, which involves experiences, feelings and emotions not easily rationalised or measured in a purely quantitative way. The lack of conclusive evidence derived from large samples is often invoked to argue against prioritising quality improvement over additional health care.¹⁷

The research presented here is predominantly qualitative, based on interviews and hypothetical situations especially with regard to patient and health professional experiences. This research is supported by broader results of related research activity that has taken place in recent years. There is now a considerable body of peer-reviewed open disclosure literature and accumulated knowledge from a range of healthcare systems.^{18–22} The findings of this research, much of which has taken place in Australia, suggest general consensus on various dimensions of open disclosure upon which policy can be constructed.

1.4 Definitions and terminology

There are various terms used in healthcare services, and in the evidence, to describe key concepts in this report. The glossary at the beginning of the report provides definitions for key terms. This section provides an explanation of some of these terms and how they are used in this report.

Much of the discussion in this report revolves around the issue of harm, how it is perceived and whose interpretation is used. The World Health Organization defines harm as '[i]mpairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological'.² This is the definition upon which the discussion in the report is based.

In this report, the term 'adverse event' means (an) incident in which harm resulted to a person receiving health care. In addition, the term 'harmful incident' will also be used in this report to refer to an adverse event. This term is used in literature to link adverse events specifically to open disclosure and to accommodate various interpretations of harm and other issues such as preventability, expected complication and error.

Open disclosure involves a range of individuals and organisations. For patients, the process will often involve family members, loved ones, partners, carers or guardians. Unless otherwise specified, the term 'patient' implies all of these individuals, as do other ways of describing a person receiving care such as 'resident' or 'client'. The term 'consumer' is used in a broader sense to signify individuals who may not, at the time, be receiving care but who, as potential patients, have an interest in healthcare services.

'Healthcare professionals' is the term used to encompass the clinical workforce and the non-clinical workforce who have a role in open disclosure. It may include nurses, midwives, allied health professionals, managers, pharmacists, surgeons or physicians. The term 'staff' is sometimes used and also refers to both clinical and administrative professionals.

While the term 'healthcare service' is preferred in this report, other terms are also used such as institution, organisation, healthcare facility or hospital. These terms may be understood to include residential care facilities, nursing homes and domiciliary service providers. 'Institution' can also refer to professional organisations, learned colleges, associations and educational facilities.

Open disclosure is sometimes referred to simply as disclosure in this report.

References

2. WHO (World Health Organization). *The international classification for patient safety*. Geneva: WHO, 2009.
5. WHO (World Health Organization). *World alliance for patient safety*. Geneva: WHO, 2004.
6. Institute of Medicine. *To err is human: Building a safer health system*. Washington DC, 2000.
7. Leape L. Institute of Medicine medical error figures are not exaggerated. *Journal of the American Medical Association* 2000;284(1):95.
8. Wilson R, McL., Harrison BT, Gibberd RW, Hamilton JD. An analysis of adverse events from the quality in Australian health care study. *Medical Journal of Australia* 1999;170:411–415.
9. Wilson R, Runciman WB, Gibberd RW, Harrison B, Newby L, Hamilton J. The quality in Australian health care study. *Medical Journal of Australia* 1995;163(9):458–471.
10. Australian Council for Safety and Quality in Health Care. Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care. Canberra, 2003.
15. Ovreteit J. Understanding the conditions for improvement: Research to discover which context influences affect improvement success. *BMJ Quality and Safety* 2011;20(Suppl 1):i18–i23.
16. Ovreteit J, Shekelle P, Sydney M, McDonald K, Hempel S, Pronovost P, et al. How does context affect interventions to improve patient safety? An assessment of evidence from studies of five patient safety practices and proposals for research. *BMJ Quality and Safety* 2011.;20:604–610 doi:10.1136/bmjqs.2010.047035
17. Millar A. Is money spent on quality improvement better spent on clinical care? — yes. *Medical Journal of Australia* 2011;194(12):640.
18. Iedema R, Sorensen R, Piper D. Open disclosure: Review of the literature. Sydney: ACSQHC (Australian Commission on Safety and Quality in Health Care), 2008.
19. Piper D, Iedema R. *Literature review: Incident disclosure policy, legal reform and research since 2008*. Sydney: Centre for Health Communication (University of Technology Sydney) and ACSQHC (Australian Commission on Safety and Quality in Health Care), 2011
20. Allan A, Munro B. *Open disclosure: A review of the literature*. Perth: Edith Cowan University, 2008.
21. O'Connor E, Coates HM, Yardley IE, Wu AW. Disclosure of patient safety incidents: A comprehensive review. *International Journal on Quality in Health Care* 2010;22(5):371–379.
22. Gallagher TH. A 62-year-old woman with skin cancer who experienced wrong-site surgery. *Journal of the American Medical Association* 2009;302(6):669–677.



Background

Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology, expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

2 Background

Modern health care has developed into one of the most complex human endeavours.²³ While patient harm is obviously to be avoided as far as possible, the reality is that some adverse events are to be expected in this complex and challenging discipline. A recent Productivity Commission report in support for Australians with disabilities proposes that injury and disability caused by medical 'accidents' be included in a national injury insurance scheme.²⁴ This therefore assumes patient harm is an unavoidable issue in health care. System responses to patient harm are starting to be considered in a similar fashion as those to other sources of injury and disability such as motor vehicle accidents.

It is therefore an opportune time to revive a national conversation on open disclosure as a key part of managing patient harm, as well as its role in a humane, responsive and patient-focused healthcare system for all Australians.

2.1 Patient harm — a global issue

The past two decades have seen increased recognition and scrutiny of preventable patient harm that was caused by error, system failure and lapses in healthcare quality. A series of government inquiries have been conducted internationally and in Australia.^{25–28} Academic and empirical investigations into the incidence and causes of patient harm have enlarged the evidence on the scope and scale of healthcare safety and quality issues.^{8, 9, 29–31}

These investigations suggest that approximately ten per cent of all clinical interventions result in patient harm, and that about half of these are preventable. More recent examination of patient harm suggests that these figures could significantly underestimate the true rates and preventability of adverse events.^{32–35} Results from the 2009 *Australian Labour Force Survey* indicate that almost 900 000 Australians aged 15 years and over experienced harm from medication, medical care, treatment or investigation in one year.³⁶ Only a small proportion of adverse events are reported to existing incident reporting mechanisms.^{35, 37–40} Media scrutiny of patient harm remains high.^{41, 42}

Several key themes relevant to this review emerge from patient safety research:

Patient harm

- Patient harm occurs in all hospitals, health services and clinical settings and in all countries.
- Individual incidents are often preventable. Statistically, however, unexpected events and outcomes are inevitable over time.⁴³

Patients

- Evidence suggests that only a small proportion of adverse events are disclosed to patients, with an even smaller proportion of disclosure meeting patient needs and expectations.^{11, 44–50, 19(p40)}
- Patients' expectations, views and preferences of healthcare safety and quality often differ to those of healthcare providers.^{47, 51–54}

- Patients (families and carers) are increasingly recognised as key members of the healthcare team, both as holders of critical care information across the care continuum and as contributors towards clinical decision-making.^{13, 39, 55}

Organisations

- Health care has evolved from an individual 'craft' into a complex and intricate undertaking both at individual and system levels.^{56, 57}
- Health care is delivered by teams of professionals; within which, effective communication is increasingly recognised as the key ingredient in maximising safety and quality.^{58–64}
- Organisational cultures promoting openness, transparency and a desire to learn from errors typify high-quality healthcare organisations; opacity and denial feature in organisations with poor safety records.^{65–67}
- Theory and knowledge from other disciplines and human endeavour (e.g. industrial production, economics, human factors research, behavioural science and sociology) are frequently drawn upon to explain and remedy deficiencies in healthcare delivery.^{68, 69}

2.2 Open disclosure in Australia and overseas

In the past, healthcare professionals often discussed unexpected care outcomes openly and directly with patients. However, in the late 1980s a movement towards organisational responses to medical errors began to be described, acted upon and championed by leading clinicians, consumers and others as an integral aspect of ethical, transparent and patient-centred care.^{31, 70–75} Formal, institutionally led disclosure remains an evolving phenomenon. Over the last two decades, open disclosure has been seen variously as a strategic response to rising legal costs, and as an ethical practice on the part of health services seeking to restore patient trust, repair harms and improve processes of care.^{48, 74, 76, 77}

According to the United Kingdom's National Patient Safety Agency, 'being open when things go wrong is clearly fundamental to the partnership between patients and those who provide their care.'^{78(p6)}

Australia was an early adopter of open disclosure when in 2003, Australian health ministers endorsed the Standard.¹⁰ Evidence for the value and the benefits of disclosure has grown considerably in the years since the release of the Standard. Open disclosure has become a part of health policy across most continents.^{10, 78–80} Examples of these policies include the United Kingdom's *Being Open — Communicating Patient Safety Incidents with Patients, their Families and Carers*, made available in 2005⁸¹ and re-launched in 2009,⁷⁸ and the *Canadian Disclosure Guidelines* released in 2008⁷⁹ with a revised draft currently under consultation.⁸² New Zealand frames incident disclosure as a patient right, and it is a component of that country's *Health and Disability Service Standards*.^{83, 84} In 2006, the Harvard hospitals released a consensus statement on open disclosure titled *When things go wrong: Responding to adverse events*.⁷³

2.3 Benefits of open disclosure

Open Disclosure might succeed where other health care reform initiatives have thus far failed: Accomplishing a new structure of attention that favours open communication and responsive relationships among all stakeholders in health care.^{85(p155)}

Effective open disclosure is achievable through a combination of leadership, change management and collaboration between stakeholders including patients, providers, institutions, professional associations, insurers and the legal profession.

The benefits of open disclosure include:

For patients

- ameliorating feelings of anger, guilt, grief or helplessness
- restoring trust in health care
- encouraging patients to participate in health care quality improvement processes.

For healthcare providers

- enabling healthcare professionals to mitigate ongoing negative consequences of harmful incidents
- enabling healthcare professionals to manage the stress and affective consequences of a harmful incident or complaint
- ameliorating feelings of guilt and shame
- facilitating a full and frank incident investigation which can be used to improve safety and quality
- fulfilling professional, ethical and moral obligations to truthfully disclose information on harmful incidents.

A consolidated view of the current literature suggests that the benefits of systematically implemented open disclosure could extend beyond the immediate context of any particular case and into service improvement more broadly. These additional benefits may include:

- improved system responsiveness to patient needs
- improved clinical communication skills resulting in better care, diagnostic skills and patient-centred outcomes
- leverage for cultural reform through
 - embedding transparency and openness into healthcare services
 - flattening hierarchies, reducing barriers between disciplines and professions, and promoting a team-based ethic
- increased and improved notification, reporting and investigation of incidents (including the patient's perspective on the trajectory of their care), resulting in more targeted quality improvement activity
- improved staff morale and retention
- strengthened public trust in healthcare institutions, including the patient-provider relationship.

This broader range of benefits is perhaps more evident from open disclosure than other quality improvement initiatives, and should be considered when discussing the resource implications of open disclosure. They assist an economic case for open disclosure to be made (see Section 9.2).

2.4 The national *Open Disclosure Standard*

I think in some ways they [staff] are relieved because ... there is a plan: this is what we are going to do with this family. Director, Clinical Department^{+B6(p18)}

The intention of the Standard was to facilitate open communication by health services with patients and their families about adverse events in health care. It recognised that reducing error in complex systems required active encouragement of health professionals to report error in a supported environment and that error reporting was critical to organisational learning.

The Standard specifies that the open disclosure process should entail, at a minimum, an expression of regret, explanation of what has occurred, and description of the action being taken to manage the incident and prevent recurrence.

The Australian experience of open disclosure has been subject to significant review and investigation into:

- the *National Open Disclosure Pilot*
- health professional perspectives
- patient perspectives
- legal barriers to open disclosure practice.



2.4.1 Evaluation of the *National Open Disclosure Pilot*

In January 2005, Australian health ministers endorsed an implementation plan, which included piloting the Standard in the public and private sectors. The *National Open Disclosure Pilot* involved 40 facilities in seven jurisdictions and the private sector. It included development of open disclosure policies, protocols and tools by jurisdictions and participating facilities. Some jurisdictions trained health professionals in open disclosure and implemented the Standard statewide; in others only some services participated. Pilot sites were highly variable in scale, in the exact model of open disclosure practised, in their subsequent practical experience of open disclosure, and in the extent and nature of the open disclosure provided. The pilot officially concluded in December 2007.

The Australian Commission on Safety and Quality in Health Care (the Commission) subsequently funded an extensive independent evaluation of the national pilot. The basis for the study was 154 semistructured and in-depth interviews ranging from 45 minutes to 2 hours in duration: 131 with health professionals, 15 with patients and 8 with family members. The transcripts were analysed, capturing both the detail of open disclosure experiences and the emotional and interpersonal subtleties embedded in the responses. In addition, a survey questionnaire was circulated among healthcare providers and organisations. Eighty completed surveys were received.

Three main aspects of open disclosure revealed in the evaluation were:⁸⁶

- 1 Open disclosure is met with approval and relief on the part of both health professionals and patients:
 - staff could now discuss matters that were often seen as too difficult to discuss in the past
 - patients felt pleased that they had been told what happened.
- 2 There are ongoing uncertainties about:
 - which incidents 'trigger' open disclosure
 - the impact of open disclosure on staff and their organisation's reputation
 - the legal and insurance implications of open disclosure
 - whether colleagues would support those carrying out open disclosure.
- 3 Staff and patients want to integrate open disclosure more firmly and consistently in everyday clinical practice.

The evaluation is a rich source of quantitative and qualitative data on the practice of, and attitudes to, open disclosure. The following quotes derived from the interviews encapsulate the more positive aspects of the findings.⁸⁶

Before March I blamed the hospital, I blamed myself, I blamed everybody. Like, the guilt was just so raw with me. My own guilt and the guilt that I'd let my son down, and the blame that I needed to pass on to the hospital, and all of that. Since the Open Disclosure I know for a fact that there has been measures put in place so that this doesn't happen ... The Open Disclosure actually lifted a great weight off my shoulder. I didn't feel like it was about guilt any more. It was about acceptance. This happened which shouldn't have happened but it did and I have to accept that and move on. Patient^(p115)

We had a massive case of an absolutely horrendous situation involved and we went through an Open Disclosure process and that was the most amazingly kind of positive experience. Senior Medical Manager^(p19)

In April 2008, Australian health ministers considered the results of the evaluation and agreed to work towards implementation of the Standard in all healthcare facilities. Ministers also recommended that additional investigation of patient views and experience of open disclosure be undertaken.

2.4.2 Investigating the patient experience of open disclosure

The Commission subsequently funded large-scale independent research into the patient experience of open disclosure. The study conducted approximately 116 in-depth interviews to describe and document patient stories of harmful incidents and subsequent organisational responses to them. Qualitative data analysis software (NVivo) was used to identify high-frequency themes found in the interview data. The project findings have been published in several peer-reviewed journals, with others forthcoming.^{11-13, 87}

Generally, interviewees felt that disclosure lacked a sincere apology and an ongoing care plan, was not conducted as a dialogue, and did not contain enough information on how future incidents would be prevented. The main concerns or shortcomings identified in the interviews were:¹¹

- inadequate preparation for open disclosure discussions for patients and by staff
- lack of appropriate closure, and insufficient dialogue facilitating an exchange of experiences, views, questions and expectations on the part of stakeholders in the incident
- disclosure of unexpected outcomes in an inappropriate fashion
- lack of follow-up support
- insufficient integration of open disclosure with quality and patient safety improvement processes.

Several ancillary issues were also identified:

- lack of ready acknowledgment for incidents
- absence of internal complaint mechanisms that trigger disclosure in the interest of the consumer
- inappropriate level of formality and explanation during the process, including inadequate information about the process itself
- unsuitable times and locations for discussions
- lack of opportunity to arrange a personal support person(s)
- lack of consultation with patients with regard to which staff members would be present.

The study identifies several aspects of open disclosure practice that are in need of improvement and suggests several changes to the current practice of open disclosure including:

- commencing the open disclosure process as soon as possible following the incident, even if all the facts have not yet been established
- enacting open disclosure as facilitated dialogue rather than as clinician-centred information provision
- creating a clear documentation trail
- integrating open disclosure with practice improvement
- arranging opportunities for patients to become involved in incident investigation, service re-design, and practice improvement evaluation (with their explicit consent if other individuals such as family members or carers are involved in the conversation).

These findings align with, and support, previous research into patient concerns, expectations and experience with harmful incidents and open disclosure.^{45, 46, 49, 88–98} There is now a considerable body of international and Australian evidence relating to the patient, provider and institutional experience of open disclosure on which to base a review of the Standard.^{18–22}

2.4.3 Legal aspects of open disclosure in Australia

The Commission also initiated independent investigation of some of the uncertainty in open disclosure practice created by legal variation between Australian jurisdictions. It commissioned a study that included a survey of approximately 50 health professionals involved in open disclosure, which sought to:

- clarify the effect of qualified privilege and apology laws on the practice of open disclosure
- consider the option of legislation to support open disclosure and what this may entail.^{99, 100}

Apology laws

All Australian jurisdictions have enacted apology laws 'which protect statements of apology or regret made after "incidents" from subsequent use in certain legal settings'.⁹⁹ The protective value of apology laws in relation to open disclosure is constrained by:

- varying apology legislation across jurisdictions, especially with regard to *mea culpa* statements
- lack of clarity in relation to open disclosure activities
- exclusion in five jurisdictions (Victoria, Tasmania, Western Australia, Northern Territory and South Australia) of statements containing acknowledgments of fault or liability
- the inherently selective nature of the laws, as an expression of regret is only one element of open disclosure.

It should be noted that the apology laws were enacted without open disclosure in mind, and relate to various situations and legal contexts. In short, as a shield for open disclosure they are 'neither large nor thick'.⁹⁹ However, there is some empirical evidence from health care and other settings that apology laws restrict what can be said in these situations, and there are numerous examples in Australian common law to indicate that an apology, including one that conveys or implies fault, is not admissible, does not constitute an admission of liability and is unlikely to be given weight in an Australian court.^{101–103} Nevertheless, caution and restraint is necessary to avoid eroding public trust in health care further by, for example, making speculative statements following an incident that later emerge to be false. The legal aspect of apology is explored in more detail in Section 4.4.

Qualified privilege

Qualified privilege protects information gathered during formal investigations into (usually serious) adverse events. The purpose of these laws is to protect this information from use in legal proceedings, thus removing the inhibitions of individuals and institutions to provide complete information that would enable the causes of these events to be identified and rectified.

All Australian jurisdictions have statutes that anchor qualified privilege in a 'quality assurance committee' or similarly named entity, and none address open disclosure directly. All of these statutes have lawful pathways that should enable the release of information to patients to whom the information relates. It is generally considered that the greater obstacles to release of information to patients are likely to be non-legal, such as the reluctance of hospitals, health services or providers directly or indirectly identified in the reports to agree to the release of information.⁹⁹

Generally, it is considered that qualified privilege legislations neither create prohibitions or barriers to the release of information, nor protect information obtained through open disclosure from being used in litigation or other medico-legal actions. In other words, the contents of open disclosure dialogue, with the possible exception of the apology component, can be used in legal proceedings.^A

There are also practical considerations why qualified privilege law is not highly relevant in open disclosure. For example, most clinical incidents are not investigated under qualified privilege.

Healthcare professional perceptions of legal issues

A 2010 survey explored the attitudes of approximately 50 health professionals involved in open disclosure towards medico-legal aspects of the practice of open disclosure and the extent to which existing laws mitigate those risks.¹⁰⁰

The study found that a majority of participants considered medico-legal risks and inadequate training and education as moderate to major barriers to conducting open disclosure. There was confusion, uncertainty and a lack of knowledge about the legal parameters for open disclosure (especially regarding apology laws). Views were mixed on the extent to which existing laws encouraged open disclosure.¹⁰⁰

2.4.4 Open disclosure implementation in Australia

States and territories

Following publication of the Standard, Australian states and territories began to develop local open disclosure policies and, in some cases, integrate these into incident management systems. In the policies, open disclosure is closely linked to risk management and clinical governance. States and territories also implemented education initiatives and made available resources to support staff conducting, or involved in, open disclosure. A summary of open disclosure policy and implementation at jurisdictional level as at 1 January 2012 is presented in Table 2.

The private and primary care sectors

It is more difficult to gauge the extent of implementation of open disclosure throughout the Australian private healthcare, aged care and primary care sectors. On the whole, Australian private healthcare services have embraced patient safety with enthusiasm. The Commission's Private Hospital Sector Committee is a key component of the national safety and quality agenda and supports the national open disclosure initiative.

There are examples of comprehensive and highly successful disclosure practice in private hospitals (see Appendix). Considering the significant role of this sector in the Australian health system, it is imperative that private hospital organisational contexts are reflected in the revised Standard and that the sector is engaged in the consultation process.

A considerable amount of the research and evidence on open disclosure derives from United States (US) hospital systems, which have similarities to Australian private hospitals in terms of funding and relationship with doctors. Therefore some of the US research presented in this report may be applicable to the Australian private hospital system.

A West Australian protection under the *Health Services (Quality Improvement) Act 1994* adheres more strongly to the information once it is released to third parties.

Table 2 Overview of open disclosure policy and practice at jurisdictional level (current at 1 November 2011)

	Policy	Evaluation	Education / training	Data collection / indicators
New South Wales	2007 policy to establish a standard approach for communication with patients and support persons after an incident: www.health.nsw.gov.au/quality/opendisc/ All health services are required to have appropriate local procedures in place to ensure consistency and compliance with the policy Consistent with the national Standard	Due for evaluation in 2012	Official non-mandatory program in place	Data collected for high-level incidents (SAC 1)
Victoria	Part of the <i>Victorian Health Incident Management Policy</i> (2011); www.health.vic.gov.au/clinrisk/opendisc.htm Consistent with the national Standard	August 2007 Victorian evaluation report: www.health.vic.gov.au/clinrisk/opendisc.htm Policy due for evaluation in 2012–13	Open Disclosure eLearning Package released in October 2010; www.health.vic.gov.au/clinrisk/opendisc.htm	Statewide standardised incident data collection asks health services to indicate if an open disclosure process was followed for high-level adverse events
Northern Territory	Policy currently under development. Will be based on the national Standard.	–	–	–
South Australia	Policy released 2011: www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/safety+and+quality/open+disclosure Integrated with incident management and reporting processes Consistent with the national Standard	Review progress on education and training in 2012	Statewide training from September to November 2011, 120 staff attended Mastering Open Disclosure Workshops and 56 attended master classes E-learning package for staff orientation	Data will be collected through a clinical incident reporting
Western Australia	WA Open Disclosure Policy: Communication and Disclosure Requirements for Health Professionals Working in Western Australia (May 2009): www.safetyandquality.health.wa.gov.au/Involving_patient/open_disclosure.cfm Compliance is mandatory in public healthcare facilities Based on and consistent with the national Standard principles. Guidance on local legislative matters provided	Due for evaluation 2013 Evaluation of 'pilot' at four metropolitan hospitals produced findings and recommendations consistent with the evaluation of the national pilot	Training and education managed and implemented at an Area Health Service level	Data collected on the percentage of notified sentinel events that initiate an open disclosure process; this is published in the annual sentinel event reports (note that sentinel event reporting includes the private sector in WA)

Table 2 continued

	Policy	Evaluation	Education / training	Data collection / indicators
Tasmania	Statewide directive issued in 2010 requiring Tasmanian health services to implement the national Standard The statewide DHHS Open Disclosure Policy was released in September 2011. Based on the national Standard with additional detail regarding local legislative matters	2013	Train the trainer model has been adopted with workshops conducted throughout the state	Collection of data on consumer satisfaction and staff confidence planned for internal quality improvement purposes
ACT	ACT Open Disclosure Policy released in February 2010	2013	No mandatory education or training Program currently being developed for implementation in April 2012	Indicators currently being developed for collection in 2012
Queensland	Open disclosure is integrated into the Clinical Incident Management Implementation Standard (CIMIS): www.health.qld.gov.au/psq/od/webpages/od_homepage.asp Originally rolled out in 2003	Official evaluation completed in 2011	E-learning modules for all staff Key clinicians identified for specialised training with actors (one-day courses) Open disclosure master classes	Proportion of incidents are followed by disclosure and the outcomes reported through the Clinical Incident Management System

The Commission, in partnership with the Royal Australian College of General Practitioners, released an education module and suite of materials for general practices titled *Regaining trust after an adverse event*¹⁰⁴ with the aim of complementing existing knowledge and improving communication skills as a means of restoring patient–provider relationships when things go wrong. The appropriateness of these documents, and further support for open disclosure implementation in general practice, will be considered through the consultation process of this review.

2.4.5 Health service accreditation

Accreditation is recognised as an important driver for safety and quality improvement.¹⁰⁵ Australia's health accreditation processes are highly regarded internationally. The *National Safety and Quality Health Service (NSQHS) Standards*¹⁰⁶ have been developed by the Commission to describe how and against what an organisation's performance will be assessed in a new and nationally consistent accreditation system. There are currently ten NSQHS Standards.

A requirement to implement a formal open disclosure process forms part of the first NSQHS Standard: *Governance for safety and quality in health service organisations*. This means that incorporating open disclosure into health service policy and practice is an accrediting activity for Australian health services. The first and second NSQHS Standard (*Partnering with consumers*) set the overarching requirements for effective implementation of the remaining eight Standards, which address more specific clinical areas of patient care.

2.5 Review of the Standard

National and international developments and achievements in disclosure suggest that changes are occurring in the way that disclosure policies are being framed and practised. Reflecting implementation experiences and new evidence in a revised Standard will ensure that the national basis for open disclosure is consistent, practical and relevant.

Reviewing and updating the Standard provides several opportunities including:

- ensuring the Standard reflects the experience of Australian health services that have implemented open disclosure
- providing stakeholders with an opportunity to shape the core open disclosure document
- integrating the latest research into the Standard and supporting materials
- promoting open disclosure to Australian health services that have yet to implement it
- developing a suite of implementation resources to
 - assist health services implement open disclosure more effectively
 - support and empower patients, families and carers to participate in, and benefit from, the process
 - support and enable healthcare practitioners to conduct open disclosure consistently, confidently and without anxiety
- enabling health services to meet requirements in the new *National Safety and Quality Health Service Standards*.

The Standard was a noteworthy achievement in Australian health care and was ratified by a wide range of stakeholders. Review of the Standard will need to ensure that a similarly wide representation of interests is engaged and support obtained for the review and for its outcomes.

References

8. Wilson R, McL., Harrison BT, Gibberd RW, Hamilton JD. An analysis of adverse events from the quality in Australian health care study. *Medical Journal of Australia* 1999;170:411–415.
9. Wilson R, Runciman WB, Gibberd RW, Harrison B, Newby L, Hamilton J. The quality in Australian health care study. *Medical Journal of Australia* 1995;163(9):458–471.
10. Australian Council for Safety and Quality in Health Care. *Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care*. Canberra, 2003.
11. Iedema R, Allen S, Britton K, Piper D, Baker A, Gribich C, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The '100 patient stories' qualitative study. *British Medical Journal* 2011;343(d4423).
12. Iedema R, Allen S, Sorensen R, Gallagher TH. What prevents incident disclosure, and what can be done to promote it? *Joint Commission Journal on Quality and Patient Safety* 2011;37(9):409–417.
13. Iedema R, Allen S, Britton K, Gallagher TH. What do patients and relatives know about problems and failures in health care? *BMJ Quality and Safety* 2011;doi 10.1136/bmjqs-2011-000100.
18. Iedema R, Sorensen R, Piper D. Open disclosure: Review of the literature. Sydney: ACSQHC (Australian Commission on Safety and Quality in Health Care), 2008.
19. Piper D, Iedema R. *Literature review: Incident disclosure policy, legal reform and research since 2008*. Sydney: Centre for Health Communication (University of Technology Sydney) and ACSQHC (Australian Commission on Safety and Quality in Health Care), 2011
20. Allan A, Munro B. *Open disclosure: A review of the literature*. Perth: Edith Cowan University, 2008.
21. O'Connor E, Coates HM, Yardley IE, Wu AW. Disclosure of patient safety incidents: A comprehensive review. *International Journal on Quality in Health Care* 2010;22(5):371–379.
22. Gallagher TH. A 62-year-old woman with skin cancer who experienced wrong-site surgery. *Journal of the American Medical Association* 2009;302(6):669–677.
23. Runciman WB, Merry AF, Tito F. Error, blame, and the law in health care — an antipodean perspective. *Annals of Internal Medicine* 2003;138(12):974.
24. Productivity Commission. Disability care and support: Report no. 54. 2011. (Accessed on 15 May 2012 at http://www.pc.gov.au/__data/assets/pdf_file/0012/111270/disability-support-volume1.pdf http://www.pc.gov.au/__data/assets/pdf_file/0013/111271/disability-support-volume2.pdf)
25. Sinclair CM. *The report of the Manitoba pediatric cardiac surgery inquest: An inquiry into twelve deaths at the Winnipeg Health Sciences Centre in 1994*. Winnipeg: Provincial Court of Manitoba, 2000.
26. Kennedy I. *Learning from Bristol: The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995*. London: Department of Health, 2001.
27. Douglas N, Robinson J, Fahy K. *Inquiry into obstetric and gynaecological services at King Edward Memorial Hospital 1990–2000*. Perth: Government of Western Australia, 2001.
28. Donaldson L. *An organisation with a memory: Report of an expert group on learning from adverse events in the NHS*. Norwich, UK: NHS Stationery Office, 2000.
29. Kohn LT, Corrigan JM, Donaldson MS. *To err is human: Building a safer health system*. Washington DC: National Academy Press, 1999.

30. Brennan TA, Leape LL, Laird MM, Nan M, Hebert L, Localio AR, et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard medical practice study. *New England Journal of Medicine* 1991;324:370–376.
31. Leape LL. Error in medicine. *Journal of the American Medical Association* 1994;272(23):1851–1857.
32. Classen D, Resar R, Griffin F, Federico F. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Affairs* 2011;30(4):581–589.
33. Hauck K, Zhao X, Jackson T. Adverse event rates as measures of hospital performance. *Health Policy* 2012;104(2):146–154.
34. Zwaan L, de Bruijne M WC, Thijs A, Smits M, van der Wal G. Patient record review of the incidence, consequences and causes of diagnostic adverse events. *Archives of Internal Medicine* 2010;170(12):1015–1021.
35. Levinson DR. *Hospital incident reporting systems do not capture most patient harm*. Washington, DC: US Department of Health and Human Services, Office of the Inspector General, Report No. OEI-06-09-00091, 2012.
36. ABS (Australian Bureau of Statistics). Patient experiences in Australia 2009. Australian Bureau of Statistics. (Accessed November 2011, at <http://www.abs.gov.au/ausstats/abs@.nsf/Products/4839.0.55.001~2009~Chapter~Harm+and+harmful+side-effects?OpenDocument>)
37. Christiaans-Dingelhoff I, Smits M, Zwaan L. To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims and incident reports? *Health Services Research* 2011;11(49) doi:10.1186/1472-6963-11-49.
38. Sari ABA, Sheldon TA, Cracknell A, Turnbull A. Sensitivity of routine systems for reporting patient safety incidents in an NHS hospital: Retrospective patient case note review. *British Medical Journal* 2007;334(79):79–81.
39. Daniels JP, Hunc K, Cochrane D, Carr R, Shaw NT, Taylor A, et al. Identification by families of pediatric adverse events and near misses overlooked by health care providers. *Canadian Medical Association Journal* 2012; 184(1):29–34.
40. de Feijter JM, de Grave WS, Muijtens AM, Scherpbier AJJA, Koopmans RP. A comprehensive overview of medical error in hospitals using incident-reporting systems, patient complaints and chart review of inpatient deaths. *PLoS ONE* 2012;7(2):e31125.
41. Robotham J.. How could this happen? Hospital blunder turns a family's joy into heartbreak. Sydney: *Sydney Morning Herald*, 1 August 2010.
42. Editorial. State falters at first test of hospital reform. Melbourne: *The Age* 19 August 2011.
43. Merry AF, Peck DJ. Anaesthetists, errors in drug administration and the law. *NZ Medical Journal* 1995;108(185–187).
44. Kronman AC, Paasche-Orlow M, Orlander JD. Factors associated with disclosure of medical errors by housestaff. *BMJ Quality and Safety* 2011;doi:10.1136/bmjqs-2011-000084.
45. Gallagher T, Waterman A, Garbutt J, Kapp J, Chan D, Dunagan W, et al. US and Canadian physicians' attitudes and experiences regarding disclosing errors to patients. *Archives of Internal Medicine* 2006;166(15):1605–1611.
46. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *Journal of the American Medical Association* 2003;289(8):1001–1007.
47. Espin S, Levinson W, Baker R, Lingard L. Error or 'act of God'? A study of patients' and operating room team members' perceptions of error definition, reporting, and disclosure. *Surgery* 2006;139(1):6–14.
48. Truog RD, Browning DM, Johnson JA, Gallagher TH. *Talking with patients and families about medical error: A guide for education and practice*. Baltimore: Johns Hopkins University Press, 2011.
49. Gallagher TH, Lucas MH. Should we disclose harmful medical errors to patients? If so, how? *Journal of Clinical Outcomes Management* 2005;12(5):253–259.

50. Iezzoni LI, Rao SR, DesRoches CM, Vogeli C, Campbell EG. Survey shows that at least some physicians are not always open or honest with patients. *Health Affairs* 2012;31(2):383–391.
51. Valentine N, Darby C, Bonsel GJ. Which aspects of non-clinical quality of care are most important? Result from WHO's general population surveys of 'health system responsiveness' in 41 countries. *Social Science and Medicine* 2008;66:1939–1950.
52. Blendon R, DesRoches C, Brodie M, Benson M, Rosen A, Schnieder E, et al. Views of practising physicians and the public on medical errors. *New England Journal of Medicine* 2002;347(24):1933–1940.
53. Kenagy JW, Berwick DM, Shore MF. Service quality in health care. *Journal of the American Medical Association* 1999;281:661–665.
54. Garbutt J, Waterman AD, Kapp JM, Dunagan WC, Levinson W, Fraser V, et al. Lost opportunities: How physicians communicate about medical errors. *Health Affairs* 2008;27(1):246–255.
55. ACSQHC (Australian Commission on Safety and Quality in Health Care). *Patient-centred care: Improving quality and safety through partnerships with patients and consumers*. Sydney: ACSQHC, 2011.
56. Bodenheimer T. Coordinating care — a perilous journey through the health care system. *New England Journal of Medicine* 2008;358(10):1064–1071.
57. Haggerty JL, Reid RJ, Freeman GK, Starfield BH, Adair CE, McKendry R. Continuity of care: A multidisciplinary review. *British Medical Journal* 2003;327(7425):1219–1221.
58. Lewis GH, Vaithanathan R, Hockey PM, Hirst G, Bagian J. Counterheroism, common knowledge, and ergonomics: Concepts from aviation that could improve patient safety. *The Milbank Quarterly* 2011;89(1):4–38.
59. Gawande A. *The checklist manifesto: How to get things right*. New York: Metropolitan Books, 2010.
60. Gawande A. 'Cowboys and pit crews' speech to Harvard medical graduates 26 May 2011.
61. Morey JC, Simon R, Jay GD. Error reduction and performance improvement in the emergency department through formal teamwork training: Evaluation results of the med teams project. *Health Service Research* 2002;37:1553–1581.
62. Nugus P, Greenfield D, Travaglia J. How and where clinicians exercise power: Interprofessional relations in health care. *Social Science and Medicine* 2010;71:898–909.
63. Espin SL, Lingard LA. Time as a catalyst for tension in nurse–surgeon communication. *Association of Operating Room Nurses Journal* 2001;74(5):672–682.
64. Fischer M, Ereaut G. *Can changing clinician–patient interactions improve healthcare quality? A scoping report for the health foundation*. London: Health Foundation, 2011.
65. Pronovost P. Navigating adaptive challenges in quality improvement. *BMJ Quality and Safety* 2011;20(7):560–563.
66. Braithwaite J, Skinner CA, Doerin ML. A values-based health system. *Medical Journal of Australia* 2011;194(5):259–262.
67. Cannon J, Berwick DM. A new frontier in patient safety. *Journal of the American Medical Association* 2011;305(21):2221–2.
68. Foye R, Ovretveit J, Shekelle P. The role of theory in research to develop and evaluate the implementation of patient safety practices. *BMJ Quality and Safety* 2011;20:453–459.
69. Espin S, Lingard L, Baker GR, Regehr G. Persistence of unsafe practice in everyday work: An exploration of organizational and psychological factors constraining safety in the operating room. *Quality and Safety in Health Care* 2006;15(3):165–170.
70. Peterkin A. Guidelines covering disclosure of errors now in place at Montreal Hospital. *Canadian Medical Association Journal* 1990;142(1990):984–985.
71. Berwick D. What patient-centered care should mean: Confessions of an extremist. *Health Affairs* 2010;28(4):w555–w565.
72. Wachter RM. The end of the beginning: Patient safety five years after 'to err is human'. *Health Affairs* 2004;November 2004:W4/534–545.

73. Massachusetts Coalition for the Prevention of Medical Errors. *When things go wrong: Responding to adverse events (a consensus statement of the Harvard hospitals)*, 2006.
74. Kraman SS, Hamm G. Risk management: Extreme honesty may be the best policy. *Annals of Internal Medicine* 1999;131(12):963–967.
75. Berwick D. *Escape the fire: Lessons for the future of health care*. New York: Commonwealth Fund, 2002.
76. Woods MS. *Healing words: The power of apology in medicine*. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations, 2007.
77. Kraman SS, Cranfill L, Hamm G, Woodard T. Advocacy: The Lexington Veterans Affairs Medical Center. John M. Eisenberg patient safety awards. *Joint Commission Journal for Quality Improvement* 2002;28(12):646–650.
78. National Patient Safety Agency. *Being open: Communicating patient safety incidents with patients, their families and carers*. London: NHS (National Health Service), 2009.
79. Canadian Patient Safety Institute. *Canadian disclosure guidelines*. Edmonton, AB: Canadian Patient Safety Institute, 2008.
80. DVA (Department of Veterans Affairs). *Disclosure of adverse events to patients (VHA directive 2008-002)*. Washington: DVA, Veterans Health Administration, 2008.
81. National Patient Safety Agency. *Being open. Communicating patient safety incidents with patients and their carers*. Whitehall, London: NHS (National Health Service), 2005.
82. Disclosure Working Group. *Canadian open disclosure guidelines: Being open and honest with patients and families*. Edmonton, AB: Canadian Patient Safety Institute, 2011.
83. Health & Disability Commissioner. *Code of health and disability services consumers' rights New Zealand*. 1996. (Accessed November, 2011, (Accessed 15 May 2012 at <http://www.hdc.org.nz/the-act--code/the-code-of-rights>)
84. Health & Disability Commissioner. *Guidance on open disclosure policies*. Wellington, New Zealand: Health & Disability Commissioner, 2009.
85. Iedema R, Jorm C, Wakefield J, Ryan C, Sorensen R. A new structure of attention? Open disclosure of adverse events to patients and families. *Journal of Language & Social Psychology* 2009;28(2):139–157.
86. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. *Final report: Evaluation of the National Open Disclosure pilot program*. Sydney: The Australian Commission on Safety and Quality in Health Care (ACSQHC), 2008.
87. Pace WD, Staton EW. Improving the disclosure of medical incidents: A genuine apology is only the first step in the process. *British Medical Journal* 2011;342:d4340.
88. Gallagher TH. *Disclosing harmful errors to patients: Recent developments and future directions*. Open Disclosure Seminar. Sydney: University of Technology Sydney, 2009.
89. Gallagher TH, Denham CR, Leape LL, Amori G, Levinson W. Disclosing unanticipated outcomes to patients: The art and practice. *Journal of Patient Safety* 2007;3(3):158–165.
90. Gallagher TH, Garbutt JM, Waterman AD, Flum DR, Larson EB, Waterman BM, et al. Choosing your words carefully: How physicians would disclose harmful medical errors to patients. *Archives of Internal Medicine* 2006;166(August 14–28):1585–1593.
91. Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *New England Journal of Medicine* 2007;356(2007):2713–2719.
92. Wu A, Huang IC, Stokes S, Pronovost P. Disclosing medical errors to patients: It's not what you say, it's what they hear. *Journal of General Internal Medicine* 2009;24(9):1012–1017.
93. Hopgood C, Peck C, Gilbert B, Chappell K, Zou BI. Medical errors - what and when: What do patients want to know? *Academic Emergency Medicine* 2002;9:1156–1161.

94. Duclos CW, Eichler M, Taylor L, Quintela J, Main DS, Pace W, et al. Patient perspectives of patient-provider communication after adverse events. *International Journal for Quality in Health Care* 2005;17(6):479–486.
95. Rathert C, Brandt J, Williams ES. Putting the ‘patient’ in patient safety: A qualitative study of consumer experiences. *Health Expectations* 2011;doi:10.1111/j.1369-7625.2011.00685.
96. Fisseni G, Pentzek M, Abholz HH. Responding to serious medical error in general practice — consequences for the GPs involved: Analysis of 75 cases from Germany. *Family Practitioner* 2008;25(1):9–13.
97. Hopgood C, Tamayo-Sarver JH, Weiner B. Patient race/ethnicity, age, gender and education are not related to preference for or response to disclosure. *Quality and Safety in Health Care* 2008;17:65–70.
98. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. The National Open Disclosure Pilot: Evaluation of a policy implementation initiative. *Medical Journal of Australia* 2008;188(2008):397–400.
99. Studdert D, Richardson MW. Legal aspects of open disclosure: A review of Australian law. *Medical Journal of Australia* 2010;193(5):273–276.
100. Studdert D, Piper D, Iedema R. Legal aspects of open disclosure II: Attitudes of health professionals — findings from a national survey. *Medical Journal of Australia* 2010;193(6):351–355.
101. Brown D. *Open disclosure: Morally right, but is it legally safe?* Medico-Legal Society of NSW Inc Scientific Meeting. Sydney, 2008.
102. Vines P. Apologising to avoid liability: Cynical civility or practical morality? *Sydney Law Review* 2005;27(3):483–505.
103. Vines P. *The power of apology: Mercy, forgiveness or corrective justice in the civil liability arena?* University of New South Wales Faculty of Law Research Series 2007;2007(30):1–29.
104. RACGP (Royal Australian College of General Practitioners). *Regaining trust after an adverse event. An education module on managing adverse events in general practice*. Melbourne: RACGP, ISBN 978-0-86906-292-0, 2008.
105. Paterson R. *The review team for the review of future governance arrangements for safety and quality in health care. National arrangements for safety & quality of health care in Australia: The report of the review of future governance arrangements for safety and quality in health care*. Canberra: Australian Health Ministers’ Conference, 2005.
106. ACSQHC (Australian Commission on Safety and Quality in Health Care). *National Safety and Quality Health Service (NSQHS) Standards*. Sydney, 2011.



Openness and timely acknowledgment

Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology, expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

3 Openness and timely acknowledgment

I think that it's the willingness to accept and acknowledge error [that determines the success of Open Disclosure]. I think that's the one thing that the whole thing hangs on ... I think it's that willingness to accept failure and accountability, and the acceptance of accountability for that are probably the two critical things the whole thing falls on. Senior Medical Manager^{86(p77)}

Principle 1: Openness and timeliness of communication

When things go wrong, the patient and their support person should be provided with information about what happened, in an open and honest manner at all times. The open disclosure process is fluid and may involve the provision of ongoing information.

Principle 2: Acknowledgment

All adverse events should be acknowledged to the patient and their support person as soon as practicable. Healthcare organisations should acknowledge when an adverse event has occurred and initiate the open disclosure process.¹⁰

The first two principles of the Standard align with current evidence. Patients consistently express a preference for immediate acknowledgment and notification of adverse events even if all the facts behind the event have not yet been established.¹¹ They expect timely, open, honest and accurate communication from providers following harm. Lack of these qualities in post-incident communication can lead to a breakdown of trust and possibly increase negative perceptions and trauma. Healthcare professionals express a desire to disclose harmful incidents but can feel constrained by various real and perceived barriers.

3.1 Patient views and experience

Many patients consider that open disclosure is not done promptly enough, is not conducted in a spirit of openness and transparency, and is performed in a one-directional manner. Recent Australian patient open disclosure research has identified a number of key issues for patients:¹¹

- inadequate preparation for open disclosure discussions for patients and by staff
- lack of appropriate closure, and insufficient dialogue facilitating an exchange of experiences, views, questions and expectations on the part of stakeholders in the incident
- disclosure of unexpected outcomes in an inappropriate fashion
- lack of follow-up support
- insufficient integration of open disclosure with quality and patient safety improvement processes.

Several changes to the current practice of open disclosure were suggested by interviewees to address these problems, including:¹¹

- commencing the open disclosure process as soon as possible following the incident, even if all the facts have not yet been established
- enacting open disclosure as facilitated dialogue rather than as clinician-centred information provision.

Other research supports the findings, including a recent study that found provider responses following harm continue to fall short of patient expectations.¹⁰⁷ Patients expect full, immediate and transparent disclosure of harmful events. The need for an advocate to participate in disclosure processes is also expressed.^{46, 92–94} There is little to suggest gender, racial, demographic or cultural differences affect patient preferences in relation to these issues.^{97, 108, 109}

3.1.1 Lack of openness and acknowledgment: key motivators for medico-legal action by patients

Malpractice suits often result when an unexpected adverse outcome is met with a lack of empathy from physicians and a withholding of essential information.^{110(p2205)}

The importance of the first two principles of the Standard becomes clear when harmed patient motivations for legal action against providers are examined. Lack of openness and transparency are cited as key drivers for patients to pursue legal remedies. Litigation is most often initiated in order to receive a full explanation of what happened, and why, in response to perceived defensiveness and opacity by the health service or the provider(s).^{97, 111, 112} Patients report relief and closure after receiving access to a full report of the investigation of the incident:

I felt as though the medical authorities were clamming up as soon as I expressed my concern ... so much evidence has come to light [after seeing a solicitor]. If nothing else comes from all this, I have the satisfaction of knowing that it wasn't just my imagination or me simply making a fuss.^{113(p1611)}

Financial compensation is only one of a range of factors considered when patients, families and carers choose to pursue legal or disciplinary action.^{22, 114} Its importance has been observed to increase, however, in cases of more severe injury and greater economic loss.¹¹⁵

Generally, motivation to pursue disciplinary or legal action is related to how the incident was managed as opposed to the nature of the incident itself. A lack of clear and sympathetic explanation by providers and a failure to appreciate the emotional needs of patients are just as important as the physical aspects of the harmful incident. For patients, disclosure encompasses issues such as corrective justice and restoration of dignity. Schwappach and Koeck note that an honest, empathic and accountable approach decreased patients' desire for strong disciplinary actions by 59 per cent.¹¹⁶ Albert Wu, a long-standing champion of open disclosure, suggests that 'confronted by an empathetic and apologetic physician, patients and families can be astonishingly forgiving'.¹¹⁷

Another key motivation to pursue disciplinary or legal action is to ensure a similar incident does not happen to somebody else. Ensuring that health services learn from harm helps patients, families and carers to cope with pain, loss or grief by being reassured that some

good resulted from the incident.^{22, 48, 93, 118} This is an important consideration in terms of the entire disclosure process, especially with regard to:

- assuring the patient that the incident is investigated to ascertain its system-related causes
- ensuring that the 'loop is closed' and any system improvement resulting from the investigation is fed back to the patient.

It is not suggested that open disclosure alone will reduce medico-legal activity and associated costs in healthcare organisations. However, the evidence highlights the importance of openness, transparency and timeliness in meeting post-incident patient responses and expectations so that further harms are not generated.

3.2 Providers, services and institutions

All my experience with [open disclosure] is positive. It is contributing to the culture [...] it is about getting it off people's chest [...] there is no dealing of hidden agendas, there is no feelings of [distrust], there is true transparency. Nursing manager^{86(p115)}

According to the available evidence, open disclosure is almost universally supported by individual healthcare professionals as the right thing to do.^{12, 45, 46, 98, 119–127} In its Code of Conduct, the Australian Medical Board advises that good medical practice involves '[b]eing aware of the importance of the principles of open disclosure and a non-punitive approach to incident management'.^{128(p11)}

However, there exists a considerable gap between the views of providers and patients on which incidents require disclosure and what constitutes sufficient disclosure.^{11, 46, 49, 50, 52, 90, 125, 129–132} These differences seem to reflect what is valued more generally by the two groups in healthcare processes. Through their training and professional socialisation, clinicians tend to see their practice predominantly in its concrete relevance to clinical outcomes through the interventions they are able to provide.^{46, 133, 134} Patients, on the other hand, value a broader set of qualities, competencies and 'soft skills' in providers.^{51, 135} This is not a new insight. In 1927, Francis Peabody wrote that 'one of the essential qualities of the clinician is interest in humanity, for the secret of the care of the patient is in caring for the patient'.^{136,B}

Healthcare providers recognise that special skills are required to participate confidently in open disclosure, which, on the whole, is 'seen to harbour uncertainties, including what should trigger a formal response, the unknown impact on individuals' and the organisation's reputation, unclear legal and insurance implications, and unreliable support by colleagues for those carrying out open disclosure'.^{98(p398)} Ensuring systematic acquisition of these skills is critical for successful open disclosure practice.

3.2.1 Institutions and insurers

Healthcare facilities, institutions and professional indemnity insurers play a key part in how incidents are managed. Institutions and their insurers must be involved in the formulation of (local) open disclosure policies (as is recommended in the Standard) and in preparation for pre-arranged open disclosure meetings. However, they need to be cognisant of patient expectations and the effect on the provider and organisational risk profile if these

B The institutional and professional factors underlying this discordance are explored further in Chapter 5.

expectations are not met, especially in the context of open and timely acknowledgment of a harmful incident.

There is a tension in the current Standard between the principles of openness and timely acknowledgment, and the requirement for providers to 'take early advice from their insurer following a harmful incident'.^{10(p15)} This can undermine best practice open disclosure, as described by patients, by delaying communication with the patient, family or carer.

3.2.2 Clinical communication

Iledema and colleagues noted that, in order to optimise its effect, open disclosure must 'be conducted by staff who have excellent communication and listening skills'.^{98(p398)} This expectation is also shared by patients. However, the most striking difference between consumer and healthcare professional views is in the area of communication, with research suggesting that:^{11, 21, 22, 39, 64, 94, 95, 137–140}

- Patients want more information than is given.
- Providers over-estimate the amount of information they have provided.
- Providers ascribe instrumental value to communication — it enables them to make a correct diagnosis and prescribe the correct treatment. Patients, on the other hand, value communication intrinsically — it is as much part of the 'care' process as prescribed treatment and subsequent outcome.
- Empathic and compassionate communication is highly valued by patients. It affects ratings of their healthcare experience more than clinical outcomes or the presence of complications.
- Communication style is important in developing trust between provider and the harmed party, influencing the eventual outcome of the disclosure process. Acceptance of responsibility and apology also fosters trust. Trust is, in turn, linked to patients being prepared to accept errors as inevitable and forgivable.

Of course, interpersonal communication can be highly complex. It is not effortless and requires personal investment in time and emotional labour. 'It involves imparting, receiving, and deciphering knowledge. The effective interchange of various signs, signals, information and data, written, verbal and nonverbal discourse connects people together, facilitates collaboration and lays the groundwork for forms of consensus. The reverse is also true'.^{141(p357)} For providers, open disclosure draws on a set of attributes rather than one specific technical skill.⁴⁸

The importance of communication also applies at the organisational level. In the Bristol, King Edward Memorial Hospital (KEMH) and Manitoba inquiry reports, the words 'communication' and 'trust' are mentioned a total of 439 and 67 times, respectively.¹⁴¹ The KEMH inquiry argued that 'the provision of adequate information is an essential prerequisite to the development of trust. It underpins the honesty between professional and patient'.^{26(p287)}

3.2.3 Differences between professions

Divergence in how open disclosure is viewed and executed is emerging among various health professions. Nurses are more likely to report incidents but less likely to disclose them. Although nurses routinely disclose events that fall within their accountability, disclosure of more serious events is seen to be the responsibility of doctors. Through delays

in commencing open disclosure, nurses are often being placed in ethically compromising positions by having to continue to care for patients who have been harmed, and who may be 'asking difficult questions'.¹⁴² Professional boundaries are often ambiguous in the context of disclosure.¹⁴³ There is also inter-disciplinary variation within the medical profession. For example, surgeons tend to disclose less information than physicians.^{90, 124}

Risk managers have varying involvement in open disclosure both in terms of coaching and execution.⁹⁰ A United States study suggests that risk managers are more likely than physicians to recommend disclosure that includes a full description of action to prevent similar events from occurring but are less likely to provide a full apology that recognised the harm caused by the event.¹⁴⁴

Recent interviews with a small set of Australian risk, safety and quality improvement managers reveals that open disclosure is becoming embedded into the routine practice of some Australian hospitals. However the research also described a disparity in how open disclosure is viewed by medical staff and safety and quality staff.¹⁴

3.3 What to disclose

The need for formal open disclosure will be evident in the majority of incidents. However, in some incidents the course of action will not be as clear and identifying a threshold for enacting open disclosure can be confusing.⁴⁶ For example, should all incidents be disclosed — including incidents where harm or preventability is disputed, near misses, or when there is unmet expectation due to poor communication?

There is evidence of what may be termed a 'paternalistic' attitude among some providers. This results in decisions that disclosure may do more harm than good. Some consider a decision not to disclose as 'patient-centred care'.^{22, 46, 145} Several papers describe situations of open disclosure being withheld or restrained for reasons including:^{46, 90, 122, 124, 127}

- clinicians feeling that the incident was trivial
- patients being unaware that an event occurred
- clinicians believing that the patient would not understand the explanation
- clinicians believing that the patient would not want to know.

Chapter 5 addresses establishing the need for open disclosure in more detail and from different perspectives. In deciding whether an incident constituted 'harm' and whether open disclosure should be enacted the following principles/questions may serve as a guide:

- Has the incident contravened policy such as the *Charter of Healthcare Rights*?
- Have expectations generated by pre-care and early-care activity been met?
- Was the patient treated with respect and dignity throughout the entire episode?
- Will the incident have any ongoing effect on the patient?
- Does the patient believe they have been harmed?

Some patient experiences suggest that their attempts to convey concern, or the belief that an incident had occurred, were not given credence. Research indicates that identifying an incident and the need for disclosure is often in the context of a 'view that medical expertise should be allowed to trump lay persons' personal experience...[and that]...the way health

services, clinical risk managers and policy makers classify incidents consistently favours biomedical over socio-psychological criteria.^{11, 19(p40)} There are risks in this approach. Patient perceptions are of primary importance in fulfilling the role of open disclosure in restoring trust between patients and healthcare providers. In addition, if biomedical criteria and processes are given precedence, disclosure may occur some time after the event, triggered by a patient complaint. This is contrary to patient preferences identified in the literature, and risks the harmed patient being dissatisfied with the process.¹⁴⁵

It is unlikely that a debate between the provider and the patient on whether the incident constituted a 'harmful' incident will be productive,⁴ the patient's perception of whether there has been an incident or not should inform clinical and managerial decision-making.

Patient perception and behaviour following an incident are primarily determined by communication with the health service and its staff.⁹² Effective disclosure raises patient ratings of services and of the quality of care provided.¹²⁹ There is evidence of a correlation between patient appraisals of quality and clinical risk of harm, suggesting that engaging with patient concerns can avert some incidents escalating into crises, and provide long-term quality of care benefits.^{95, 130, 137, 146–149}

3.3.1 Preventability

Preventability, and whether the incident was a genuine mistake or a normal complication of the disease or procedure, should not dominate decision-making on the need for open disclosure. Preventability is difficult to define and is, in any case, a fluid concept.^c It bears little relevance to patients who most often are seeking an explanation of why the result of their care was unexpected or harmful. Based on available evidence, it is prudent for providers and organisations to adopt an 'if in doubt, enact open disclosure' approach to incidents for which preventability is not immediately clear.

Conway and colleagues argue that 'many of the most challenging and poorly handled serious clinical adverse events occur when too much time is spent on determining preventability and not enough on empathy and support.'^{4(p4)} The following quote from an Australian healthcare provider illustrates this:

It does not have to be something really that arises from a mistake. And the ones I have been involved with especially have been complications that are considered even routine or considered part of what would be expected in the care of a complicated and unwell patient. Even just identifying that even if there is a complication can be considered an adverse outcome, not just a surgeon made a big mistake. That in itself improves not only patient's perceptions but also their outcome at the end of the day. Medical manager^{86(p29)}

3.3.2 Near misses and no harm incidents

Both providers and patients are divided on whether near misses or no harm incidents should be disclosed. No clear findings can be gleaned from available research.^{82, 145, 150, 151}

For providers, the question is interwoven with other concerns such as time constraints and preconceptions of patient ability to comprehend. The duty to disclose may also be

C For example, it has been demonstrated that certain types of iatrogenic harm in critical care previously considered unpreventable can be reduced and even eradicated. See Berenholtz SM, Pham JC, Thompson DA, Needham DM, Lubomski LH, Hyzy RC, et al. Collaborative cohort study of an intervention to reduce ventilator-associated pneumonia in the intensive care unit. *Infection Control and Hospital Epidemiology* 2011;32:305–314 and Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *New England Journal of Medicine* 2006;355:2725–2732.

outweighed by the duty not to harm (i.e. providers can feel it is counterproductive to worry patients with information about near misses). In addition, scarce resources may be expended on indiscriminate disclosure of near misses or no harm incidents ahead of other patient safety priorities.⁷²

Incidents not apparent to patients are much less likely to be disclosed.^{129, 145} However, as discussed in the previous section, patient and provider interpretations of an incident may differ considerably. In addition, the consequences of not disclosing a near miss or no harm incident can be grave, as the opportunity may be missed to alert both provider and patient to be more vigilant about care. Another consideration is that disclosure of near misses can be used as training for open disclosure, as well as facing challenging clinical communication more generally, as the absence of harm is likely to make for an easier disclosure.¹⁵²

The degree to which evidence can inform policy and practice here is limited. Research indicates that disclosure should not be indiscriminate in these circumstances, and decisions should be guided by context and the peculiarities of individual cases. Table 3 provides a modified example of an approach to address this issue, which was originally developed by the Canadian Patient Safety Group.⁸²

Table 3 Potential health service responses to various incident types

Incident type	Communication
1 Harm from natural progression of condition or disease process e.g. a treatment for cancer was unsuccessful	Discuss and explain with patient
2 Complication or natural disease progression <ul style="list-style-type: none"> a. Anticipated by patient/family via education and consent process b. Not anticipated by patient/family via education and consent process (go to 3.) e.g. patient not adequately informed of the possibility of respiratory complications of general anaesthesia; feels that this would have altered their decision to proceed with treatment 	<ul style="list-style-type: none"> a. Discuss and explain b. Open disclosure
3 Patient harm / harmful incident e.g. wrong-site surgery	Open disclosure
4 Clinical ('no harm') incident: reaches patient but no 'harm' e.g. wrong medication dose with no effect on patient	Generally disclose. This is because: <ul style="list-style-type: none"> • harm may be latent or been perceived by patient • patient may find out about incident through other means, eroding trust in provider / health service
5 Clinical ('near miss') incident: doesn't reach patient e.g. an intercepted wrong-patient biopsy	Team decision based on: <ul style="list-style-type: none"> • context • circumstances • potential ramifications
6 Patient perception or report of harm e.g. patient perception of delay in diagnosis resulting in poor patient outcome	Discuss and agree on appropriate form of disclosure

3.3.3 When does open disclosure begin and end?

[Open disclosure] needs to be continuous, [it] is one of frequent and cumulative disclosure rather than just disclosing and then okay now we've done that. Senior clinical manager^{86(p65)}

There is often confusion about when open disclosure begins and ends, and whether meetings constitute formal open disclosure or an informal discussion.¹⁵³ Patients can be confused about the extent of the open disclosure and its aims. Healthcare professionals can be confused about when and how to conduct open disclosure. However, it may be counterproductive to be too prescriptive about disclosure process boundaries because it is fundamentally an organic process and unlikely to follow a neat and predictable trajectory. The starting point is the clear evidence for patient expectations of open, spontaneous and prompt acknowledgment of an incident. From there, circumstances will dictate the nature and duration of the process.

Depending on the context and the nature of the incident, open disclosure may begin when acknowledging that an incident has (or may have) occurred, or during a discussion to ascertain whether harm has occurred. Alternatively, the initial acknowledgment may only signal the need for a future open disclosure meeting. This is likely to be the case for more serious incidents when preparations and arrangements for the open disclosure meeting are required. Patients and families may also initiate the open disclosure process by reporting that they have been harmed. (The validity of such reports has been evidenced.³⁹)

The literature provides practical advice and 'things to do' in initiating open disclosure.^{19(p42),154,D} It consistently supports preparation and planning before disclosure as well as signalling to the patient as soon as possible that an open disclosure dialogue may be necessary, even if all facts have not been established at that point.¹¹

Open disclosure is becoming understood as an achievement that is accomplished with patients. Any discussions or meetings should include the patient and examine the possibility of harm as early as possible; the revised Standard will need to reflect this possibility. This is supported by evidence of low incident notification rates by providers in the absence of consultation.¹²⁹

Evidence supports disclosure as an open and frank exchange of views, perceptions and ideas, not as a didactic information provision exercise. The discussion should involve an explanation, an apology, a plan for the patient, a plan for system improvement and pledges for ongoing support and information on what effects the incident investigation may have on quality improvement.^{4, 11, 22, 48, 155} Depending on the severity of harm, this can occur over the course of several meetings and discussions.

Finalisation should occur when all participants are ready. It should include an undertaking to inform the patient of final system improvement outcomes, and an offer for involvement in the process itself if appropriate.^{4, 155} The health service may decide to cease the process in the event that further disclosure will not provide additional benefit. However, should there be unresolved issues, patients should be provided with options outside of disclosure.

D See also the Appendix for examples and models of carrying out open disclosure.

Helmchen and colleagues recommend:

- 'Get there early. As soon as possible after the incident, pledge to injured patients and their relatives that you will assist and accompany them in their recovery as long as necessary.
- Stay late and follow through on your pledge.'^{156(p9)}

3.4 Legal matters

The principles of openness and acknowledgment in open disclosure can conflict with legal constraints.

3.4.1 Qualified privilege

Qualified privilege (QP) protects information generated in an investigation of an incident by a 'declared committee' (such as a root cause analysis committee) in order to facilitate free and thorough inquiry and information gathering and to maximise learning from incidents.

In reality, the disclosure process and the activities of quality improvement committees operating under QP are unlikely to intersect formally to any significant degree. None of the Australian QP statutes relate to open disclosure directly. Although there are variations between the jurisdictional QP laws, none impose prohibitions or barriers on disclosure, nor protect content and information conveyed in disclosure processes. There are legal pathways for information generated under QP to be transferred to those whose care the investigation concerns (that is, the harmed patient).

A barrier to release of information for disclosure purposes is likely to include the reluctance of healthcare services to provide information for fear of legal proceedings because of misconceptions about the extent and effect of these laws.^{99, 100}

3.4.2 Statutory duty to disclose

Several jurisdictions in the United States have legislated for the professional/ethical obligation to disclose medical error. In Australia to date there is no legislation mandating open disclosure, or indeed any laws designed to influence its practice.

However, in Australia there is the suggestion of an emerging common law action relating to loss resulting from nondisclosure of medical errors. According to Madden and Cockburn, '[a]s a breach of duty to disclose medical error can give rise to an independent cause of action, even where the original mistake was not negligent, the patient may recover damages for the additional loss suffered as a result of not being told of the mistake.'^{157(p522)}

A statutory duty to enact open disclosure following harmful incidents is said to 'put teeth' in guidelines and ethical standards,¹⁵⁸ but evidence for its effectiveness in reducing the disclosure 'gap' and, more importantly, improving the quality of open disclosure dialogue is not yet available. Legal reform is beyond the scope of a review of the Standard but it may be envisaged as a separate initiative in the future.

3.5 Implications for a revised national Standard

Openness and timely acknowledgment, the first two principles of the Standard, firmly align with what patients express as vital aspects of open disclosure. In keeping with contemporary thinking of its time, the Standard frames the communication process as one-way information dissemination. However, more recent evidence indicates that the process should be two-way and extend beyond 'provision of ongoing information'.^{10(p2)}

Recommendation 1.1: The revised Standard should emphasise that the open disclosure process is a two-way exchange of valuable information and an ongoing dialogue that can:

- redress harm and repair damaged relationships
- contribute towards health system improvement.

There is a gap between 'disclosable' and 'disclosed' events (current evidence suggests that approximately 70 per cent of incidents are undisclosed)^{19(p40),22} and there are gaps between how disclosure is delivered and patient expectations. This is highlighted in the evidence for the key motivations behind medico-legal action. Often these are rooted simply in a desire to receive an explanation and are moderated, to a large extent, by how an event is managed rather than by the event itself.

Recommendation 1.2: The revised Standard should emphasise that early management of an incident, especially the way communication is undertaken with patients, has been found to have a powerful effect on:

- patient perceptions of the incident itself
- levels of patient trust
- medico-legal implications and results
- eventual outcomes and residual harm.

To enable and institutionalise sound disclosure practice, clinicians should be informed and educated about the process, its medico-legal context and the expectations of their patients. Misinformation and uncertainty are cited by health professionals as barriers to open disclosure. There is also a discernible difference between provider and patient views and priorities in open disclosure. Patient views should be considered when determining which incidents to disclose and how disclosure should occur.

Recommendation 1.3: The revised Standard should:

- promote support for open disclosure implementation, particularly healthcare professional education on managing post-incident communication and interaction with patients
- emphasise that all aspects of disclosure are to take place in a fair manner, without bias and in keeping with the ethos of patient-centeredness
- stress the importance of supporting providers throughout the process.

All concerns and complaints should be responded to appropriately and investigated to test what degree and form of communication is necessary. The apprehension that a harmful

incident has occurred should be communicated immediately to the patient even if all the facts are still being gathered. Planning and preparation is vital prior to any meetings.

Recommendation 1.4: The revised Standard should:

- stress early intervention and communication
- provide guidance on which part of the post-incident communication spectrum applies in specific situations.

Following an incident, the healthcare team should share information and openly discuss the circumstances and contributing factors. An absence of communication can create professional anxiety and lead to potentially damaging speculation. Respectful communication, or creating a psychologically safe environment, can circumvent this problem, as can an active and appropriate leadership.

Recommendation 1.5: The revised Standard should describe an inter-disciplinary, inter-professional and multi-sector approach to disclosure based on the same principles of openness and transparency described in the current Standard.

The current Standard requires providers to 'take early advice from' their insurer following an adverse event. This risks suboptimal disclosure by potentially delaying communication with the patient. Insurers need to be involved in incident management, but should also be cognisant of patient and provider needs immediately following harm, and the organisational risk if these expectations are not met.

Recommendation 1.6: The revised Standard should:

- explicitly address the tension between immediately providing patients with information and taking preliminary advice from insurers and, where applicable, employers
- recognise insurer and, where applicable, employer roles and responsibilities in overall open disclosure policy development as well as in individual cases.

References

4. Conway J, Federico F, Stewart K, Campbell M. *Respectful management of serious clinical adverse events* (2nd ed.). Cambridge, MA: Institute for Healthcare Improvement, 2011.
10. Australian Council for Safety and Quality in Health Care. Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care. Canberra, 2003.
11. Iedema R, Allen S, Britton K, Piper D, Baker A, Gribich C, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The '100 patient stories' qualitative study. *British Medical Journal* 2011;343(d4423).
12. Iedema R, Allen S, Sorensen R, Gallagher TH. What prevents incident disclosure, and what can be done to promote it? *Joint Commission Journal on Quality and Patient Safety* 2011;37(9):409–417.
14. ACSQHC (Australian Commission on Safety and Quality in Health Care). Independent research into patient and provider views and experiences with open disclosure: University of Technology, Sydney, 2011.

19. Piper D, Iedema R. *Literature review: Incident disclosure policy, legal reform and research since 2008*. Sydney: Centre for Health Communication (University of Technology Sydney) and ACSQHC (Australian Commission on Safety and Quality in Health Care), 2011:21. O'Connor E, Coates HM, Yardley IE, Wu AW. Disclosure of patient safety incidents: A comprehensive review. *International Journal on Quality in Health Care* 2010;22(5):371–379.
21. O'Connor E, Coates HM, Yardley IE, Wu AW. Disclosure of patient safety incidents: A comprehensive review. *International Journal on Quality in Health Care* 2010;22(5):371–379.
22. Gallagher TH. A 62-year-old woman with skin cancer who experienced wrong-site surgery. *Journal of the American Medical Association* 2009;302(6):669–677.
26. Kennedy I. *Learning from Bristol: The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995*. London: Department of Health, 2001.
39. Daniels JP, Hunc K, Cochrane D, Carr R, Shaw NT, Taylor A, et al. Identification by families of pediatric adverse events and near misses overlooked by health care providers. *Canadian Medical Association Journal* 2012; 184(1):29–34.
45. Gallagher T, Waterman A, Garbutt J, Kapp J, Chan D, Dunagan W, et al. US and Canadian physicians' attitudes and experiences regarding disclosing errors to patients. *Archives of Internal Medicine* 2006;166(15):1605–1611.
46. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *Journal of the American Medical Association* 2003;289(8):1001–1007.
48. Truog RD, Browning DM, Johnson JA, Gallagher TH. *Talking with patients and families about medical error: A guide for education and practice*. Baltimore: Johns Hopkins University Press, 2011.
49. Gallagher TH, Lucas MH. Should we disclose harmful medical errors to patients? If so, how? *Journal of Clinical Outcomes Management* 2005;12(5):253–259.
50. Iezzoni LI, Rao SR, DesRoches CM, Vogeli C, Campbell EG. Survey shows that at least some physicians are not always open or honest with patients. *Health Affairs* 2012;31(2):383–391.
51. Valentine N, Darby C, Bonsel GJ. Which aspects of non-clinical quality of care are most important? Result from WHO's general population surveys of 'health system responsiveness' in 41 countries. *Social Science and Medicine* 2008;66:1939–1950.
52. Blendon R, DesRoches C, Brodie M, Benson M, Rosen A, Schnieder E, et al. Views of practising physicians and the public on medical errors. *New England Journal of Medicine* 2002;347(24):1933–1940.
64. Fischer M, Ereaut G. *Can changing clinician–patient interactions improve healthcare quality? A scoping report for the health foundation*. London: Health Foundation, 2011.
72. Wachter RM. The end of the beginning: Patient safety five years after 'to err is human'. *Health Affairs* 2004;November 2004;W4/534–545.
82. Disclosure Working Group. *Canadian open disclosure guidelines: Being open and honest with patients and families*. Edmonton, AB: Canadian Patient Safety Institute, 2011.
86. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. *Final report: Evaluation of the National Open Disclosure pilot program*. Sydney: The Australian Commission on Safety and Quality in Health Care (ACSQHC), 2008.
90. Gallagher TH, Garbutt JM, Waterman AD, Flum DR, Larson EB, Waterman BM, et al. Choosing your words carefully: How physicians would disclose harmful medical errors to patients. *Archives of Internal Medicine* 2006;166(August 14–28):1585–1593.
92. Wu A, Huang IC, Stokes S, Pronovost P. Disclosing medical errors to patients: It's not what you say, it's what they hear. *Journal of General Internal Medicine* 2009;24(9):1012–1017.
93. Hopgood C, Peck C, Gilbert B, Chappell K, Zou BI. Medical errors - what and when: What do patients want to know? *Academic Emergency Medicine* 2002;9:1156–1161.

94. Duclos CW, Eichler M, Taylor L, Quintela J, Main DS, Pace W, et al. Patient perspectives of patient-provider communication after adverse events. *International Journal for Quality in Health Care* 2005;17(6):479–486.
95. Rathert C, Brandt J, Williams ES. Putting the ‘patient’ in patient safety: A qualitative study of consumer experiences. *Health Expectations* 2011;doi:10.1111/j.1369-7625.2011.00685.
97. Hopgood C, Tamayo-Sarver JH, Weiner B. Patient race/ethnicity, age, gender and education are not related to preference for or response to disclosure. *Quality and Safety in Health Care* 2008;17:65–70.
98. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. The National Open Disclosure Pilot: Evaluation of a policy implementation initiative. *Medical Journal of Australia* 2008;188(2008):397–400.
99. Studdert D, Richardson MW. Legal aspects of open disclosure: A review of Australian law. *Medical Journal of Australia* 2010;193(5):273–276.
100. Studdert D, Piper D, Iedema R. Legal aspects of open disclosure II: Attitudes of health professionals — findings from a national survey. *Medical Journal of Australia* 2010;193(6):351–355.
107. Mazor KM, Greene SM, Roblin D. More than words: Patients’ views on apology and disclosure when things go wrong in cancer care. *Patient Education and Counseling* 2011(August 6).
108. Okamoto S, Kawahara K, Algren M. Transformative possibilities of communication in medical error cases in Japan. *International Journal on Quality in Health Care* 2011;23(1):26–35.
109. Nie J-B. The ‘cultural differences’ argument and its misconceptions: The return of medical truth-telling in China. In: Rudnick A, editor. *Bioethics in the 21st century*. Shanghai: InTech, 2011:103–120.
110. Clinton HR, Obama B. Making patient safety the centerpiece of medical liability reform. *New England Journal of Medicine* 2006;354(2006):2205–2208.
111. Dauer EA. Medical injury, patients’ claims and the effect of government responses in Anglo-American legal systems. *BMJ Quality and Safety* 2011;9:735–737.
112. Golann D. Dropped medical malpractice claims: Their surprising frequency, apparent causes, and potential remedies. *Health Affairs* 2011;30(7):1343–1350.
113. Vincent CA, Young M, Phillips A. Why do people sue doctors? A study of patients and relatives taking legal action. *Lancet* 1994;343:1609–1613.
114. Taylor J. *The impact of disclosure of adverse events on litigation and settlement: A review for the Canadian patient safety institute*. Ottawa: Canadian Patient Safety Institute, 2007.
115. Bismark M, Dauer E, Paterson R, Studdert D. Accountability sought by patients following adverse events from medical care: The New Zealand experience. *Canadian Medical Association Journal* 2006;175(2006):889–894.
116. Schwappach DLB, Koeck CM. What makes an error unacceptable? A factorial survey on the disclosure of medical errors. *International Journal for Quality in Health Care* 2004;16(4):317–326.
117. Wu AW. Medical error: The second victim. *British Medical Journal* 2000;320(7237):726–727.
118. Peto RR, Tenerowicz LM, Benjamin EM, Morsi DS, Burger PK. One system’s journey in creating a disclosure and apology program. *Joint Commission Journal on Quality and Patient Safety* 2009;35(10):487–496.
119. Finkelstein D, Wu AW, Holtzman N, et al. When a physician harms a patient by medical error: Ethical, legal, and risk-management considerations. *Journal of Clinical Ethics* 1997;8:330–335.
120. Sweet MP, Bernat JL. A study of the ethical duty of physicians to disclose errors. *Journal of Clinical Ethics* 1997;8(4):341–318.
121. Hingorani M, Wong T, Vafidis G. Patients’ and doctors’ attitudes to amount of information given after unintended injury during treatment: Cross sectional, questionnaire survey. *British Medical Journal* 1999;318(7184):640–641.

122. Kaldjian LC, Jones EW, Rosenthal GE. Facilitating and impeding factors for physicians' error disclosure: A structured literature review. *Journal on Quality and Patient Safety* 2006;32(4):188–198.
123. Engel KG, Rosenthal M, Sutcliffe KM. Residents' responses to medical error: Coping learning and change. *Academic Medicine* 2006;81:86–93.
124. Garbutt J, Brownstein DR, Klein EJ. Reporting and disclosing medical errors: Paediatricians' attitudes and behaviors. *Archives of Paediatric Adolescent Medicine* 2007;161:179–185.
125. Kaldjian LC, Jones EW, WU BJ, et al. Disclosing medical errors to patients: Attitudes and practices of physicians and trainees. *Journal of General Internal Medicine* 2007;22:988–996.
126. White AA, Gallagher TH, Krauss MJ, Garbutt J, Waterman AD, Dunagan WC, et al. The attitudes and experiences of trainees regarding disclosing medical errors to patients. *Academic Medicine : Journal of the Association of American Medical Colleges* 2008;83(3):250–256.
127. Evans SB, Yu JB, Chagpar A. How radiation oncologists would disclose errors: Results of a survey of radiation oncologists and trainees. *International Journal of Radiation Oncology Biology Physics* 2012.
128. Medical Board of Australia. Good medical practice: A code of conduct for doctors in Australia. Canberra: Medical Board of Australia, 2011. (Accessed on 15 May 2012 at <http://www.medicalboard.gov.au/Codes-Guidelines-Policies.aspx>)
129. Lopez L, Weissman JS, Schneider EC. Disclosure of hospital adverse events and its association with patients' ratings of the quality of care. *Archives of Internal Medicine* 2009;169:1888–1894.
130. Weissman JS, Schneider EC, Weingart SN, Epstein AM, David-Kasdan J, Feibelman S, et al. Comparing patient-reported hospital adverse events with medical record review: Do patients know something that hospitals do not? *Annals of Internal Medicine* 2008;149(2):100–108.
131. Schoen C, Osborn R, Huynh PT, Doty M, Zapert K, Peugh J, et al. Taking the pulse of health care systems: Experiences of patients with health problems in six countries. *Health Affairs* 2005;Web Exclusive W5–509.
132. Loren DJ, Klein EJ, Garbutt J, Krauss MJ, Fraser V, Dunagan WC, et al. Medical error disclosure among pediatricians: Choosing carefully what we might say to parents. *Archives of Pediatrics & Adolescent Medicine* 2008;162(10):922–927.
133. Rabow MW, Remen RN, Parmelee DX, Inui TS. Professional formation: Extending medicine's lineage of service into the next century. *Academic Medicine* 2010;85(2):310–317.
134. Hojat M, Vergare MJ, Maxwell K. The devil is in the third year: A longitudinal study of erosion of empathy in medical school. *Academic Medicine* 2009; 84(9):1182–1191.
135. Hojat M, Louis DZ, Marham FW. Physicians' empathy and clinical outcomes for diabetic patients. *Academic Medicine* 2011;86(3):359–364.
136. Peabody F. The care of the patient. *Journal of the American Medical Association* 1927;88(12):882.
137. Prictor M, Hill S. Does communication with consumers and carers need to improve? In: Hill S, editor. *The knowledgeable patient: Communication and participation in health - a Cochrane handbook*. Oxford, UK: Wiley-Blackwell Publishing Ltd, 2011.
138. Young-Xu Y, Neily J, Mills PD, Carney BT, West P, Berger DH, et al. Association between implementation of a medical team training program and surgical morbidity. *Archives of Surgery* 2011;146(12):1368–1373.
139. Hull L, Arora S, Aggarwal R, Darzi A, Vincent C, Sevdalis N. The impact of nontechnical skills on technical performance in surgery: A systematic review. *Journal of the American College of Surgeons* 2012;214(2):214–230.
140. Ambady N, LaPlante D, Nguyen T, Rosenthal R, Chaumeton N, Levinson W. Surgeons' tone of voice: A clue to malpractice history. *Surgery* 2002;132(1):5–9.
141. Braithwaite J, Iedema R, Jorm C. Trust, communication, theory of mind and the social brain hypothesis: Deep explanations for what goes wrong in health care. *Journal of Health Organisation and Management* 2007;21(4/5):353–367.

142. Shannon SE, Foglia MB, Hardy M, Gallagher TH. Disclosing errors to patients: Perspectives of registered nurses. *Joint Commission Journal on Quality and Patient Safety* 2009;35(1):5–12.
143. Jeffs L, Espin S, Rorabeck L. Not overstepping professional boundaries: The challenging role of nurses in simulated error disclosure. *Journal of Nursing Care Quality* 2011;26(4):320–327.
144. Loren DJ, et al. Risk managers, physicians, and disclosure of harmful medical errors. *Joint Commission Journal on Quality and Patient Safety* 2010;36(March 2010):101–108.
145. Chamberlain CJ, Koniaris LG, Wu AW, Pawlik TM. Disclosure of ‘nonharmful’ medical errors and other events: Duty to disclose. *Archives of Surgery* 2012;147(3):282–286.
146. Weingart S, Zhu J, Chiappetta L. Hospitalized patients’ participation and its impact on quality of care and patient safety. *International Journal on Quality in Health Care* 2011;23(3):269–277.
147. Weingart SN, Pagovich O, Sands DZ, Li JM, Aronson MD, Davis RB, et al. What can hospitalized patients tell us about adverse events? *Journal of General Internal Medicine* 2005;20(9):830–836.
148. Peat M, Entwistle V, Hall J, et al. Scoping review and approach to appraisal of interventions intended to involve patients in patient safety. *Journal of Health Service Research and Policy* 2010;15(Suppl. 1):17–25.
149. Rathert C, Huddleston N, Pak Y. Acute care patients discuss the patient role in patient safety. *Health Care Management Review* 2011;36:134–144.
150. Wu AW. Is there an obligation to disclose near-misses in medical care? In: Sharpe VA, editor. *Accountability: Patient safety and policy reform*. Washington DC: Georgetown University Press, 2004:135–142.
151. Disclosure Working Group. *Canadian disclosure guidelines*. Edmonton, AB: Canadian Patient Safety Institute, 2008.
152. Wu A, Iedema R, Gallagher TH. Disclosing close calls to patients and their families. In: Wu A, editor. *The value of close calls in improving patient safety: Learning how to prevent and mitigate patient harm*: Joint Commission Resources, 2010.
153. Sorensen R, Iedema R, Piper D, Manias E, Williams A, Tuckett A. Disclosing medical error to patients: Can practice inform policy? *Health Expectations* 2009;13:148–159.
154. Weiss PM, Koch S, Lara-Torre E, Scarrow PK. To air the error: Lowering the barriers to successful disclosure conversations. *The Female Patient* 2011;36:17–21.
155. McDonald TB, Helmchen LA, Smith KM. Responding to patient safety incidents: The ‘seven pillars’. *Quality and Safety in Health Care* 2010;19:e11.
156. Helmchen LA, Richards MR, McDonald TB. Successful remediation of patient safety incidents: A tale of two medication errors. *Health Care Management Review* 2011;April–June 2011.
157. Madden B, Cockburn T. Bundaberg and beyond: Duty to disclose adverse events to patients. *Journal of Law and Medicine* 2007;14(2007):501–527.
158. Lamb RM, Studdert DM, Bohmer RMJ, Berwick DM, Brennan TA. Hospital disclosure practices: Results of a national survey. *Health Affairs* 2003;22(2):73–83.



Saying sorry

Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology, expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

4 Saying sorry

An apology would go such a long way, it really would, simple apology. We don't want anything, we never have. An apology. How can you get so caught up with rhetoric and paperwork and policy that we just can't say to a family we did the wrong thing and we are sorry. Patient's family member^{11(Box 2)}

Principle 3: Expression of regret

As early as possible, the patient and their support person should receive an expression of regret for any harm that resulted from an adverse event.¹⁰

The current Standard's third principle, expression of regret, has emerged as a key aspect of open disclosure. Recent research identifies the importance in successful disclosure practice of saying sorry^E in the context of an apology or, when appropriate, an expression of regret. This chapter examines the role of apology or expressions of regret in health care and discusses the latest evidence in the context of the current Standard. The legal aspects of apology are discussed in Section 4.4.

4.1 Role of an apology

Saying sorry, in the context of an apology, has grown in prominence in policy¹⁵⁹ and public and political discourse, acquiring socio-cultural currency over the past two decades.¹⁶⁰ The functions of apologising primarily involve:

- responding to the harmed person's need for recognition
- offering the individual or organisation the opportunity to make amends
- laying the foundation for a better relationship between both parties.

Apology is an important and meaningful device in all cultures and societies. In Western countries it is increasingly considered an important aspect of corrective justice, in particular its equalising effect on power asymmetries, and its restoration of dignity that may be lost as a result of a harmful incident (medical or other).¹⁰²

The role of reimbursement in service recovery is examined in the next chapter. However, apology is also an important part of restitution. It is said to 'do part of the work' in terms of 'reparation for the emotional and moral pain suffered by the victim.'¹⁰³ This perhaps helps to explain individuals' diminished propensity to litigate following apology.^{161–163}

In this light, apologies can certainly be viewed as 'secular remedial rituals' that are able to 'reconcile by affirming societal norms and vindicating victims.'^{164(p113)} They play a role not only in individual cases, but also within the broader moral community.¹⁶⁴

E It should be recognised that the word 'sorry' may convey different meanings and implications in different languages or cultures. In this document the standard English interpretation is used.

4.2 Apology and open disclosure

And it was one of the most dramatic experiences I ever had. As soon as I offered that [statement about taking responsibility for the adverse event] to them, it's almost like there was a breath of fresh air coming into this room, and you really could see him physically change ... His tone changed, his body language changed, and he was saying things like, 'so where do we go from here?' So that to me was a very eye opening experience, very. Medical manager^{86(p50)}

Recent research has identified full and sincere apology (evidenced by saying sorry) as a key aspect of open disclosure. For patients, it is the most valued part of open disclosure and fundamental in the post-incident reconciliation process. Apology has a tangible utility in quality improvement leading to rigorous investigation of the causative factors of an incident. It also has an important 'non-material dimension — the aspect that makes hearts turn and transforms perceptions, without reduction to any manual or calculation.'^{165(p175)}

The critical feature of apology in open disclosure appears to be saying sorry sincerely. Lack of humility and disingenuousness are commonly cited as reasons why apologies in open disclosure fail.^{166, 167} Sincere apologies are not easy, require considerable 'emotional labour' and run counter to some of the tenets of Western medical practice.¹⁶⁸ The humbling aspect of saying sorry, and the possible power equalisation and dignity restoration it offers the harmed party, reinforces the corrective justice overtones of apologising. The moral aspect of apology may seem at odds with the objective and rational nature of health care. Nevertheless, it is the moral aspect that requires careful consideration, for it is this that affects and influences the participants following a harmful incident.

4.2.1 Apology and patients

The literature highlights the restorative psycho-physiological effects of apology, especially the words *I am* or *we are sorry*, on patients, and suggests that 'apology may accrue significance beyond its in situ enactment.'^{160(p272)}

Links between being harmed and a perpetual state of stress have been established. These manifest physiologically in increased levels of cortisol, ongoing hyper-arousal of the sympathetic nervous system and emotionally as guilt and shame. The state of negative effect is termed 'unforgiveness' and can last until closure is achieved.¹⁶⁹ These effects are evident in patients who suffered healthcare-associated harm and may result in:

- impairment to physical and mental recovery following adverse events
- reduced trust in healthcare professionals and health care more broadly, with health implications for the affected individuals.

The 'fight' response of sympathetic arousal following a perception that one has been wronged can also result in revenge-taking behaviour, manifesting in formal complaints or litigation. This is consistent with research suggesting that patients who are not given an explanation for an incident may be more likely to seek legal action.¹⁶⁹

It has been demonstrated that the cognitive and physiological components of this state can be ameliorated by forgiveness.^{170, 171} Allan and McKillop propose parallels with people harmed in health care, suggesting that a full and frank apology, including an explanation of the facts and an admission of responsibility, can facilitate forgiveness, ameliorate deleterious effects and assist in the recovery of those harmed by:

- redressing a power imbalance
- restoring dignity
- achieving closure and stopping the search for an explanation or information
- reducing the impulse for redress by making them feel that they have been treated respectfully and fairly.¹⁶⁹

Apology and trust

Apology can restore trust in health care and in relationships with the healthcare team.^{166, 169, 172–174} In fact, some patients and families report increased trust in health services after an adverse event, providing it was handled openly and honestly.¹⁶⁷ According to Duclos, acceptance of responsibility and apology fosters patient and consumer trust in the clinical team and the health service. However, accepting responsibility without apology yields no such benefit and, in fact, produces a more negative judgement of the patient experience.⁹⁴ This counterintuitive response has been repeatedly observed. For instance, patients who receive a full apology from their general practitioner following adverse events are more likely to remain with the practitioner.⁹⁶

In a recent Australian case, five of eleven cardiac patients died due to a contaminated drug used during surgery. Following the revelation of the contamination, the health service contacted the families affected, acknowledged the error, apologised and indicated that no further surgery would be undertaken until the source for the contamination was identified. Consequently, two of the patients who survived returned to the same hospital to have repeat procedures with the same surgeons. According to Professor Cliff Hughes, these patients 'had confidence that the clinicians were on their side and were empathic with them. And, surely, in this day and age we can allow our clinicians to be empathic with the people that, after all, they went to work to help.'^{175(p14)}

The positive psycho-physiological effects of apology mirror those of compassionate and empathic patient–provider relationships, which are being increasingly recognised, observed and measured.^{133, 135, 176, 177} As noted by Riess, '[t]his is not simply a moral or philosophical issue; empathy is an important component of clinical competence, without which there can be serious consequences.'¹⁷⁶

4.2.2 Apology and healthcare providers

I think open disclosure is a therapy. Nurse manager^{160(p266)}

Everybody that's been involved with it have felt quite relieved. Support personnel^{186(p18)}

Healthcare professionals undergo considerable stress following harmful incidents, with some left feeling 'permanently wounded'.^{117, 178} Current evidence suggests that healthcare professionals want to apologise and seek forgiveness from patients who were harmed while under their care. This may have a similar restorative effect on them as it has on patients.^{179, 180} Openly discussing adverse events with patients, families and carers, and as a result enabling and witnessing their closure and forgiveness, can assist healthcare professionals achieve their own closure and ameliorate feelings of shame or guilt.^{76, 123, 181, 182}

Gallagher and colleagues studied physician and patient views on disclosure of adverse events using a focus group approach. They found that the emotional needs of healthcare professionals following medical errors were not met despite notions of a 'blame-free' culture.

More importantly, following errors clinicians reported instinctively turning 'to the affected patient for support and, through disclosure, sought forgiveness from the patient.'^{46(p1006)}

4.3 Elements of an apology

Apology is defined in a number of ways. For example, Lazare defines apology as an individual, group or institution acknowledging a grievance or error, and accepting responsibility for it.¹⁸³ It is generally accepted in the literature that an apology includes the following elements:^{22, 162, 165–167, 184, 185}

- acknowledgment that harm or grievance has occurred
- expression of sorrow and remorse (at a minimum, the conversation or exchange should contain the words *I am* or *we are sorry*¹⁷²)
- explanation of why the harm or grievance has occurred
- commitment to restorative action.

Some authors suggest that the fourth component is implied in the authentic and sincere expression of the apology.¹⁸⁶ However, in the main, the literature places importance on making a commitment to the harmed party that things will be set right in direct relation to the harm when appropriate, and also in terms of addressing the underlying causes of an incident.^{22, 167, 187}

An apology may often include an acceptance of responsibility. As noted by Taft and others, 'without a meaningful and unequivocal expression of wrongdoing, apology cannot be an authentic moral act'^{172, 183} and there is considerable literature indicating that an apology is not regarded as real or complete if it does not include an admission of wrongdoing.^{188–190} This observation holds in health care,¹⁹ even when the causes of a harmful incident are often not attributable to an individual person or act. If indicated by the facts of an incident, healthcare providers and their employers should accept individual or collective responsibility for the harm. This is not an admission of liability, but an important part of the restorative process.

4.3.1 Wording

It is recommended that providers prepare carefully for open disclosure, including planning how an apology or expression of regret is made.

Examples of recommended phrases during an apology:

- 'I am/we are sorry.'
- Factual statements explaining how the incident occurred. ('This incident occurred because the wrong label was mistakenly placed on your specimen sample')
- Explaining what is being done to ensure it doesn't happen again. ('We are currently investigating what exactly caused this breakdown in the process and will inform you of the findings and steps taken to fix it as soon as we know')

Examples of phrases to avoid during an apology:

- 'It's all my/our/his/her fault. I'm liable.'
- 'I was/we were negligent.'
- Speculative statements.

4.3.2 Apology versus expression of regret

For the purpose of this report, an apology and expression of regret are defined similarly:

- An expression of regret is an expression of sorrow by an individual, group or institution for a harm or grievance, and should include the words *I am* or *we are sorry*. The current Standard defines an expression of regret as ‘an expression of sorrow for the harm experienced by the patient’.
- An apology goes further. It is an expression of sorrow, sympathy and (where applicable) remorse for a harm or grievance. It should include the words *I am* or *we are sorry*. It may also include an acknowledgment of responsibility, which is not an admission of liability.

While apologising is encouraged and saying sorry should always form part of open disclosure, in some circumstances an expression of regret may be more suitable. These may include harmful incidents where all preventable measures had been taken, or incidents involving complications of medical treatment.

Nevertheless, because of the benefits described in the literature, the words *I am* or *we are sorry* should still be used in these cases. For example, following an adverse drug reaction with no prior knowledge of allergy an apology including remorse and acceptance of responsibility may not be appropriate. However, a provider may say:

‘I am really sorry you had a reaction to drug X we prescribed you. As we explained when we asked you if you had ever taken it before, unfortunately you are one of the small number of people who react to this medication. We will make sure this allergy is recorded in your medical record and that you are never given this drug in the future. We will write down all its alternative names for you. Please make sure you advise other healthcare providers of this allergy in the future.’

An apology should also be timely and spontaneous.¹⁸⁸ However, as it will often be an ongoing process, the components of an apology can be enacted over a series of conversations as facts and events emerge. As such, the appropriateness of an expression of regret versus an apology may change over time as new information comes to hand during the open disclosure process.

4.3.3 Explanation and speculation

So, it’s all about maintaining people’s confidence and trust and treating them respectfully whilst not saying things that aren’t knowable ... and sort of being able to ... deal with that.
Staff member¹⁴

Apology is arguably the most concerning and anxiety-provoking aspect of open disclosure for providers, insurers and institutions. Aside from legal matters, there are some practical considerations that must be taken into account when apologising to harmed parties. These can be important in terms of the open disclosure principles of openness and timely acknowledgment, and the context of often stressful circumstances in which these conversations take place.

First, the distinction between an apology or expression of regret, and a factual explanation of the incident should be understood by providers and institutions. These two aspects of open disclosure should not be confused, especially as an apology/expression of regret and factual explanation can often occur during the same conversation. As timeliness is the key in acknowledging and apologising for a harmful incident to patients,^{11, 46, 48} often all the facts behind the incident will not have been established at the time (aside from the essential fact that harm had occurred). In such circumstances, phrases such as the following may be useful:

'I/we are sincerely sorry that this has occurred. It is clear that something went wrong and we are investigating it right now. We will give you any information as it comes to hand. An important part of this is getting your version of what happened. We can either go through this now if you like, or we can wait until you are ready to talk about it.'

Second, and related to the above, it is essential that providers avoid making speculative statements during an initial disclosure conversation and apology or expression of regret. While this may be self-evident when discussing open disclosure in the abstract, statements that go too far can easily be made in the 'heat of the moment'. The following points should be considered when preparing for, and conducting, an apology:

- Speculation on the causes of an incident should not be entered into (even hypothetically).
- Blame must not be apportioned to any individual, group or system.
- Investigation results must not be pre-empted.

One of the principal aims of open disclosure is to restore trust in the provider and the institution. While patients appreciate and need early acknowledgment and apology or expression of regret to achieve this aim, over-promising and making statements that then have to be retracted can undermine it.

The literature suggests that such conversations be practised as part of open disclosure training and that specific wording be considered ahead of the actual dialogue with patients, families and carers.^{48, 191–193} The challenge is to balance this with appropriate sincerity, empathy and a degree of spontaneity. Education, training and the development of sound communication skills is the most prudent approach to achieving this balance.²² Ability and confidence in this regard provides the necessary flexibility for providers and clinical teams to manage these difficult situations. Chapter 6 discusses actively supporting professionals in more detail.

4.4 Legal aspects of apology

Section 2.4.3 briefly outlined several legal aspects of open disclosure, including apology. However, this topic warrants further discussion owing to its sensitivity and its considerable complexity, and the fact that it interacts across three domains: civil, legal and professional. These interactions concern providers as does the possibility that the contents of an apology may be used in disciplinary processes.

The various jurisdictional apology laws were not framed in the context of open disclosure and, on balance, neither protect nor hinder its practice.⁹⁹ Case law does not indicate significant risk from providing a full apology.^{101–103, 194} Indeed, evidence exists for apology having a neutralising effect on harmed patients seeking redress through the courts (and its absence as one of several key motivators for legal action).

However, misunderstanding among providers and insurers may be a significant barrier to full apology in open disclosure. A survey of approximately fifty Australian healthcare professionals suggests widespread hesitancy and misunderstanding about the effect of apology law on open disclosure. Respondents considered medico-legal risks (including apology) as moderate to major barriers to open disclosure but also cited inadequate training and education as key factors.¹⁰⁰ As such, concerns about apology and civil law liability may be founded in perception rather than reality.

Apology laws share common features across jurisdictions but variations exist that affect the scope and strength of these laws. Five Australian apology statutes (Western Australia, Victoria, Northern Territory, Tasmania, South Australia) expressly exclude statements containing acknowledgment of fault or liability in the definition of the apology, although the wording of these acts can be interpreted in various ways.^{194, F} It is presumed that the rationale for stipulating an 'expression of regret' rather than an apology in the Standard was based on the least protective statutes. While the legislative situation remains unaltered, the evidence supporting use of sincere apology or expression of regret (including the words *I am* or *we are sorry*) in open disclosure has grown, as has case law supporting its use in other contexts. There is also variation in the types of legal proceedings to which these laws apply.⁹⁹ These variations are summarised in Table 4.

An additional consideration is that apology or expression of regret forms just one component of comprehensive open disclosure dialogue. In practice, this means that apology laws protect only selected parts of a conversation or statement from legal proceedings, while other parts remain exposed. For instance, a factual explanation of an incident may be given immediately after an apology. At which point in the conversation does the protection given to the apology cease? Legally, this may be difficult to interpret especially for providers who are unlikely to have a detailed knowledge of how the laws apply to the enactment of disclosure conversations.

Table 4 Key jurisdictional variations in Australian apology law (adapted from Studdert and Richardson 2010⁹⁹)

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	<i>Civil Liability Act 2002</i>	✓	✗ s69(1)(a)	✗ s69(1)(b)	✗ s69(2)
Vic	<i>Wrongs Act 1958</i>	✗ s141	✗ s14J(1)(a),(b)	✓	✓
Qld	<i>Civil Liability Act 2003</i>	✓ s72C	✗ s72D(1)(a)	✗ s2D(1)(b)	✗ s2D(2)
SA	<i>Civil Liability Act 1936</i>	✓	✗ s.75	✓	✓
WA	<i>Civil Liability Act 2002</i>	✗ s5AF	✗ s5AH(1)(a)	✗ s5AH(1)(b)	✗ s5AH(2)
Tas	<i>Civil Liability Act 2002</i>	✗ s7(3)	✗ s7(1)(a)	✗ s7(1)(b)	✗ s7(2)
NT	<i>Personal Injuries (Liabilities and Damages) Act 2003</i>	✗ s12(b)	✓* s7(1)(a)	✓* s7(1)(b)	✗ s13
ACT	<i>Civil Law (Wrongs) Act 2002</i>	✓	✗ s14(1)(a)	✗ s14(1)(b)	✗ s14(2)

s = section

* Implicit from the nature and purpose of related sections

F South Australian apology law implies this restriction.

4.4.1 Apology, admission of fault and case law

No matter how many times doctors, hospital administrators, attorneys and malpractice insurers are told so, they still have a hard time believing that there has yet to be a case in which an apology was used as evidence and made a difference in the outcome.¹⁹⁵

Laws protecting apology have been enacted in a variety of countries and jurisdictions over the past decade or more.¹⁰³ The laws vary in detail, definition and the level of protection but commonly enable the natural 'humane response' of apologising by dissociating apology from liability.

There is limited case law on apology in health care. Broadly, apology laws disallow apology as evidence of fault or liability in civil actions. While this is useful in a healthcare context, there is little evidence that apology is regarded as an admission that generates liability. Case law in Australia and overseas indicates that courts do not find expressions of regret, apologies or admissions of duty of care failures as evidence of liability.

In the absence of common law examples of apology in health care, the leading Australian apology case which provides guidance is *Dovuro Pty Ltd v. Wilkins* (2003) HCA51; CLR 317; 201 ALR 139; 77 ALJR 1706.¹⁹⁶ The Dovuro company imported canola seeds from New Zealand, which were advertised as '99%' pure. The one per cent impurities prompted the West Australian Government to take protective regulatory action, which resulted in financial losses to farmers such as Wilkins. The argument was that Dovuro should have foreseen regulatory changes.

Dovuro decided to issue two statements of apology, including 'we apologise to canola growers and to industry personnel. This situation should not have occurred...' and a letter from its Chief Executive which included the following:

I'd like to stress at this stage that this does not excuse Dovuro in failing in its duty of care to inform growers of the presence of these weed seeds. We got it wrong in this case, and new varieties will not be brought in on the market again in this manner. Dovuro will not be producing seeds in New Zealand again. The company will continue in bulking up its varieties (as it does every year) in Western Australia.¹⁹⁶

Dovuro's statements go beyond full apology and would not be protected under apology law in any jurisdiction. However, the High Court upheld Dovuro's appeal agreeing that admissions of negligence were of little value to a court in judging the actual actions in question and that, in this case, admission as part of an apology provided no basis for negligence.¹⁹⁶

4.4.2 Reasons for inadmissibility of full apology

A key aspect of the Dovuro case, as noted by Vines, is that the 'determination [of fault] is for the court, not for the parties to make.'^{102(p495-496)} In other words, an admission of fault (whether contained within an apology or not) is, in the eyes of the law, merely the defendant's opinion. Whether this opinion is correct must be established by the facts, not by what is said. Apology is viewed by the law as a humane act and a civil norm.

Generally, the law does not accept these opinions as determinative of legal outcomes.¹⁰³ Lay people, including healthcare professionals, will not have the knowledge to judge whether their behaviour has met all the requirements for liability. More importantly, they will not

necessarily word an apology correctly,¹⁹⁴ often in circumstances involving considerable stress and pressure. In criminal law, a voluntary confession does not automatically create guilt.

Another important part of apology is the need to realise that this act, as a 'self-critical' stance, is actually a natural, human response to harming another person (even if the harm was inadvertent and blameless). Williams calls the reaction 'agent regret', noting that it is natural to feel this even in the clear absence of personal culpability and that for somebody to fail to exhibit this would be seen as abnormal.¹⁹⁷ Some argue that a full apology is evidence of a personal standard of conduct and not objective proof of negligence.¹⁹⁸ For Helmreich, these are 'humane impulses', made in the moment, rather than admissions of liability: 'one can appropriately *feel* guilty, or take a morally self-critical view of one's past behaviour, without *finding* oneself guilty'.^{198(p24)} He goes on to note that it is precisely this self-critical aspect of apology that makes it valuable.¹⁹⁸ Absence of humility, and of a degree of self-criticism, may undermine an apology following harm, and specifically its capacity to redress a power asymmetry.

These propositions may be particularly applicable to health care. First, rarely is a harmful incident the fault of one individual or practitioner. Second, providers are deeply invested in not harming their patients, to a greater extent than ordinary people are invested in not harming their fellow citizens.

The risks and fears of full apology may therefore be overestimated, especially when viewed through the lens of openness and transparency. Smith argues that '[e]xcept in NSW and ACT, saying "I'm sorry I did this to you" can still be pleaded as an admission of liability. But if the facts ultimately showed no liability, the facts would dominate'.¹⁹⁹ In a paper on the legal situation regarding open disclosure in Western Australia (whose *Civil Liability Act 2002* arguably affords the narrowest parameters for apology), Allan makes the following observation:

American, Australian and Canadian courts have therefore in the past indicated that they do not consider apologies, even those that incorporate admissions of liability, as compelling when deciding whether defendants are in fact liable. This is confirmed by an Australian lawyer with vast experience in the medical malpractice area who stated that he has [...] not actually encountered a case where, in court, a decision on liability turned in any significant way on an apology or even on words which stated or implied an admission after the event.^{194(p7)}

4.4.3 Apology law outside of Australia

... contemporary empirical research has [...] generally found that apologies influence claimants' perceptions, judgments, and decisions in ways that are likely to make settlements more likely — for example, altering perceptions of the dispute and the disputants, decreasing negative emotion, improving expectations about the future conduct and relationship of the parties, changing negotiation aspirations and fairness judgments, and increasing willingness to accept an offer of settlement.^{161(p2)}

Medical apology laws, intended to overcome provider concerns of saying sorry for errors, have been enacted in at least thirty-six of the United States. There is evidence in health care and other settings of apology exerting a neutralising effect on medico-legal claims, and enhancing acceptance of out-of-court settlement.^{161–163, 200}

Canadian apology statutes are arguably the strongest in protecting apologies. In addition to preventing express and implied admission of fault, the British Columbia statute states that an apology does not void or impair any insurance coverage.¹⁹⁴ In countries with 'no fault' or 'no blame' compensation schemes (New Zealand and the Scandinavian nations) the need to protect or privilege apology following harmful healthcare incidents is, to a significant extent, eliminated.

4.4.4 The role of legal professionals and insurers

Perspectives on apology differ between the legal profession and patients. Robbennolt's research indicates that 'attorneys react differently to apologies than do claimants'. On one hand, 'apologies tend to lower claimants' aspirations and estimates of a case's fair settlement value' whereas 'apologies pushed attorneys' aspirations and estimates of fair settlement values in a different direction'.¹⁶¹ While this research took place in the United States, it is prudent to consider these observations.

It is important to engage the legal and insurance professions in open disclosure, particularly at policy levels and in educating providers on the legal aspects of disclosure. Insurers in particular have a strong influence on clinician behaviour directly and through influence over the regulatory environment. Some insurers have instituted programs that engage their physician clients through open disclosure and practice (see Appendix). Apology is a domain of open disclosure that creates the most anxiety (but generates the greatest dividend) for its participants, and potential tension among stakeholders.

The uncertainty about the intersection of apology laws and open disclosure would, to a large extent, be resolved through nationally consistent apology legislation that aligns with provisions contained within the respective laws of NSW, ACT and Queensland. Until this occurs, indemnity insurance contracts, while not explicitly prohibiting apology, will continue to place limitations on what can be said during the conversation.

4.5 Implications for a revised national Standard

For patients, saying sorry is the most important aspect of disclosure. Saying sorry as part of an apology or expression of regret, when it is delivered in an empathic, honest and sincere manner, can produce many positive results for all participants. On the other hand, guarded and 'managerial' language can escalate feelings that might not otherwise have been provoked.

The current Standard stipulates an expression of regret but stops short of requiring the words *I am* or *we are sorry* as part of the expression or in the context of a full apology. Evidence and research suggests that a revised Standard will need to specify that open disclosure should include saying sorry and in the context of a full and sincere apology when appropriate. However, beyond that it will be difficult to prescribe what an apology or expression of regret should entail and how it is to be phrased. It will depend on, and be shaped by, a variety of factors.

Recommendation 2.1: The revised Standard should change the name of Principle 3 to *Saying sorry*.

Recommendation 2.2: The revised Standard should:

- specify the need for saying sorry within either an apology or an expression of regret in open disclosure as appropriate
- outline how saying sorry (as part of an apology or expression of regret) is beneficial for patients and providers
- describe the basic principles and components of an apology or expression of regret (including the words *I am* or *we are sorry*) in the context of patient harm, but not be too prescriptive due to
 - the complexity and uniqueness of individual incidents and consequent disclosure process
 - variations in legislative context between jurisdictions
- stress that the need for an expression of regret versus an apology may change over time as new information comes to hand during the open disclosure process.

There is misunderstanding and a lack of clarity about the legal aspects of apology and how this influences communication during the open disclosure process.

Recommendation 2.3: The revised Standard should:

- state explicitly that an apology or expression of regret may interact with jurisdictional law
- highlight the importance of avoiding speculative statements during the initial disclosure and delivery of an apology or expression of regret (illustrating with examples based on jurisdictional laws)
- recommend professional development and training aimed specifically at building understanding, knowledge and skills to approach apologising or expressing regret confidently during open disclosure.

Balancing consumer preference and expectation with protection of healthcare professionals and institutions is important. This will need to be addressed during the Standard review consultation process.

References

10. Australian Council for Safety and Quality in Health Care. *Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care*. Canberra, 2003.
11. Iledema R, Allen S, Britton K, Piper D, Baker A, Gribich C, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The '100 patient stories' qualitative study. *British Medical Journal* 2011;343(d4423).
14. ACSQHC (Australian Commission on Safety and Quality in Health Care). *Independent research into patient and provider views and experiences with open disclosure*. Sydney: University of Technology, 2011.
19. Piper D, Iledema R. *Literature review: Incident disclosure policy, legal reform and research since 2008*. Sydney: Centre for Health Communication (University of Technology Sydney) and ACSQHC (Australian Commission on Safety and Quality in Health Care), 2011.

22. Gallagher TH. A 62-year-old woman with skin cancer who experienced wrong-site surgery. *Journal of the American Medical Association* 2009;302(6):669–677.
46. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *Journal of the American Medical Association* 2003;289(8):1001–1007.
48. Truog RD, Browning DM, Johnson JA, Gallagher TH. *Talking with patients and families about medical error: A guide for education and practice*. Baltimore: Johns Hopkins University Press, 2011.
60. Gawande A. 'Cowboys and pit crews' speech to Harvard medical graduates 26 May 2011.
76. Woods MS. *Healing words: The power of apology in medicine*. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations, 2007.
86. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. *Final report: Evaluation of the National Open Disclosure pilot program*. Sydney: The Australian Commission on Safety and Quality in Health Care (ACSQHC), 2008.
94. Duclos CW, Eichler M, Taylor L, Quintela J, Main DS, Pace W, et al. Patient perspectives of patient-provider communication after adverse events. *International Journal for Quality in Health Care* 2005;17(6):479–486.
96. Fisseni G, Pentzek M, Abholz HH. Responding to serious medical error in general practice — consequences for the GPs involved: Analysis of 75 cases from Germany. *Family Practitioner* 2008;25(1):9–13.
99. Studdert D, Richardson MW. Legal aspects of open disclosure: A review of Australian law. *Medical Journal of Australia* 2010;193(5):273–276.
100. Studdert D, Piper D, Iedema R. Legal aspects of open disclosure II: Attitudes of health professionals — findings from a national survey. *Medical Journal of Australia* 2010;193(6):351–355.
101. Brown D. *Open disclosure: Morally right, but is it legally safe?* Medico-Legal Society of NSW Inc Scientific Meeting. Sydney, 2008.
102. Vines P. Apologising to avoid liability: Cynical civility or practical morality? *Sydney Law Review* 2005;27(3):483–505.
103. Vines P. *The power of apology: Mercy, forgiveness or corrective justice in the civil liability arena?* University of New South Wales Faculty of Law Research Series 2007;2007(30):1–29.
117. Wu AW. Medical error: The second victim. *British Medical Journal* 2000;320(7237):726–727.
123. Engel KG, Rosenthal M, Sutcliffe KM. Residents' responses to medical error: Coping learning and change. *Academic Medicine* 2006;81:86–93.
133. Rabow MW, Remen RN, Parmelee DX, Inui TS. Professional formation: Extending medicine's lineage of service into the next century. *Academic Medicine* 2010;85(2):310–317.
135. Hojat M, Louis DZ, Marham FW. Physicians' empathy and clinical outcomes for diabetic patients. *Academic Medicine* 2011;86(3):359–364.
159. ACSQHC (Australian Commission on Safety and Quality in Health). Australian safety and quality framework for health care. Sydney: ACSQHC, 2010. (Accessed January 2012, at <http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/NSQF>)
160. Iedema R, Jorm C, Wakefield J, Ryan C, Dunn S. Practising open disclosure: Clinical incident communication and systems improvement. *Sociology of Health & Illness* 2009;31(2):262–277.
161. Robbennolt J. Attorneys, apologies and settlement negotiation. Social Science Research Network, 2008. (Accessed 15 May 2012, at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1275419)
162. Wheeler C. *Apologies liability and the public sector*. Sydney: NSW Ombudsman, 2009.
163. Keeva S. Does law mean never having to say you're sorry? *ABA Journal* 1999;64.

164. Bibas S, Bierschbach R. Integrating remorse and apology into criminal procedure. *Yale Law Journal* 2004;114:85.
165. Alberstein M, Davidovitch N. Apologies in the healthcare system: From clinical medicine to public health. *Duke Law Review* 2011;74:151–175.
166. Lazare A. Apology in medical practice. *Journal of the American Medical Association* 2006;296(11):1401–1404.
167. Bismark M. The power of apology. *New Zealand Journal of Medicine* 2009;122(1304):96–106.
168. Berlinger N. Avoiding cheap grace. *Hastings Center Report* 2003;33(6):28–36.
169. Allan A, McKillop D. The health implications of apologizing after an adverse event. *International Journal on Quality in Health Care* 2010;22(2):126–131.
170. Lundahl BW, Taylor MJ, Stevenson R, Roberts KD. Process-based forgiveness interventions: A meta-analytic review. *Resources of Social Work Practice* 2009;18(5):465–478.
171. Worthington EL, Scherer M. Forgiveness is an emotional focussed coping strategy that can reduce health risks and promote health resilience: Theory, review and hypothesis. *Psychology and Health* 2004;19:385–405.
172. Taft L. Apology subverted. Commodification of apology. *Yale Law Journal* 2000;109:1135.
173. Wojcieszak D, Saxton JW, Finkelstein MM. *Sorry works! Disclosure, apology and relationships prevent medical malpractice claims*. Indiana: Bloomington, 2006.
174. Berlinger N. *After harm: Medical error and the ethics of forgiveness*. Baltimore: Johns Hopkins Press, 2005.
175. NSW (New South Wales) Parliament. *Proceedings before the General Purpose Standing Committee No. 2. Inquiry into review of complaints handling within New South Wales Health*. Sydney: NSW Parliament, 2006.
176. Riess H. Empathy in medicine — a neurobiological perspective. *Journal of the American Medical Association* 2010;304(14):1604–5.
177. Street R, Makoul G, Arora N, Epstein RM. How does communication heal? Pathways linking clinician–patient communication to health outcomes. *Patient Education & Counseling* 2009;74:295–301.
178. Wears RL, Wu A. Dealing with failure: The aftermath of errors and adverse events. *Annals of Emergency Medicine* 2002;39:344–346.
179. Armstrong D. The power of apology: How saying sorry can leave both patients and nurses feeling better. *Nursing Times* 2009;105(44):16–19.
180. Cohen ML. The power of apology. *Family Practice Management* 2010;17(1):40.
181. Wu A, Folkman S, Mcphee S, Lo B. How house officers cope with their mistakes. *Western Journal of Medicine* 1993;159:565–569.
182. Lester H, Tritter JQ. Medical error: A discussion of the medical construction of error and suggestions for reforms of medical education to decrease error. *Medical Education* 2001;35:855–861.
183. Lazare A. *On apology*. New York: Oxford University Press, 2004.
184. Taft L. Apology and medical mistake. *Annals of Health Law* 2005;66:14.
185. McDonald T, Smith K, Chamberlin W, Centomani N. Full disclosure is more than saying ‘I’m sorry’. *Focus on Patient Safety* 2008;11:1–3.
186. Tavuchis N. *Mea culpa: A sociology of apology and reconciliation*. Stanford, MA: Stanford University Press, 1991.
187. Robson R, Pelletier E. Giving back the pen: Disclosure, apology and early compensation discussions after harm in the healthcare setting. *Healthcare Quarterly* 2008;11(Special Issue):85–90.
188. Brown J. The role of apology in negotiation. *Marquette Law Review* 2004;87:665.

189. O'Hara E, Yarn D. On apology and consilience. *Washington Law Review* 2002;77:1121.
190. Latif E. Apologetic justice: Evaluating apologies tailored toward legal solutions. *Boston University Law Review* 2001;81:289.
191. Fallowfield L, Jenkins V. Communicating sad, bad, and difficult news in medicine. *The Lancet* 2004;363(9405):312–319.
192. Iedema R. Creating safety by strengthening clinicians' capacity for reflexivity. *BMJ Quality and Safety* 2011;20(Suppl 1):i83–i6.
193. Liebman CB, Hyman CS. A mediation skills model to manage disclosure of errors and adverse events to patients. *Health Affairs* 2004;23(4):22–32.
194. Allan A. *Implementing the Australian open disclosure standard: The legal situation in Western Australia*. Perth: Edith Cowan University, 2008.
195. Eisenberg D. When doctors say 'we're sorry'. *Time Magazine*, 2005.
196. *Dovuro Pty Ltd v Wilkins*. HCA 51; 215 CLR 317; 201 ALR 139; 77 ALJR 1706, 2003.
197. Williams B. *Moral luck*. Cambridge: Cambridge University Press, 1981.
198. Helmreich JS. Does 'sorry' incriminate? Evidence, harm and the meaning of apologies. *Cornell Journal of Law and Public Policy* 2012;21(3):567.
199. Smith P. Sorry mess over apologies. *Australian Doctor* 2007;10 January.
200. Ho B and Liu E. Does sorry work? The impact of apology laws on medical malpractice. 2010. (Accessed November 2011, at <http://ssrn.com/abstract=1744225>)



Meeting the needs and expectations of patients

Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology, expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

5 Meeting the needs and expectations of patients

There is a difference between complication of treatment and stuff-ups of treatment. We have to be open about complications and stuff-ups. Senior clinician^{86(p29)}

Principle 4: Recognition of the reasonable expectations of patients and their support person

The patient and their support person may reasonably expect to be fully informed of the facts surrounding an adverse event and its consequence, treated with empathy, respect and consideration and provided with support in a manner appropriate for their needs.¹⁰

This principle refers to the expectations of patients, families and carers in relation to post-incident management. This chapter examines the needs and expectations of patients in relation to:

- actions and communication following harmful incidents
- the broader healthcare process, which can strongly influence the patient experience, affecting how harmful incidents are recognised and managed.

Current evidence suggests that the quality of incident management, including how openly and responsively providers communicate with patients, considerably influences how the open disclosure process is viewed by the patient.^{11, 48} Moreover, the extra-clinical attributes of care (including respect, communication, empathy, and maintenance of dignity) are universally valued by patients. Patient expectations of the healthcare process are emerging as an important health policy driver and key aspect of open disclosure, particularly regarding what patients may interpret as 'harm'.

Harm is not restricted to the physical dimension and can be psychological and social.² Harm may result from an unexpected outcome, such as side effects and complications, as well as from the extra-clinical dimensions of care.²⁰¹ The current Standard requires that the 'patient's view should trigger the open disclosure process, regardless of whether an initial assessment suggests a recognised complication, or clinical or system error'.^{10(p5)} However, as previously discussed, there is misalignment between provider and patient views of what constitutes harm.^{19(p40–41)} Health care is perhaps lagging behind other services and institutions in accepting and harnessing consumer preferences as a key driver of quality and service delivery standards.

5.1 Citizen-centred policy, patient-centred care

Open disclosure cuts across academic boundaries and disciplines. In the context of a comprehensive review of the Standard it is useful to briefly outline the development of contemporary understanding of health policy within which public institutions operate.

The trend of the informed consumer is emerging in health care. Sir Bruce Keogh, British National Health Service medical director, recently said that '[p]eople are now their own bankers, their own travel agents and their own checkout cashiers. They expect to have

data immediately available to make choices.²⁰² The growing focus on transparency and accountability in public institutions manifests as patient involvement in health care. In 2011, the Australian Commission on Safety and Quality in Health Care (the Commission) released a discussion paper providing a broad overview of how a patient-centred approach can improve healthcare delivery.⁵⁵ It is recognised that patients and their families and carers have at their disposal clinical information that often can be critical to clinical decision-making and quality improvement more broadly.^{55, 130, 147, 148} The informed and engaged patient also has a significantly reduced risk of suffering healthcare-associated harm.^{146, 203, 204}

At the clinical interface, providers are increasingly urged to treat people as opposed to diseases.^{205, 206} At the system level, policy makers are recognising that the most important stakeholders of healthcare systems are patients and the public.^{55, 66, 207} Locally and internationally there is a shift towards increased transparency and accountability in health care. As such, current reforms in Australia include the establishment of the MyHospitals website,⁶ where the public can compare hospitals based on a range of quality domains. Since October 2011, hospitals with high rates of *Staphylococcus aureus* bacteraemia have been identified on the website.²⁰⁸ Healthscope, Australia's second largest private healthcare provider, recently commenced publishing quality and performance measures, including healthcare-associated infection and readmission rates.²⁰⁹

5.2 Patient needs and expectations

The expectations of a patient about all aspects of care are generated far in advance of admission. They are shaped in a range of ways (the media, word of mouth and previous experience). Healthcare providers have a responsibility to ascertain, clarify and manage these expectations through the provision of clear communication with patients, families and carers from the start of the episode of care or the beginning of the patient-provider relationship.

Provider perceptions of what patients expect from health care are not always complete and can be inaccurate. It has been observed for some time that in addition to medical outcomes, the non-technical, extra-clinical aspects of health care, such as respect, dignity, communication and empathy (also referred to as 'service quality')⁵³ are valued by patients.^{51, 210–212} The extra-clinical aspects of care are also not only valued by patients but can enhance clinical outcomes and healthcare quality.^{135, 138, 139, 177, 213, 214} Interaction has been observed between patient engagement, subjective quality appraisal, extra-clinical aspects of care and clinical outcomes.^{177, 215, 216} Moreover, a satisfied patient is more likely to be engaged in their care and, as mentioned above, there is growing evidence that engaging patients lowers the risk of harm.⁵⁵

Supporting the patient valuation of non-technical aspects of care, only a minority of patients believe that the concept of 'error-free medicine' should be a primary focus for health services and educational institutions.⁹³

There is evidence suggesting that there are deficiencies in preparing patients for the effects of some medical interventions and addressing expectations. Little and colleagues compared interviews with bone-marrow transplant recipients and their carers before, and during, the course of treatment. Participants were highly satisfied with the information provided prior to treatment but retrospectively all gave overwhelmingly negative appraisals. While the healthcare team provided excellent physical care, participants suggested there was

insufficient communication and information provision as well as support for coping with the various side effects of the transplant process.²¹⁷ A skilled practitioner will, through effective communication, minimise the information asymmetry that exists between practitioner and the patient. However, this epistemic distance will never be completely bridged and misunderstandings may still occur.

The expectations of patients and providers in relation to open disclosure can also be quite distinct.^{11, 13, 46, 98, 218} Events, actions and communication following harmful incidents reflect the differences. The challenge for policy makers, management, practitioners and support staff is to align their knowledge, practice and skills with the expectations of patients. However, this does not necessarily mean a wholesale reorganisation of practice. As the example in the paragraph above illustrates, and as discussed in the remainder of this chapter, the divergence can often be due to deficient communication creating improbable patient expectations. Sound communication from the beginning of an episode of care or the patient-provider relationship can help bridge this gap and ease the management of a harmful incident.

5.2.1 Defining harm

The consequence of the outcome was small. The significance for the patients or relatives or something may have been higher than that. So we've done those and we've certainly done an Open Disclosure on a [low harm incident]. Support personnel^[86(p28)]

Harm can be physical, but it can also cross into social and psychological domains.² It can be caused by a variety of factors directly related to an error or system failure, an unintentional use of a wrong plan, or a failure to carry out a planned action as intended.²³ A study of patient perspectives on adverse events in primary care reports that breakdowns in relationships with clinicians were more prominently cited as errors than 'technical errors in diagnosis and treatment'.²¹⁹ Patients highly value clinicians' communication skills and wish to understand the underlying thoughts and actions of those involved in a harmful incident, in addition to its technical (or 'system') aspects.^{11, 13} On the other hand, providers tend to focus on biomedical outcomes when identifying harm in preference to the aspects of care valued by their patients.^{51, 220, 221}

Patients feel aggrieved when they are not adequately informed of, and prepared for, all aspects of care and for manifested risks that were not discussed prior to treatment. Even if they are a recognised possibility, unexpected or unanticipated outcomes of an intervention, by their very nature, can distress patients and constitute harm.^{19(p40–41)} Equally, patients who feel that their dignity was not respected will seek an explanation and an apology. Research demonstrates that disrespectful and inconsiderate remarks are not only unhelpful but harmful.^{140, 219, 222–224} Psychological and emotional harm can be longer lasting and more difficult to reverse than physical harm, and may be especially relevant in paediatric settings.²⁰¹ This type of harm is, however, largely preventable through good communication and an empathic approach to care.

It follows that harm can be understood to include:

- misunderstandings, or unrealised expectations, connected to unforeseen side effects and complications of care
- deficiencies in the extra-clinical aspects of care.

Research indicates that the criteria for determining harm should be the patient's experience.²²⁵ The King Edward Memorial Hospital inquiry recommended that staff work collaboratively with patients in a way that does not diminish patients' subjective experiences.²⁷ Providers can be expected to explain perceived harm in such situations,^{11, 13, 46, 226} and are increasingly asked to do so. The Joint Commission's accreditation manual requires practitioners to 'clearly explain the outcome of any treatment or procedure to the patient and, when appropriate, the family, whenever those outcomes differ significantly from the anticipated outcomes.'²²⁷ The Health Quality Council of Alberta stipulates that enacting open disclosure and '[the] nature of the apology will depend on whether there was a deviation from the expected standard of care.'^{228(p10)}

Table 3 describes some potential responses to various types of harm (see Section 3.3.2).

The value of the patient experience

But there are some [adverse events] where we've done one Open Disclosure where, in fact, it didn't meet the criteria as an incident. Now that seems really odd. But it became evident over the progression of time that perhaps we should have called it an incident. Perhaps there were elements that started to come from the family that we weren't quite aware of and then we said in the first meeting, 'Okay, we need to go back and do some analysis on this and see what we can improve and we'll come back and see you again'. So you sort of have to be guided by the family's needs. Support personnel^{86(p28)}

Defining what constitutes reasonable patient expectations is important given the sensitivity of open disclosure. Integrating patient perspectives into defining harm and expected standards is critical.

Aside from the growing empirical support for this approach, a patient-centred healthcare service should value the patient experience in its own right,²⁰⁶ and thus allow that perspective into deciding what constitutes harm. If this is accepted as a logical position, any perceived deficiency in reasonable patient expectations should be acknowledged and explained, and an apology given.

Formal guidance on what constitutes 'reasonable' expectations is readily available via publications such as the *Australian Charter of Healthcare Rights* (endorsed by Australian health ministers in 2008) and material from institutions such as the World Health Organization 'Patients for Patient Safety' movement.^{229, 230}

Complaints: an underutilised tool

The definition and interpretation of harm plays a key role in incident detection, and the role of complaints in clinical incident detection and quality improvement is increasingly emphasised.²¹ Complaints are seen as mechanisms for detecting harmful incidents and their causes,³⁹ and a source of information that can be harnessed for quality and service improvement. In conjunction with involving patients as decision-makers in their care, there is growing consensus that:

- complaint processes should be linked to clinical incident detection and notification systems to ensure the open disclosure needs of consumers are met¹¹³
- complaints can capture quality and patient safety lapses missed by other incident reporting and notification mechanisms.^{130, 231}

5.2.2 Consent and open disclosure

In the majority of cases, consent is the first step in the episode of care that providers and patients address together. It involves the provision of information on the risks, benefits, side effects and possible outcomes of an intervention, enabling a patient to make the most informed choice possible²³² before consenting to the procedure.

Consent is outside the scope of the current Standard. Yet it is a critical component of clinical communication in modern medicine and its array of highly complex procedures and interventions, and it is emerging as a key aspect of open disclosure. In fact the two contain some similarities in that they:

- involve trust between patient and provider
- are contingent on communication
- are morally and legally supported
- involve elements of free, informed choice.²³³

The value and effectiveness of current consent processes has been questioned, as has the very notion of 'informed' consent,²³³ as illustrated in the study by Little and colleagues.²¹⁷ Gogos and colleagues recently analysed seven years of Victorian claims data, and found that perceived problems with informed consent feature prominently in negligence claims and conciliated complaints. Most occurred in the surgical setting, particularly around comprehensive explanation of risks, undisclosed complications and failures to discuss alternative treatment options. Allegations included 'situations in which patients felt rushed, pressured to proceed, or regarded the language used as incomprehensible.'^{234(p342)} Situations such as these, which appear to occur quite often, can lead to patients, families and carers feeling aggrieved at unanticipated (yet clinically possible) outcomes.

It is clear that the consent process has significance in the context of the Standard, particularly in:

- contributing to the foundation of the patient-provider relationship
- meeting needs and expectations
- deciding whether an incident warrants disclosure.

While the technical and legal aspects of consent fall outside of the scope of a revised Standard, its effect on patient perceptions of health care and, ultimately, judgements of whether harm has occurred are beyond question.

Legal nomination of support person

Following a harmful incident the patient can often be incapacitated, leading to confusion over which support person is authorised to make decisions on the patient's behalf, or to whom information can be released. The consent process can be critical in formally nominating a support person in case of a harmful incident, with regard to release of information and participation in post-incident management. It can also be the first point in the episode of care when risk can be discussed along with the role of open disclosure in relation to harmful incidents.

5.3 Actions following a harmful incident

I can look back and I'm proud that has changed. That wasn't good enough but now they've listened and you've got to think of how incredibly important it is to that family unit that that person has been given an opportunity to engage in that. Mother^{13(p7)}

There are two essential elements central to patient coping and reconciliation, and to service recovery following a harmful incident. One is understanding providers' intentions, decisions, statements and actions. The other is that the providers and the system learn from an incident (and as illustrated in the quote above). Patients want to understand the specific intentions and decision-making of providers during the clinical process,^{11, 13} and open disclosure should be viewed as the correct mechanism to achieve this. Understanding the clinical intervention and consequences is only part of the picture for the patient and their family or carer(s), especially if the incident was fatal.

What also matters for patients are the perceptions formed during open disclosure. Even if providers say all that is necessary, the patient may not understand, or may misinterpret the information if the non-verbal aspect of the communication is not congruent with or supportive of the message delivered. Patients strongly indicate the need to educate clinicians in effective communication skills, including showing consideration, empathy and active listening.⁹²

5.3.1 Out-of-pocket expenses

Patients appreciate sincerity and are wary of 'being managed'. Open disclosure should be accompanied by a pledge to patients for support in coping with the effects of harm, as well as steps taken to prevent recurrence. The literature advocates prompt initiation of service recovery and an offer of reimbursement for out-of-pocket expenses as a direct result of the harmful incident (for example meals, transport and child care).^{4, 22, 48, 155} This sends a strong signal of sincerity to the patient. According to Boothman, as cited by Conway and colleagues, 'not every patient wants compensation and not all compensation is financial, but the inability or unwillingness to offer it signals insincerity and suggests that apologies are really affectations or strategies, not an integrated step borne out of a commitment to honesty.'^{4(p22)}

Successful open disclosure resolutions described in the literature are most often combined with a prompt and fair offer of reimbursement and of service recovery for patients.^{74, 155, 187, 235, 236} Reimbursement can be made on an ex gratia basis which, by definition, does not recognise any liability or legal obligation. It is suggested that health services consider having protocols in place to manage this aspect of patient expectations consistent with local policies.

5.4 Implications for a revised national Standard

Current literature demonstrates strong and consistent patient expectations with regard to open disclosure and health care more broadly. The current Standard recognises patient expectations. The evidence suggests that patient experience and expectations should significantly inform health service and provider actions following harmful incidents.

Recommendation 3.1: The revised Standard should:

- recommend that patient perception of harm be considered when deciding whether open disclosure is necessary
- recommend a holistic approach to the assessment of harm and impact on a patient using the patient's experience of their care as well as biomedical factors.

The expectations of patients span a broad spectrum of qualities, and their perceptions are amenable and malleable through proficient clinical communication. The current Standard indicates that disclosure can be triggered by patient complaints sparked by a variety of factors, including unmet expectations of the treatment or care.

Recommendation 3.2: The revised Standard should recognise that:

- the needs and preferences of patients should be a principal driver of open disclosure policy and procedure
- patient and provider views and expectations may differ on what should be disclosed and how
- there is a need for modulated communication and a nuanced way in which information is exchanged.

Recommendation 3.3: The revised Standard should:

- recommend that the need for disclosure be triggered by a range of mechanisms including patient reports of their experience, and formal and informal complaints
- promote the involvement of patients, families and carers in incident investigation and quality improvement
- highlight the importance and effect of the consent process on incident management and on open disclosure.

Research has established a considerable disclosure gap in Australia and overseas, particularly with regard to a reluctance of providers to acknowledge patient views on whether harm has occurred.^{19(p40)}

Recommendation 3.4: The revised Standard should be supported by materials and resources to assist implementation, and address the gaps in the current Standard with regard to management of expectation throughout the entire episode of care.

References

2. WHO (World Health Organization). *The international classification for patient safety*. Geneva: WHO, 2009.
4. Conway J, Federico F, Stewart K, Campbell M. *Respectful management of serious clinical adverse events* (2nd ed.). Cambridge, MA: Institute for Healthcare Improvement, 2011.
10. Australian Council for Safety and Quality in Health Care. *Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care*. Canberra, 2003.
11. Iedema R, Allen S, Britton K, Piper D, Baker A, Gribich C, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The '100 patient stories' qualitative study. *British Medical Journal* 2011;343(d4423).

13. Iedema R, Allen S, Britton K, Gallagher TH. What do patients and relatives know about problems and failures in health care? *BMJ Quality and Safety* 2011;doi 10.1136/bmjqs-2011-000100
19. Piper D, Iedema R. *Literature review: Incident disclosure policy, legal reform and research since 2008*. Sydney: Centre for Health Communication (University of Technology Sydney) and ACSQHC (Australian Commission on Safety and Quality in Health Care), 2011
21. O'Connor E, Coates HM, Yardley IE, Wu AW. Disclosure of patient safety incidents: A comprehensive review. *International Journal on Quality in Health Care* 2010;22(5):371–379.
22. Gallagher TH. A 62-year-old woman with skin cancer who experienced wrong-site surgery. *Journal of the American Medical Association* 2009;302(6):669–677.
23. Runciman WB, Merry AF, Tito F. Error, blame, and the law in health care — an antipodean perspective. *Annals of Internal Medicine* 2003;138(12):974.
27. Douglas N, Robinson J, Fahy K. *Inquiry into obstetric and gynaecological services at King Edward Memorial Hospital 1990–2000*. Perth: Government of Western Australia, 2001.
39. Daniels JP, Hunc K, Cochrane D, Carr R, Shaw NT, Taylor A, et al. Identification by families of pediatric adverse events and near misses overlooked by health care providers. *Canadian Medical Association Journal* 2012; 184(1):29–34.
46. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *Journal of the American Medical Association* 2003;289(8):1001–1007.
48. Truog RD, Browning DM, Johnson JA, Gallagher TH. *Talking with patients and families about medical error: A guide for education and practice*. Baltimore: Johns Hopkins University Press, 2011.
51. Valentine N, Darby C, Bonsel GJ. Which aspects of non-clinical quality of care are most important? Result from WHO's general population surveys of 'health system responsiveness' in 41 countries. *Social Science and Medicine* 2008;66:1939–1950.
53. Kenagy JW, Berwick DM, Shore MF. Service quality in health care. *Journal of the American Medical Association* 1999;281:661–665.
55. ACSQHC (Australian Commission on Safety and Quality in Health Care). *Patient-centred care: Improving quality and safety through partnerships with patients and consumers*. Sydney: ACSQHC, 2011.
66. Braithwaite J, Skinner CA, Doerin ML. A values-based health system. *Medical Journal of Australia* 2011;194(5):259–262.
74. Kraman SS, Hamm G. Risk management: Extreme honesty may be the best policy. *Annals of Internal Medicine* 1999;131(12):963–967.
86. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. *Final report: Evaluation of the National Open Disclosure pilot program*. Sydney: The Australian Commission on Safety and Quality in Health Care (ACSQHC), 2008.
92. Wu A, Huang IC, Stokes S, Pronovost P. Disclosing medical errors to patients: It's not what you say, it's what they hear. *Journal of General Internal Medicine* 2009;24(9):1012–1017.
93. Hopgood C, Peck C, Gilbert B, Chappell K, Zou BI. Medical errors - what and when: What do patients want to know? *Academic Emergency Medicine* 2002;9:1156–1161.
98. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. The National Open Disclosure Pilot: Evaluation of a policy implementation initiative. *Medical Journal of Australia* 2008;188(2008):397–400.
113. Vincent CA, Young M, Phillips A. Why do people sue doctors? A study of patients and relatives taking legal action. *Lancet* 1994;343:1609–1613.
130. Weissman JS, Schneider EC, Weingart SN, Epstein AM, David-Kasdan J, Feibelman S, et al. Comparing patient-reported hospital adverse events with medical record review: Do patients know something that hospitals do not? *Annals of Internal Medicine* 2008;149(2):100–108.
135. Hojat M, Louis DZ, Marham FW. Physicians' empathy and clinical outcomes for diabetic patients. *Academic Medicine* 2011;86(3):359–364.

138. Young-Xu Y, Neily J, Mills PD, Carney BT, West P, Berger DH, et al. Association between implementation of a medical team training program and surgical morbidity. *Archives of Surgery* 2011;146(12):1368–1373.
139. Hull L, Arora S, Aggarwal R, Darzi A, Vincent C, Sevdalis N. The impact of nontechnical skills on technical performance in surgery: A systematic review. *Journal of the American College of Surgeons* 2012;214(2):214–230.
140. Ambady N, LaPlante D, Nguyen T, Rosenthal R, Chaumeton N, Levinson W. Surgeons' tone of voice: A clue to malpractice history. *Surgery* 2002;132(1):5–9.
146. Weingart S, Zhu J, Chiappetta L. Hospitalized patients' participation and its impact on quality of care and patient safety. *International Journal on Quality in Health Care* 2011;23(3):269–277.
147. Weingart SN, Pagovich O, Sands DZ, Li JM, Aronson MD, Davis RB, et al. What can hospitalized patients tell us about adverse events? *Journal of General Internal Medicine* 2005;20(9):830–836.
148. Peat M, Entwistle V, Hall J, et al. Scoping review and approach to appraisal of interventions intended to involve patients in patient safety. *Journal of Health Service Research and Policy* 2010;15(Suppl. 1):17–25.
155. McDonald TB, Helmchen LA, Smith KM. Responding to patient safety incidents: The 'seven pillars'. *Quality and Safety in Health Care* 2010;19:e11.
177. Street R, Makoul G, Arora N, Epstein RM. How does communication heal? Pathways linking clinician–patient communication to health outcomes. *Patient Education & Counseling* 2009;74:295–301.
187. Robson R, Pelletier E. Giving back the pen: Disclosure, apology and early compensation discussions after harm in the healthcare setting. *Healthcare Quarterly* 2008;11(Special Issue):85–90.
201. Rees C. Iatrogenic psychological harm. *Archives of Disease in Childhood* 2011. .doi:10.1136/archdischild-2011-300362
202. Boseley S and Campbell D. Negligence claims against GPs rising. *The Guardian*, 29 July 2011. (Accessed November 2011, at <http://www.guardian.co.uk/society/2011/jul/29/negligence-claims-gps-rising>)
203. Edgcumbe D. Patients' perceptions of hospital cleanliness are correlated with rates of methicillin resistant staphylococcus aureus bacteraemia. *Journal of Hospital Infection* 2009;71(1):99–101.
204. Isaac T, Zaslavsky AM, Cleary PD, Landon BE. The relationship between patients' perception of care and measures of hospital quality and safety. *Health Services Research* 2010;45(4):1024–1040.
205. Duckett S. Health care reform: Are we ready for the next big thing? *Medical Education* 2009;90(12):687–688.
206. Berwick D. *The moral test: Keynote presentation at the 23rd IHI annual national forum on quality improvement in health care*. Orlando, FL, December 2011.
207. Department of Health. *The operating framework for the NHS in England 2012/13*. Whitehall, London: National Health Service (NHS), 2011.
208. Australian Government. MyHospitals website. (Accessed November 2011, at <http://www.myhospitals.gov.au>)
209. Healthscope, 2011. MyHealthscope — accreditation, quality & safety: Measures of hospital performance. (Accessed 15 May 2012, at <http://www.healthscopehospitals.com.au/index.php/myhealthscope>)
210. Donabedian A. *Explorations in quality assessment and monitoring: The definition of quality and approaches to assessment*. Ann Arbor, MI: Health Administration Press, 1980.
211. Mooney G. Beyond health outcomes: The benefits of health care. *Health Care Analysis* 1998;6(2):99–105.
212. Campbell SM, Roland MO, Buetow SA. Defining quality of care. *Social Science and Medicine* 2000;51:1611–1625.

213. Hojat M. Ten approaches for enhancing empathy in health and human services culture. *Journal of Health and Human Services Administration* 2009;31:412–450.
214. Taylor BB, Marcantonio ER, Pagovich O, Carbo A, Bergmann M, Davis RB. Do medical inpatients who report poor service quality experience more adverse events and medical errors? *Medical Care* 2008;46(2):224–8.
215. Larson CO, Nelson EC, Gustafson D, Batalden P. The relationship between meeting patients' information needs and their satisfaction with hospital care and general health status outcomes. *International Journal for Quality in Health Care* 1996;8(5):447–456.
216. Greaves F, Pape UJ, King D, Darzi A, Majeed A, Wachter RM, et al. Associations between web-based patient ratings and objective measures of hospital quality. *Archives of Internal Medicine* 2012;172(5):435–436.
217. Little M, Jordens CFC, McGrath C, Montgomery K, Lipworth W, Kerridge I. Informed consent and medical ordeal: A qualitative study. *Internal Medicine Journal* 2008;38:624–8.
218. Iedema R, Sorensen R, Manias E, Tuckett A, Piper D, Mallock N, et al. Patients' and family members' experiences of open disclosure following adverse events. *International Journal for Quality in Health Care* 2008;20(6):421–432.
219. Kuzel AJ, Woolf SH, Gilchrist VJ, Engel JD, LaVeist TA, Vincent C, et al. Patient reports of preventable problems and harms in primary health care. *Annals of Family Medicine* 2004;2(4):333–340.
220. Walshe K, Shortell S. When things go wrong: How health care organizations deal with major failures. *Health Affairs* 2004;23(23):109–118.
221. Mooney G. *Challenging health economics*. New York: Oxford University Press, 2009.
222. Entwistle VA. Hurtful comments are harmful comments: Respectful communication is not just an optional extra in health care. *Health Expectations* 2008;11:319–320.
223. Huyard C. What, if anything, is specific about having a rare disorder? Patients' judgements on being ill and being rare. *Health Expectations* 2009;12:361–370.
224. Phillips, Y. Fetus mum sues hospital. *The Sunday Times*, 21 August 2011.
225. Cantor MD, Barach P, Derse A, Maklan CW, Wlody GS, Fox E. Disclosing adverse events to patients. *Joint Commission Journal on Quality and Safety* 2005;31(1):5–12.
226. Burroughs T, Waterman A, Gallagher TH. Patients' concerns about medical errors during hospitalization. *Joint Commission Journal on Quality and Patient Safety* 2007;33:5–14.
227. Joint Commission. *Comprehensive accreditation manual: The official handbook*. Oakbrook Terrace, IL: Joint Commission, 2011.
228. Health Quality Council of Alberta. *Disclosure of harm to patients and families: Provincial framework*. Calgary, AB: Health Quality Council of Alberta, 2006.
229. ACSQHC (Australian Commission on Safety and Quality in Health Care). *Australian charter for health care rights*. Sydney: ACSQHC, 2008.
230. Newell SM, Jones DA, Hatlie MJ. Partnership with patients to improve patient safety. *Medical Journal of Australia* 2009;92(2):63–64.
231. Cunningham W, Wilson H. Complaints shame and defensive medicine. *BMJ Quality and Safety* 2011;Doi 10.1136/bmjqs.2011.051722.
232. Berg JW, Appelbaum PS, Lidz CW, Parker LS. *Informed consent: Legal theory and clinical practice* (2nd ed). New York, NY: Oxford University Press, 2001.
233. Cassell EJ, Leon AC, Kaufmann SG. Preliminary evidence of impaired thinking in sick patients. *Annals of Internal Medicine* 2001;134(12):1120–23.
234. Gogos AJ, Clark RB, Bismark MM, Gruen RL, Studdert DM. When informed consent goes poorly: A descriptive study of medical negligence claims and patient complaints. *Medical Journal of Australia* 2011;195:340–344.

235. Kachalia L, Kaufman S, Boothman R. Liability claims and costs before and after implementation of a medical error disclosure program. *Annals of Internal Medicine* 2010;153:213–221.
236. Mello MM, Gallagher TH. Malpractice reform — opportunities for leadership by health care institutions and liability insurers. *New England Journal of Medicine* 2010;362:1353–56.



Supporting healthcare professionals

Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology, expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

6 Supporting healthcare professionals

To start with when it first occurred they both wanted to resign and leave and never nurse again, and they're now still working so I think it certainly helped them as well [...] the error occurred because of a practice that was happening in that it wasn't a standard that we would have accepted and they've actually been the change agents in changing that practice in that facility. So they not only benefited from it, they learned from it and they're now teaching others. Support personnel^{86(p117)}

Principle 5: Staff support

Healthcare organisations should create an environment in which all staff are able and encouraged to recognise and report adverse events and are supported through the open disclosure process.¹⁰

Healthcare professionals are profoundly affected by being involved in harmful incidents, and are sometimes referred to as the 'second victim'.¹¹⁷ As such, these clinicians require support to:

- report clinical incidents
- prepare for, and engage in, open disclosure with confidence and security
- manage the personal effect of open disclosure processes and the aftermath of adverse events.

There is confusion about what clinicians consider to be appropriate action and dialogue following patient harm. They feel uneasy and under-skilled to participate confidently in open disclosure, which is 'seen to harbour uncertainties, including what should trigger a formal response, the unknown impact on individuals' and the organisation's reputation, unclear legal and insurance implications, and unreliable support by colleagues for those carrying out open disclosure'.^{98(p398)} Iedema and colleagues describe the difficult position health professionals find themselves in following an incident thus:

[C]linicians find themselves wedged precariously in between the limits dictated by their lawyers, the prescriptions of their insurance contracts, the policies put out by health departments and healthcare organisations, colleagues' disapproval of disclosure, and patients' and family members' anger, guilt, and despair.^{85(p151)}

There is confusion, lack of knowledge and uncertainty about the medico-legal aspects of open disclosure. Indeed, Studdert and colleagues' survey of Australian healthcare professionals found that these issues are cited as major to moderate barriers to enacting open disclosure. However, it is possible that 'what really chills their [clinicians'] interest is a complicated mix of factors, including reputational concerns and fundamental human instincts to avoid conflict'.^{100(p354)}

Healthcare professionals who are involved in adverse events require assistance and support to cope with the emotional effects of their experience. The support should include

participation in the open disclosure process and, where possible, an opportunity to apologise to patients if appropriate.²³⁷

More broadly, what is required is an institutional climate where openness and responsiveness are supported. A psychologically safe environment is a prerequisite for good incident reporting, management and disclosure.^{21, 142} In modern medicine, harmful incidents are statistically inevitable during the course of a clinical career.⁴³ Practitioners require support to accept adverse events as a reality, to report and investigate them openly, and to confidently navigate the consequences.²³⁸

Effective support for open disclosure spans all dimensions of a healthcare organisation's functioning. The open disclosure process works best for healthcare staff when:⁹⁸

- it is planned, conducted and closely supported and monitored by staff who have been trained and are experienced in carrying out open disclosure
- it is coordinated and supported by staff with specialised administrative and managerial appointments (e.g. patient safety officer, clinical governance director or equivalents)
- senior clinical (particularly senior medical) staff participate
- it is conducted in circumstances where clinicians involved in the adverse event have already established a good relationship and understanding with the patient (and family)
- it is a sub-component of an established clinical governance system
- it encompasses careful pre-planning, responsive disclosure, adequate follow-up and internal as well as independent counselling support
- it is structured to include consideration of paying for patient and/or family member out-of-pocket expenses.

6.1 Support following an incident

You're opening all sorts of emotional cans of worms, and I think that if it's not done carefully and sensitively by people who have a bit of an idea of what they're doing, you can do quite a lot of damage emotionally to the clinicians involved and family members. You're dealing with some pretty raw emotions and you can do a lot of damage if you don't know what you're doing. Certainly you get your buttons pushed, [and] you're going to push them right back.

Medical manager¹⁴

The importance of providing care to healthcare professionals following adverse events and during open disclosure processes is evidenced in the literature. Numerous studies detail powerful emotions experienced by healthcare professionals following adverse events. These responses can diminish quality of life, and can manifest as sleeplessness, depression and anxiety.^{21, 46, 239} Apart from the personal effect, clinicians face burnout, an increased likelihood of leaving the profession, impairment of clinical decision-making that may endanger patients, and a predisposition to practise potentially inefficient or ineffective 'defensive medicine'.²³¹ All of these can, of course, adversely affect the efficiency and the quality of care.²³⁷

While the current Standard addresses these matters, in practice there is inconsistent institutional support for clinicians to 'do the right thing' following harmful incidents.^{12, 22, 45, 46, 88} In terms of enabling systematic implementation of open disclosure, the focus must be firmly on system enablers.²⁴⁰

6.1.1 Institutional concerns

I'm floored by the fact that these [clinicians] deal with these [incidents] every day and yet behave this way. I cannot get my head around that. I believe that patient care is all about people, regardless of their journey. Daughter of a patient who died¹⁴

Healthcare professionals report a lack of knowledge, clarity and guidance around which events should be disclosed. Studies repeatedly describe situations where disclosure is withheld for reasons including:^{90, 122, 124}

- clinicians feeling that the event was trivial
- patients being unaware that an event occurred
- clinicians believing that the patient would not understand the explanation
- clinicians deciding that the patient would not want to know.

There is also evidence of a lack of confidence and knowledge about how to approach this difficult and uncomfortable subject. Healthcare professionals should be equipped to make appropriate decisions in difficult situations, and this must include open and honest collaboration with their colleagues. The teamwork championed by the professions within their own professional groups should be applied across the whole healthcare team.⁵⁹

These limitations do not indicate that clinicians are immoral or do not have their patients' best interests at heart, and it should again be stressed that open disclosure is supported almost universally among individual healthcare professionals as the right thing to do.^{12, 45, 46, 98, 119–127} The lack of guidance and knowledge among staff is more likely to be the result of insufficient support, or the culture within the organisation where they work or were trained. It highlights cultural problems both at the organisational and professional practice level.

Section 5 of the current Standard lists the responsibilities of organisations to support their staff. However, research indicates that harmful incidents are more often not disclosed than disclosed to patients. When open disclosure does take place, it most often fails to meet the expectations of patients.^{11, 21, 22, 46, 48, 50} A range of institutional and cultural barriers to disclosure uptake are said to exist.^{12, 122, 225, 241, 20(p16–19)} The current Standard acknowledges this by advocating for a 'safety culture' as a platform upon which open disclosure practice can be built. While there are examples of successful safety cultures, there is little evidence suggesting that safety cultures generally, and open disclosure specifically, have been systematically embedded throughout Australian health care. A similar situation is described in other countries.^{65, 67, 241–246}

6.1.2 Healthcare culture and open disclosure

Culture can be defined as a reflection of values, norms and unwritten code of conduct within an organisation. Values are principles or qualities that are inherently desirable.²⁴⁷ In this regard, the aspirations of the current Standard align with current thinking and evidence around safety and quality in health care. The Standard encourages the development of an environment that is conducive to openness and transparency. However, there are widely held concerns that while individual practitioners support open disclosure, the broader culture within healthcare organisations and professions is not conducive to meeting patient expectations in this regard.^{21, 220, 244, 246, 248, 249}

Walshe and Shortell believe that the most important barrier to open disclosure is 'the endemic culture of secrecy and protectionism in healthcare facilities in every country.'^{220(p107)} These authors, and others, postulate that administrators often operate defensively to protect the institution rather than its patients. There is also the real or perceived need to cover up to ensure career advancement and preservation of authority.^{220, 250, 251}

Garbutt and colleagues describe 'a deeply-rooted culture that expects error-free practice, emphasises individual accountability, and tends to blame the individual when he or she fails to perform perfectly.'^{124(p183)} The authors suggest that re-framing errors as 'opportunities' is crucial to the design of better systems of care. The 'culture of infallibility' and the 'perfectibility' model where healthcare professionals are socialised from the beginning of their education to strive for error-free practice has been criticised for some time and continues to draw attention in the literature.^{31, 133, 252, 253} This model sets professionals up to fail precisely by attempting to set them up never to fail²⁵⁴ and risks producing 'hardened' providers who are out of tune with their patients' needs and expectations.

Detachment

There is a tendency to emotional detachment, neutrality and affective distance in providers and not to the softer aspects of care which are valued by patients. Hafferty describes this detachment as 'socialised amnesia.'²⁵⁵ Kronman and colleagues recently found links between organisational culture and open disclosure (and apology) by junior physicians.⁴⁴ Conducting focus groups with 204 healthcare workers, Fein and colleagues observed that 'clinicians and administrators describe a complex view of disclosure that incorporates the competing interests of self-preservation and duty to the patient and institution.'²⁵⁶

These are major barriers as they are fundamentally at odds with the principles and values of open disclosure and safety and quality more broadly. This is illustrated by commentary on a recent Australian study which found that complaints clustered around certain individuals, and that overseas-trained practitioners received fewer complaints than their locally trained counterparts.²⁵⁷ John Buntine, President of the Australian Association of Surgeons, commented that 'a common stimulus to make a complaint [...] is a perception that the doctor was overconfident, perhaps to the point of arrogance, and had little personal interest in the patient's welfare' and that 'the supreme confidence of some highly experienced Australian-trained doctors may go against them when something goes wrong'. He adds 'good manners, kindness, demonstration of personal interest and concern, and a degree of humility all discourage complaints!'^{258(p325)}

This view is repeatedly reinforced by patient commentary in open disclosure research. For example:

It was when we had the next appointment with the oncologist and we raised the [incident] then and they, well he played it down and washed over it and didn't really admit to anything or think it was a problem. Husband of a woman who died¹⁴

Shame

A related impediment to open disclosure is 'self-protection' from the psychological effects of causing harm to patients. Cunningham and Wilson couch the clinician response to error in the context of shame. They propose that a provider's personal self-image is closely linked to their professional identity. As such, any mistake or failure of judgement can be perceived or misconstrued as a personal failure. Clinical practice can 'quite readily induce a shame response, with its potentially damaging outcomes.'²³¹ Similarly, Banja argues that a

harmful incident is perceived by the provider as an assault on their competency, triggering various protective, defensive psychological responses that lead to avoidance of open communication.²⁵³ If this is true, it should concern patients and policy makers alike and raise questions on how providers are developed and socialised.

Heroic individualism, and viewing errors as a personal and moral failing, is a vestige of solo practice, which was previously the dominant model of medical care. It is now largely considered to be a hindrance to attempts to improve patient safety.^{48, 56, 57, 206, 259–261} A culture conducive to achieving maximum healthcare quality will include:

- patient-centredness
- openness and transparency
- strong leadership from executive and senior clinicians
- team-based approaches to health care that include the patient
- reduction of silos, power differentials and hierarchies
- a commitment to harnessing error for learning and improvement.

The current Standard acknowledges the importance of culture in implementing open disclosure as part of wider safety and quality activity. However, there is not much evidence of universal implementation, or of systemic safety culture improvement in Australian health care. The next section suggests harnessing open disclosure and education as a vehicle to encourage a cultural transformation.

6.2 Development through education and training

I think [open disclosure] makes for a healthier organisation. Medical manager^{86(p18)}

The way open disclosure is approached and managed at a clinical level has evolved considerably. This includes a heightened sensitivity to how incidents are identified, including an increasing role for complaints processes and ‘regular rounding’ by specialist quality and safety staff. There has also emerged a more nuanced approach to how each incident is managed and disclosed ensuring all parties are protected.^{11, 14, 48, 98}

Healthcare professionals want to engage in open dialogue with patients and families following harmful incidents, but lack the skills and knowledge to do so confidently and without hesitation. Evidence indicates that providers require training and education, particularly in the communication skills necessary for open disclosure which require a high degree of listening skills, empathy and patience. This furnishes staff with the ability to confidently approach and carry out open disclosure and is likely to generate additional benefits. For example, health professional open disclosure training and education can drive the cultural transformation needed for disclosure to flourish (see Section 6.2.2).

6.2.1 Preparing providers for open disclosure

Australian healthcare facilities where open disclosure has been implemented successfully are modulating their approach to open disclosure. A two-step approach is advocated. First, all staff are provided with an introduction to open disclosure. Second, a core group is trained as experts who can guide other colleagues. Their training includes simulation, role-playing and facilitated discussions. This cadre of experts can be called upon to assist, mediate and

facilitate actual open disclosure dialogue. In addition, junior staff who need to participate in an open disclosure process are provided with 'just in time' training either by these experts or external contractors.^{14, 193}

Introductory training should ideally:

- cover all staff
- occur at regular intervals
- be part of official staff induction
- stress the significance of the process (in addition to the outcome) to patients, families and carers
- emphasise the communication skills necessary to conduct open disclosure successfully
- test participants for knowledge.

The core inter-professional group of open disclosure 'specialists' can counsel other staff when required or step in to perform open disclosure and are also responsible for linking open disclosure to quality improvement and clinical risk management. Training of this group should:

- utilise simulation and role-playing (where possible)
- include facilitated discussion of the simulation to maximise learning
- include feedback on performance
- occur regularly to ensure staff maintain proficiency.

The use of video feedback as a tool to stimulate reflection and learning has been trialled with clinicians. The technique has proved useful for activities such as clinical handover and could offer value in open disclosure, especially if combined with patient accounts of their experiences.¹⁹² Echoing Donabedian,²⁶² the Australian experience is that open disclosure training and development is more effective in influencing practice when combined with complementing structures of governance, policies and formal processes.

6.2.2 Additional value of open disclosure development

Disclosure policy has [...] at its heart transforming a system anchored in traditional, hierarchical, taken-for-granted professional values and practices into one that values explicit accountability to patients.^{153(p155)}

It is recognised that true cultural transformation cannot be achieved solely by a top-down process, but must be accompanied by a bottom-up approach requiring effective communication across the organisation.²⁶³ Communication is the bedrock of clinical practice and of organisational functioning and effectiveness. Poor communication is one of the root causes of patient harm, as well as an underlying factor in organisational failure.²⁶⁴

Sorensen and colleagues suggest that implementing open disclosure can serve as a useful tool to help to achieve an important transformation by reframing provider perspectives on outcomes in health care, remobilising their attitudes towards their patients (and colleagues), reorienting professional practice, and redesigning support systems to reflect the values espoused by, and necessary for, good practice.¹⁵³ Achieving what amounts to a significant cultural transformation would be difficult without the education of providers in the relational

aspects of open disclosure and its required communication skills. In addition, the process may exert a subtle but valuable 'ethicising impact'¹⁶⁰ on the workforce.²⁶⁵

System versus individual actions

A commonly identified difficulty when building an improvement culture is a disbelief in the ability of individual actions to influence 'the system'. Iedema and colleagues explored the links between open disclosure training and systems improvement, drawing on a facilitated simulation of an open disclosure dialogue (using a hypothetical missed diagnosis of cancer). The risks of a systems approach to error are highlighted, in particular the potential of individual practitioners to divorce their actions and role from the complex 'ecology of practices in which they are entwined'.^{85(p271)} In other words, while it is true that medical error is predominantly due to a confluence of interlinked events that result in breakdown of a complex system,²⁶⁶ what is often overlooked is that individual actions can:

- serve as environments for other members of that system
- reconfigure an activity within its broader operational context.¹⁶⁰

The authors contend that the process of acquiring the requisite skills for open disclosure can address this detachment, and enable the appreciation that one's actions and the 'system' are not separate. This engages all members of the healthcare team in a broader quality improvement ethic. Simulation and role-playing are, again, useful methods for upskilling healthcare professionals in communication, empathy and compassion.²⁶⁷ These attributes are necessary to engage in the open disclosure process on terms that are important to patients, families and carers. They can foster other positive benefits in addition to a 'connectedness to the broader dimensions of what might previously have appeared to them as 'the (unchangeable) system'.^{160(p274)}

The organisational environment

The importance of the ethical environment on employee behaviour is documented in organisational theory research.²⁶⁸ Organisations in which the prevailing moral codes align with those of its staff are more stable and harmonious.^{269, 270} The superiority of values-based over regulatory ethical environments in terms of employee loyalty, trust and commitment has been demonstrated. This is especially so in health services, due to the inherently moral nature of health care, which can potentially benefit from a 'positive ethical climate'.^{270, 271} This is then reflected in outcomes such as improved productivity, efficiency and profitability.^{263, 268}

Investing in open disclosure training and development may foster such an atmosphere. It could serve as a strong signal of the moral and ethical orientation of the organisation, and the value it places on honesty, transparency, integrity and patient-centeredness. There is little evidence to indicate that healthcare professionals would oppose such a set of values, or that these signals would fuel disharmony. In fact, the opposite is suggested: that open disclosure development and education helps foster a values-based ethical environment and can result in staff being more satisfied and committed to their organisation.²⁷² In addition, the aspects of open disclosure training and preparation involving dialogue can also equip frontline clinical staff to deal with the trauma of a serious adverse event on a personal and collective level.²⁷³

Open disclosure development and education may emerge as a useful quality improvement tool and staff support mechanism in its own right.

Healthcare professional education at undergraduate level

Responsibility for supporting and equipping healthcare professionals with the requisite skills to communicate with patients in trying circumstances also rests with teaching institutions. There is increasing commentary and research focusing on integrating disclosure into medical curricula.^{154, 274–276} Current evidence advocates for teaching institutions to embrace contemporary thinking related to safety and quality in health care. This includes consideration of human factors, team work and the possibility of healthcare-associated harm incidents in order to prepare graduates for difficult interpersonal situations they will encounter.^{48, 277}

There are additional benefits for graduates and health services. The ‘hardening’ effects of medical training have been examined, with evidence indicating that graduates display reduced levels of empathy and ‘soft skills’.^{134, 278} The benefits of open disclosure skills and experience are likely to be felt in the graduate’s clinical repertoire in the way they interact with patients, families, colleagues, and members of the clinical microsystem and beyond. There is also research showing that these ‘soft skills’ can enhance both the patient–provider and inter-professional relationship, with positive effects on clinical outcomes.^{135, 138, 139, 176} Some of the ways in which undergraduates can develop, enhance or maintain these skills (such as by improving their interpersonal ability, analysis of video recordings of their own performance, role-playing and improving narrative skills)²¹³ mirror open disclosure training for qualified practitioners. The capabilities required for open disclosure can be put to use in a wide range of clinical scenarios, and can contribute towards shaping more rounded clinicians.

While undergraduate training and education are technically outside the scope of a national Standard, they are nevertheless important aspects of open disclosure sustainability and health care more broadly. There is perhaps also scope to explore the basis on which medical students are selected with a view to producing healthcare providers with interpersonal as well as technical skills, and humanitarian attributes.

6.3 Implications for a revised national Standard

With regard to staff support, the current Standard has the necessary components identified as essential in the literature. Healthcare professionals consider open disclosure an ethical and professional duty, and are deeply affected by incidents, often with far-reaching and devastating consequences. However, providers do not feel comfortable and supported in engaging with patients, families and carers following a harmful incident. Insufficient ‘care to the caregiver’ is a major barrier to implementation and must be an institutional priority within the context of organisational support and culture.²⁷⁹

Recommendation 4.1: The revised Standard should encourage healthcare organisations to institute current ‘best practice’ approach, including the requirement and description of a formal staff support process following a harmful incident and during the open disclosure process.

The intent and aspirations of the current Standard in terms of staff support align with latest evidence. There are, however, documented shortfalls in terms of their implementation.

Recommendation 4.2: The revised Standard should be complemented by a suite of implementation resources in a variety of formats.

The current Standard, while directing that a culture supportive of incident disclosure and investigation be cultivated does not clearly outline the ways in which this can be achieved.

Recommendation 4.3: The revised Standard should strongly advocate for open disclosure training and education of healthcare professionals as an integral part of progressing and embedding cultural change, with the aim of:

- encouraging open acknowledgment of harmful incidents as
 - an existent aspect of modern health care
 - a potential driver of quality improvement and systems learning
- making explicit the organisational values conducive to supporting staff and patients following harmful incidents
- encouraging senior staff to act as role models and mentors for less experienced staff
- viewing incidents as learning opportunities
- recognising the clinical and corporate risk management and quality improvement dimensions of communicating with patients in an empathic manner
- optimising the processes for managing harmful incidents.

The skills necessary for communicating in open disclosure are acquired, or honed, by training, education and practice. Experience in Australia and overseas suggests a modulated approach consisting of general introductory and specialised, targeted training as most effective. It can also assist the wider organisational development of a safety culture.

References

10. Australian Council for Safety and Quality in Health Care. *Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care*. Canberra, 2003.
11. Iedema R, Allen S, Britton K, Piper D, Baker A, Gribich C, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The '100 patient stories' qualitative study. *British Medical Journal* 2011;343(d4423).
12. Iedema R, Allen S, Sorensen R, Gallagher TH. What prevents incident disclosure, and what can be done to promote it? *Joint Commission Journal on Quality and Patient Safety* 2011;37(9):409–417.
14. ACSQHC (Australian Commission on Safety and Quality in Health Care). *Independent research into patient and provider views and experiences with open disclosure*. Sydney: University of Technology, 2011.
20. Allan A, Munro B. *Open disclosure: A review of the literature*. Perth: Edith Cowan University, 2008.
21. O'Connor E, Coates HM, Yardley IE, Wu AW. Disclosure of patient safety incidents: A comprehensive review. *International Journal on Quality in Health Care* 2010;22(5):371–379.
22. Gallagher TH. A 62-year-old woman with skin cancer who experienced wrong-site surgery. *Journal of the American Medical Association* 2009;302(6):669–677.
31. Leape LL. Error in medicine. *Journal of the American Medical Association* 1994;272(23):1851–1857.

43. Merry AF, Peck DJ. Anaesthetists, errors in drug administration and the law. *NZ Medical Journal* 1995;108(185–187).
44. Kronman AC, Paasche-Orlow M, Orlander JD. Factors associated with disclosure of medical errors by housestaff. *BMJ Quality and Safety* 2011;doi:10.1136/bmjqs-2011-000084.
45. Gallagher T, Waterman A, Garbutt J, Kapp J, Chan D, Dunagan W, et al. US and Canadian physicians' attitudes and experiences regarding disclosing errors to patients. *Archives of Internal Medicine* 2006;166(15):1605–1611.
46. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *Journal of the American Medical Association* 2003;289(8):1001–1007.
48. Truog RD, Browning DM, Johnson JA, Gallagher TH. *Talking with patients and families about medical error: A guide for education and practice*. Baltimore: Johns Hopkins University Press, 2011.
50. Iezzoni LI, Rao SR, DesRoches CM, Vogeli C, Campbell EG. Survey shows that at least some physicians are not always open or honest with patients. *Health Affairs* 2012;31(2):383–391.
56. Bodenheimer T. Coordinating care — a perilous journey through the health care system. *New England Journal of Medicine* 2008;358(10):1064–1071.
57. Haggerty JL, Reid RJ, Freeman GK, Starfield BH, Adair CE, McKendry R. Continuity of care: A multidisciplinary review. *British Medical Journal* 2003;327(7425):1219–1221.
59. Gawande A. *The checklist manifesto: How to get things right*. New York: Metropolitan Books, 2010.
65. Pronovost P. Navigating adaptive challenges in quality improvement. *BMJ Quality and Safety* 2011;20(7):560–563.
67. Cannon J, Berwick DM. A new frontier in patient safety. *Journal of the American Medical Association* 2011;305(21):2221–2.
85. Iedema R, Jorm C, Wakefield J, Ryan C, Sorensen R. A new structure of attention? Open disclosure of adverse events to patients and families. *Journal of Language & Social Psychology* 2009;28(2):139–157.
86. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. *Final report: Evaluation of the National Open Disclosure pilot program*. Sydney: Australian Commission on Safety and Quality in Health Care (ACSQHC), 2008.
88. Gallagher TH. *Disclosing harmful errors to patients: Recent developments and future directions*. Open Disclosure Seminar. Sydney: University of Technology Sydney, 2009.
90. Gallagher TH, Garbutt JM, Waterman AD, Flum DR, Larson EB, Waterman BM, et al. Choosing your words carefully: How physicians would disclose harmful medical errors to patients. *Archives of Internal Medicine* 2006;166(August 14–28):1585–1593.
98. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. The National Open Disclosure Pilot: Evaluation of a policy implementation initiative. *Medical Journal of Australia* 2008;188(2008):397–400.
100. Studdert D, Piper D, Iedema R. Legal aspects of open disclosure II: Attitudes of health professionals — findings from a national survey. *Medical Journal of Australia* 2010;193(6):351–355.
117. Wu AW. Medical error: The second victim. *British Medical Journal* 2000;320(7237):726–727.
119. Finkelstein D, Wu AW, Holtzman N, et al. When a physician harms a patient by medical error: Ethical, legal, and risk-management considerations. *Journal of Clinical Ethics* 1997;8:330–335.
120. Sweet MP, Bernat JL. A study of the ethical duty of physicians to disclose errors. *Journal of Clinical Ethics* 1997;8(4):341–318.
121. Hingorani M, Wong T, Vafidis G. Patients' and doctors' attitudes to amount of information given after unintended injury during treatment: Cross sectional, questionnaire survey. *British Medical Journal* 1999;318(7184):640–641.

122. Kaldjian LC, Jones EW, Rosenthal GE. Facilitating and impeding factors for physicians' error disclosure: A structured literature review. *Journal on Quality and Patient Safety* 2006;32(4):188–198.
123. Engel KG, Rosenthal M, Sutcliffe KM. Residents' responses to medical error: Coping learning and change. *Academic Medicine* 2006;81:86–93.
124. Garbutt J, Brownstein DR, Klein EJ. Reporting and disclosing medical errors: Paediatricians' attitudes and behaviors. *Archives of Paediatric Adolescent Medicine* 2007;161:179–185.
125. Kaldjian LC, Jones EW, WU BJ, et al. Disclosing medical errors to patients: Attitudes and practices of physicians and trainees. *Journal of General Internal Medicine* 2007;22:988–996.
126. White AA, Gallagher TH, Krauss MJ, Garbutt J, Waterman AD, Dunagan WC, et al. The attitudes and experiences of trainees regarding disclosing medical errors to patients. *Academic Medicine : Journal of the Association of American Medical Colleges* 2008;83(3):250–256.
127. Evans SB, Yu JB, Chagpar A. How radiation oncologists would disclose errors: Results of a survey of radiation oncologists and trainees. *International Journal of Radiation Oncology Biology Physics* 2012.
133. Rabow MW, Remen RN, Parmelee DX, Inui TS. Professional formation: Extending medicine's lineage of service into the next century. *Academic Medicine* 2010;85(2):310–317.
134. Hojat M, Vergare MJ, Maxwell K. The devil is in the third year: A longitudinal study of erosion of empathy in medical school. *Academic Medicine* 2009; 84(9):1182–1191.
135. Hojat M, Louis DZ, Marham FW. Physicians' empathy and clinical outcomes for diabetic patients. *Academic Medicine* 2011;86(3):359–364.
138. Young-Xu Y, Neily J, Mills PD, Carney BT, West P, Berger DH, et al. Association between implementation of a medical team training program and surgical morbidity. *Archives of Surgery* 2011;146(12):1368–1373.
139. Hull L, Arora S, Aggarwal R, Darzi A, Vincent C, Sevdalis N. The impact of nontechnical skills on technical performance in surgery: A systematic review. *Journal of the American College of Surgeons* 2012;214(2):214–230.
142. Shannon SE, Foglia MB, Hardy M, Gallagher TH. Disclosing errors to patients: Perspectives of registered nurses. *Joint Commission Journal on Quality and Patient Safety* 2009;35(1):5–12.
153. Sorensen R, Iedema R, Piper D, Manias E, Williams A, Tuckett A. Disclosing medical error to patients: Can practice inform policy? *Health Expectations* 2009;13:148–159.
154. Weiss PM, Koch S, Lara-Torre E, Scarrow PK. To air the error: Lowering the barriers to successful disclosure conversations. *The Female Patient* 2011;36:17–21.
160. Iedema R, Jorm C, Wakefield J, Ryan C, Dunn S. Practising open disclosure: Clinical incident communication and systems improvement. *Sociology of Health & Illness* 2009;31(2):262–277.
176. Riess H. Empathy in medicine — a neurobiological perspective. *Journal of the American Medical Association* 2010;304(14):1604–1605.
192. Iedema R. Creating safety by strengthening clinicians' capacity for reflexivity. *BMJ Quality and Safety* 2011;20(Suppl 1):i83–i6.
193. Liebman CB, Hyman CS. A mediation skills model to manage disclosure of errors and adverse events to patients. *Health Affairs* 2004;23(4):22–32.
206. Berwick D. *The moral test: Keynote presentation at the 23rd IHI annual national forum on quality improvement in health care*. Orlando, FL, December 2011.
213. Hojat M. Ten approaches for enhancing empathy in health and human services culture. *Journal of Health and Human Services Administration* 2009;31:412–450.
220. Walshe K, Shortell S. When things go wrong: How health care organizations deal with major failures. *Health Affairs* 2004;23(23):109–118.
225. Cantor MD, Barach P, Derse A, Maklan CW, Wlody GS, Fox E. Disclosing adverse events to patients. *Joint Commission Journal on Quality and Safety* 2005;31(1):5–12.

231. Cunningham W, Wilson H. Complaints shame and defensive medicine. *BMJ Quality and Safety* 2011;Doi 10.1136/bmjqs.2011.051722.
237. Schwappach DLB, Boluarte TA. The emotional impact of medical error involvement on physicians: A call for leadership and organisational accountability. *Swiss Medical Weekly* 2008;October 14.
238. Wu AW, Steckelberg RC. Medical error, incident investigation and the second victim: Doing better but feeling worse? *BMJ Quality and Safety* 2012.
239. Nash L, Daly M, Johnson M. Psychological morbidity in Australian doctors who have and have not experienced a medico-legal matter: Cross-sectional survey. *Australia and New Zealand Journal of Psychiatry* 2007;41(11):917–925.
240. Terry J, Wu A, Conway J. The second victim. 2011. GE Healthcare. (Accessed November 2011, at <http://nextlevel.gehealthcare.com/videos/webcasts/the-second-victim.php>)
241. Ghalandarpoorattar SM, Kaviani A, Asghari F. Medical error disclosure: The gap between attitude and practice. *Postgraduate Medical Journal* 2012;88(1037):130–133.
242. Appleby J, Raleigh V, Frosini F, Bevan G, Gao H, Lyscom T. *Variations in health care: The good, the bad and the inexplicable*. London: The King's Fund, 2011.
243. Runciman WB. Is money spent on quality improvement better spent on clinical care? — no. *Medical Journal of Australia* 2011;194(12):641.
244. Leape LL, Berwick DM. Five years after to err is human: What have we learned? *Journal of the American Medical Association* 2005;293(2005):2384–2390.
245. Mclennan S, Beitat K, Lauterberg J, Vollmann J. Regulating open disclosure: A German perspective. *International Journal for Quality in Health Care* 2012;24(1):23–27.
246. Raghunathan K. Checklists, safety, my culture and me. *BMJ Quality and Safety* 2012.
247. Graber DR, Kilpatrick AO. Establishing values based leadership and value systems in healthcare organisations. *Journal of Human Services Administration* 2008;31(2):179–197.
248. Lamb R. Open disclosure: The only approach to medical error. *Quality and Safety in Health Care* 2004;13(2004):3–5.
249. Wei M. Doctors, apologies and the law: An analysis and critique of apology laws. *Journal of Health Law* 2007;40(1):107–159.
250. Sorry Works! Coalition. Analysis: Why docs won't say they're sorry. 2006. (Originally accessed November 2011 at <http://www.sorryworks.net/article37.phtml>, accessed 15 May 2012 at <http://webcache.googleusercontent.com/search?q=cache:SDZAw7no8uoJ:www.sorryworks.net/article37.phtml+&cd=1&hl=en&ct=clnk&gl=au&client=firefox-a>)
251. Levinson W, Gallagher TH. Disclosing medical errors to patients: A status report in 2007. *Canadian Medical Association Journal* 2007;177(3)(3):265–267.
252. Hilfiker D. Facing our mistakes. *New England Journal of Medicine* 1984;310(118).
253. Banja J. *Medical error and medical narcissism*. Sudbury MA: Jones and Bartlett, 2005.
254. Johnstone MJ. Clinical risk management and the ethics of open disclosure. Part 1. Benefits and risks to patient safety. *Australian Emergency Nursing Journal* 2008;11(88–94).
255. Hafferty WF. *Into the valley: Death and the socialization of medical students*. New Haven, CT: Yale University Press, 1991.
256. Fein SP, Hilborne LH, Spiritus EM, Seymann GB. The many faces of error disclosure: A common set of elements and a definition. *Society of General Internal Medicine* 2007;22:755–761.
257. Bismark MM, Spittal MJ, Studdert DM. Prevalence and characteristics of complaint-prone doctors in private practice in Victoria. *Medical Journal of Australia* 2011;195(6):25–28.
258. Buntine JA. Prevalence and characteristics of compliant-prone doctors in private practice in Victoria. *Medical Journal of Australia* 2011;198(6):325.

259. Nance J. *Why hospitals should fly: The ultimate flight plan to patient safety and quality care*. Bozeman, MT: Second River Healthcare Press, 2008.
260. Bell S, Delbanco T, Anderson-Shaw L, McDonald TB, Gallagher TH. Accountability for medical error. *Chest* 2011;140(2):519–526.
261. Liang BA. A system of medical error disclosure. *Quality and Safety in Health Care* 2002;11(1):64–68.
262. Donabedian A. The quality of medical care. *Science* 1978;200:856–864.
263. Kotter JP, Heskett JL. *Corporate culture and performance*. New York, NY: Free Press, 1992.
264. Kotter JP. Leading change: Why transformational efforts fail. *Harvard Business Review* 1995;March–April:59–67.
265. Lee P, Allen K, Daly M. A ‘communication and patient safety’ training programme for all healthcare staff: Can it make a difference? *BMJ Quality & Safety* 2011.
266. Reason J. Human error: Models and management. *British Medical Journal* 2000;320(768).
267. Bonvicini KA, Bylund CL, Carroll G, Rouse RA, Goldstein MG. Impact of communication training on physician expression of empathy in patient encounters. *Patient Education Counseling* 2009;75(1):3–10.
268. DEEWR (Department of Education, Employment and Workplace Relations). *Leadership, culture and management practices of high performing workplaces in Australia*. Report prepared by Boedker C, Cogin J, Langford P, Meagher K, Mouritsen J, Runnalls M, Sheldon P, Simmons S and Vidgen R, DEEWR. Sydney: Society for Knowledge Economics, 2011. (Accessed November 2011, at http://www.ske.org.au/download/SKE_2011_Literature_Review_Diagnostic_Instruments_January_10Jan2011FINAL.pdf)
269. Fritz J, Arnett RC, Conkel M. Organizational ethical standards and organizational commitment. *Journal of Business Ethics* 1999;20(4):289–299.
270. Chen DT, WSerhane PH, Mills AE. The role of organisational ethics in critical care medicine. *Critical Care Medicine* 2007;35(2 suppl):S11–S17.
271. Silverman HJ. Organizational ethics in health care: Proactively managing the ethical climate to ensure organizational integrity. *HEC Forum* 2000;12(3):202–215.
272. Rathert C, Phillips W. Medical error disclosure training: Evidence for values based ethical environments. *Journal of Business Ethics* 2010;97:491–503.
273. Iedema R, Jorm C, Lum M. Affect is central to patient safety: The horror stories of young anaesthetists. *Social Science and Medicine* 2009;69(12):1750–1756.
274. Halbach J, Sullivan L. *Medical errors and patient safety: A curriculum guide for teaching medical students and family practice residents*. MedEdPORTAL; 2005. (Accessed November 2011, at <http://services.aamc.org/30/mededportal/servlet/s/segment/mededportal/?subid=101>)
275. Halbach JL, Sullivan LL. Teaching medical students about medical errors and patient safety: Evaluation of a required curriculum. *Academic Medicine* 2005;80:600–606.
276. Gunderson A, Smith KM, Mayer DB, McDonald T, Centomani N. Teaching medical students the art of medical error full disclosure: Evaluation of a new curriculum. *Teaching and Learning in Medicine* 2009;21(3):229–232.
277. Gillies RA, Speers SH, Young SE, Fly CA. Teaching medical error apologies: Development of a multi-component intervention. *Family Medicine* 2011;43(6):400–406.
278. Newton BW, Barber L, Clardy J, Cleveland E, O’Sullivan P. Is there hardening of the heart during medical school? *Academic Medicine* 2008;83(3):244–209.
279. National Quality Forum. *Safe practices for better health care — 2009 update: A consensus report*. Washington DC, 2009.



Governance, risk management and systems improvement

Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology, expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

7 Governance, risk management and systems improvement

Principle 6: Integrated risk management and systems improvement

Investigation of adverse events and outcomes are to be conducted through processes that focus on the management of risk (see AS/NZS 4360). Outcomes of investigations are to focus on improving systems of care and will be reviewed for their effectiveness.

Principle 7: Good governance

Open disclosure requires the creation of clinical risk and quality improvement processes through governance frameworks where adverse events are investigated and analysed to find out what can be done to prevent their recurrence. It involves a system of accountability through the organisation's chief executive officer or governing body to ensure that these changes are implemented and their effectiveness reviewed.¹⁰

The principles addressing risk management, systems improvement and governance in the current Standard reflect contemporary evidence on the need to embed open disclosure within these frameworks.^{21, 48} The Standard acknowledges the importance of sound clinical governance, accountability and risk management. However, it does not anchor open disclosure within these frameworks strongly enough. For example, Section 6 outlines organisation issues and responsibilities in these terms:

The organisation will need to determine whether the open disclosure process is to be implemented into existing systems and policies, such as risk management and identification of adverse events, or whether those systems need to be amended to take account of the open disclosure process.^{10(p9)}

The majority of Australian health services have established formal clinical governance structures. In addition, the *National Safety and Quality Health Service (NSQHS) Standards*,¹⁰⁶ recently endorsed by Australian health ministers, require healthcare facilities to implement formal governance and accountability frameworks for clinical risk management and quality improvement. The revised Standard should assume the existence of governance and accountability frameworks and focus on integrating open disclosure into them. Similarly, there is no longer a need to describe incident investigation processes (Sections 13 and 15 of the Standard).¹⁰

This chapter examines risk management, governance and its contributing factors such as transparency and measurement in light of contemporary evidence.

7.1 Governance, risk management and improvement

Features of successful, high-performing organisations include how they manage and respond to error, and how performance is measured over time. These organisations also embrace the ‘aesthetics of imperfection’ in which error is viewed as an opportunity for improvement.^{58, 266, 280–283} These efforts must be underpinned by a formal governance and risk management framework, and habitually ‘baked’ into their structures, culture and routines.²⁸⁴

Clinical governance is the framework through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care. This is achieved partly by fostering an environment in which there is transparent responsibility and accountability for maintaining standards, and by allowing excellence to flourish.¹⁰⁶

A key component of clinical governance is risk management. The *Australian Risk Management Standard AS/NZS 4360*, referred to in Principle 6, has been superseded by ISO 31000, which contains several departures from the previous document:

- Risk is defined in terms of the effect of uncertainties on objectives. The superseded document focused on risk as being the chance of something happening that will have an effect on objectives.
- It highlights a set of principles that organisations must, at all levels, follow to achieve effective risk management in a way that:
 - creates and protects value
 - is an integral part of all of the organisation’s processes
 - forms part of decision making
 - is systematic, structured and timely
 - is tailored to the organisation
 - takes human and cultural factors into account
 - is transparent and inclusive
 - is dynamic, iterative and responsive to change
 - facilitates continual improvement of the organisation.

ISO 31000 emphasises that risk management is contingent on a strong mandate and commitment from leadership. The clinical governance framework must take into account:

- understanding of the organisation’s activities and its context^H
- defining accountabilities
- integrating governance into organisational processes
- providing adequate resources to maintain the framework
- establishing internal and external communication and reporting mechanisms.²⁸⁵

H With particular attention paid to ensuring appropriateness for the size and complexity of an organisation.

These align with key themes from the open disclosure and quality improvement literature. They also reflect the evolution in healthcare quality improvement since the release of the Standard.¹⁵

7.1.1 Transparency and openness

I think it's more important to have an atmosphere of openness and frankness and that hopefully at the end of the day the participants on both sides, the doctors as well, they're forced to closely review what's happened and their own conduct, etc and that they go away learning something as well. If that happens, that's about the best you can expect. Patient's son¹⁴

As expressed in ISO 31000, managing risk effectively is contingent on communication, accountability and transparency. In terms of system learning, this is predicated on the unencumbered acknowledgment and notification of incidents. As noted by Kronman and colleagues, 'in order to learn from mistakes and develop safer systems, errors must first be identified and reported.'^{44(p1)} One of the benefits of open disclosure is its fundamental requirement to acknowledge error. Without this acknowledgment, investigations and subsequent changes to rectify failings or causes will either not be undertaken or will be underprioritised. This is another way in which open disclosure practice potentially drives cultural change, as an incident, 'once acknowledged, also allows lessons to be learned.'^{26(p14)}

A health service focused on improvement and optimal patient care recognises that things sometimes go wrong, and investigates incidents honestly and transparently. According to Truog and colleagues, '[w]hen adverse events and medical errors are widely discussed and clinicians understand that only a small minority of errors are the result of individual negligence, there is hope that the dynamics of shame and blame can give way to the kind of open and respectful learning that will lead to substantive improvements in patient safety.'^{48(p119)}

7.1.2 Clinical governance — the role of the patient

Framed as an ongoing conversation between the harmed patient and provider, open disclosure can provide a valuable pathway to elicit information about incidents and their causative factors. As discussed in Chapter 5, patients' subjective assessments of the quality of their care can be associated with harm. They provide a unique insight into the trajectory of care, patient journey and the incident cascade. The literature advocates involving patients, families and carers in the processes of notifying, reporting and investigating clinical incidents.^{48, 129, 286}

There is a gap between the Standard and current practice in this regard. As indicated in the previous chapter, health services can be reluctant to involve patients in notification, investigation and improvement.

Patient desire to be involved in the investigation and analysis of incidents that harmed them or a loved one is documented. It can yield benefits including additional evidence and can assist the patient to achieve closure following an incident.^{11, 13, 22, 46, 48} There are also moves to include the patient experience in overall assessment of the performance of health services.²⁸⁷

7.1.3 Data collection and reporting

Collecting and reporting of performance data, including clinical incidents and their causes, are key aspects of governance and quality improvement. High-performing organisations generally have strong data management and reporting systems, measure performance and regularly report this to the executive.^{284, 288, 289} Although accountability is important, the principal reason for collecting performance data is to enable and facilitate improvement within the clinical microsystem.²⁸⁴

The literature advocates measuring various aspects of open disclosure including the proportion of harmful incidents disclosed, consumer satisfaction with the open disclosure process²² and staff surveys of the way in which they are supported throughout the process. Such measurement can be embedded into broader clinical governance and improvement. These data should be used for both accountability and improvement.

Reporting of performance may also need to extend beyond the organisational level to facilitate wider accountability and assist with benchmarking in the future. Agreed measures for open disclosure could be collected as part of a national or jurisdictional quality and safety reporting framework. In the future, such results may be published, for instance, on the MyHospitals website.¹ Section 9.4 provides some potential open disclosure process and outcome measures.

7.1.4 Corporate risk

There is some evidence that in certain contexts a clinical incident management framework that includes open disclosure can positively influence the organisational risk profile of a health service.^{74, 155, 290, 291} There are individual examples suggesting that open disclosure can affect the nature and volume of litigation when integrated into risk management and clinical incident management programs.^{19(p22–26)} Full disclosure is associated with a reduced intention to take legal action and with less severe findings and orders.^{22, 74, 92, 116}

Nevertheless, despite encouraging individual results, conclusive evidence is lacking and commentators remain divided on this matter.^{99, 292–295} The effect of open disclosure practice on litigation depends on many variables such as other institutional arrangements, the safety climate, or how it is implemented and operationalised. However, as health services increasingly strive to align their clinical and corporate risk management strategies,²⁹⁶ there is little evidence to see open disclosure as an impediment to this objective. In fact, the opposite is likely to be the case. Healthcare organisations are increasingly encouraged to consider open disclosure a key part of corporate risk management.²⁹⁷

7.1.5 Primary care

The principles of clinical governance, risk management and quality improvement are becoming more prominent in the non-acute and primary care settings. The current Royal Australian College of General Practitioners *Standards for general practices* (4th ed.), published in 2010, emphasise the importance of these aspects of care.²⁹⁸ This is illustrated by a new section on clinical governance, current clinical risk management strategies such as patient identification and clinical handover, and increased emphasis on patient engagement.²⁹⁹

7.2 Implications for a revised national Standard

Thinking and practice around clinical governance and risk management has evolved considerably since the release of the Standard. Today, most Australian health services have in place mature clinical governance frameworks. The NSQHS Standards mandate a clinical governance structure for accreditation purposes. However, executive leadership is an essential component for the systematic uptake of best-practice open disclosure.

Recommendation 5.1: The revised Standard should continue to emphasise the key role of executive leadership, ownership and engagement in implementing open disclosure.

Because clinical governance, risk management and systems improvement have evolved considerably over the past decade, a revised Standard will not need to suggest that these frameworks be built (e.g. that 'healthcare organisations [...] build investigative processes to identify why adverse events occur'^{10 (p1)}). The document should, instead, advise on how open disclosure can be integrated into clinical governance and quality improvement. There is also no longer a need to describe how an incident should be graded, investigated and the ensuing recommendations implemented. Instead, a revised Standard should focus on how open disclosure can complement, and be complemented by, these parallel processes.

Recommendation 5.2: The revised Standard should:

- advise on how open disclosure can be integrated into, and enhance, existing risk management and clinical governance frameworks
- assume the existence of clinical governance frameworks and protocols for the conduct of investigations, rather than describing their development.

The evidence supports the inclusion of open disclosure within a risk management and clinical governance framework. However, the current reality is that, with a few notable exceptions, open disclosure is generally not embedded into the care process, clinical governance or clinical risk management. Generally, disclosure is still approached reactively, separate to other quality improvement activity, and as an addition to, instead of part of, the care process.^{21, 22, 160, 300}

In addition, open disclosure still tends to be carried out as a process of information dissemination as opposed to information sharing, with patients generally excluded from contributing to the investigation and improvement processes.¹⁶⁰ This has clear implications for quality improvement.

Recommendation 5.3: The revised Standard should:

- emphasise the value of open dialogue with patients in satisfying the needs of the patient
- recognise that open dialogue with patients is a key component of healthcare quality improvement, systems learning and clinical risk management.

Data collection, management and reporting to the executive is a key aspect of governance, quality improvement and risk management. It is a vehicle for generating executive support and assisting oversight.

Recommendation 5.4: The revised Standard should highlight the importance of data and information management processes to ensure:

- systems learning and improvement
- executive oversight and leadership of open disclosure
- intra-organisational accountability
- organisational accountability to external authorities.

There are clear gaps between evidence and practice in terms of positioning open disclosure within clinical governance and risk management.

Recommendation 5.5: The revised Standard should be accompanied by implementation resources to enable health services to implement and sustain open disclosure. These may include:

- staff safety culture survey templates
- risk management guidelines
- sets of standardised open disclosure outcome and process measures
- templates for executive reporting.

The current Standard most directly addresses hospital services. However, with the spread of clinical governance and the principles of risk management and quality improvement into non-acute settings, the revised Standard should also be relevant to non-acute settings.

Recommendation 5.6: The revised Standard should be made relevant to a wider spectrum of healthcare services, including non-acute and primary care settings.

References

10. Australian Council for Safety and Quality in Health Care. *Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care*. Canberra, 2003.
11. Iedema R, Allen S, Britton K, Piper D, Baker A, Gribich C, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The '100 patient stories' qualitative study. *British Medical Journal* 2011;343(d4423).
13. Iedema R, Allen S, Britton K, Gallagher TH. What do patients and relatives know about problems and failures in health care? *BMJ Quality and Safety* 2011;doi 10.1136/bmjqs-2011-000100.
14. ACSQHC (Australian Commission on Safety and Quality in Health Care). *Independent research into patient and provider views and experiences with open disclosure*. Sydney: University of Technology, 2011.
15. Ovretveit J. Understanding the conditions for improvement: Research to discover which context influences affect improvement success. *BMJ Quality and Safety* 2011;20(Suppl 1):i18–i23.
21. O'Connor E, Coates HM, Yardley IE, Wu AW. Disclosure of patient safety incidents: A comprehensive review. *International Journal on Quality in Health Care* 2010;22(5):371–379.
22. Gallagher TH. A 62-year-old woman with skin cancer who experienced wrong-site surgery. *Journal of the American Medical Association* 2009;302(6):669–677.
26. Kennedy I. *Learning from Bristol: The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995*. London: Department of Health, 2001.

44. Kronman AC, Paasche-Orlow M, Orlander JD. Factors associated with disclosure of medical errors by housestaff. *BMJ Quality and Safety* 2011;doi:10.1136/bmjqs-2011-000084.
46. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *Journal of the American Medical Association* 2003;289(8):1001–1007.
48. Truog RD, Browning DM, Johnson JA, Gallagher TH. *Talking with patients and families about medical error: A guide for education and practice*. Baltimore: Johns Hopkins University Press, 2011.
58. Lewis GH, Vaithanathan R, Hockey PM, Hirst G, Bagian J. Counterheroism, common knowledge, and ergonomics: Concepts from aviation that could improve patient safety. *The Milbank Quarterly* 2011;89(1):4–38.
74. Kraman SS, Hamm G. Risk management: Extreme honesty may be the best policy. *Annals of Internal Medicine* 1999;131(12):963–967.
92. Wu A, Huang IC, Stokes S, Pronovost P. Disclosing medical errors to patients: It's not what you say, it's what they hear. *Journal of General Internal Medicine* 2009;24(9):1012–1017.
99. Studdert D, Richardson MW. Legal aspects of open disclosure: A review of Australian law. *Medical Journal of Australia* 2010;193(5):273–276.
106. ACSQHC (Australian Commission on Safety and Quality in Health Care). *National Safety and Quality Health Service (NSQHS) Standards*. Sydney, 2011.
116. Schwappach DLB, Koeck CM. What makes an error unacceptable? A factorial survey on the disclosure of medical errors. *International Journal for Quality in Health Care* 2004;16(4):317–326.
129. Lopez L, Weissman JS, Schneider EC. Disclosure of hospital adverse events and its association with patients' ratings of the quality of care. *Archives of Internal Medicine* 2009;169:1888–1894.
155. McDonald TB, Helmchen LA, Smith KM. Responding to patient safety incidents: The 'seven pillars'. *Quality and Safety in Health Care* 2010;19:e11.
160. Iedema R, Jorm C, Wakefield J, Ryan C, Dunn S. Practising open disclosure: Clinical incident communication and systems improvement. *Sociology of Health & Illness* 2009;31(2):262–277.
266. Reason J. Human error: Models and management. *British Medical Journal* 2000;320(768).
280. Reason J. Beyond the organizational accident: The need for 'error wisdom' on the frontline. *Journal of Quality and Safety in Health Care* 2004;13:28–33.
281. Weick K. Reduction of medical errors through mindful interdependence. In: *Medical error*. Sutcliffe K, Rosenthal M (eds). San Francisco, CA: Jossey-Bass, 2004:177–199.
282. Weick K. Creativity and the aesthetics of imperfection. In: *Creative action in organisations*. Ford C, Gioia D (eds). Thousand Oaks CA: Sage, 1995:187–192.
283. Schulman PR. General attributes of safe organisations. *Quality and Safety in Health Care* 2004;13(suppl ii):ii39–ii44.
284. Bohmer RM. The four habits of high-value health care organizations. *New England Journal of Medicine* 2011;365(22):2045–2047.
285. Standards Australia. *ISO 31000: Risk management — principles and guidelines*. Sydney: Standards Australia Limited, 2009.
286. Millman A, Pronovost P, Makary MA, Wu A. Patient assisted incident reporting (PAIR): Including the patient in patient safety. *Journal of Patient Safety* 2011;7:106–108.
287. Australian Government. *A national health and hospitals network for Australia's future: delivering the reforms*. Canberra: Australian Government 2011. (Accessed 15 May 2012 at [http://www.yourhealth.gov.au/internet/yourHealth/publishing.nsf/Content/DeliveringTheReforms/\\$FILE/DeliveringTheReforms.pdf](http://www.yourhealth.gov.au/internet/yourHealth/publishing.nsf/Content/DeliveringTheReforms/$FILE/DeliveringTheReforms.pdf))
288. Weick K, Sutcliffe KM. *Managing the unexpected: Assuring high performance in the age of complexity*. San Francisco: Jossey-Bass, 2001.

289. Sepucha KJ, Fowler FF, Mulley AG. Policy supports for patient-centred care: The need for measurable improvements in decision quality. *Health Affairs* 2004;54:1–9.
290. Boothman R, Blackwell AC, Campbell DA, Commiskey E, Anderson S. A better approach to medical malpractice claims? The University of Michigan experience. *Journal of Health and Life Sciences Law* 2009;2(2):125–159.
291. Quinn RE, Eichler MC. The 3Rs program: The Colorado experience. *Clinical Obstetrics and Gynecology* 2008;51:709–718.
292. Studdert DM, Mello MM, Gawande AA, Brennan TA, Wang YC. Disclosure of medial injury to patients: An improbable risk management strategy. *Health Affairs* 2007;26(1):215–226.
293. Wakefield J, Jorm C, Ryan C. Open disclosure: Details matter — a response to studdert et al 2007. *Health Affairs* 2007;26(3):903–904.
294. Kraman SS, Hamm G. Bad modelling? *Health Affairs* 2007;26(3):903.
295. Studdert D, Mello MM, Gawande A, Brennan TA. Disclosure: The authors repond. *Health Affairs* 2007;26(3):904–905.
296. Department of Health WA (Western Australia). *Western Australian strategic plan for safety and quality in health care*. Perth: Department of Health WA, 2008.
297. Lamo N. Disclosure of medical errors: The right thing to do but what is the cost?: Lockton Insurance Companies Newsletter, Kansas City, MO: Lockton Companies, LLC, 2011:1–7.
298. RACGP (Royal Australian College of General Practitioners). *Standards for general practices* (4th edn). South Melbourne: RACGP, 2010.
299. RACGP (Royal Australian College of General Practitioners). *Standards for general practices*, 4th edition — key changes. South Melbourne: RACGP, 2010. (Accessed February, 2012, at http://www.racgp.org.au/Content/NavigationMenu/PracticeSupport/StandardsforGeneralPractices/Standards4thEd_KeyChanges.pdf)
300. Iedema R. Attitudes toward error disclosure need to engage with systems thinking. *The Joint Commission Journal on Quality and Patient Safety* 2010;36(3):99–100.



Confidentiality

Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology, expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

8 Confidentiality

Principle 8: Confidentiality

Policies and procedures are to be developed by healthcare organisations with full consideration of the patient's, carer's and staff's privacy and confidentiality, in compliance with relevant law, including Commonwealth and State/Territory Privacy and health records legislation.¹⁰

Confidentiality plays a fundamental role in all aspects of health care. Protecting confidentiality is particularly important in a highly sensitive and emotionally charged process such as open disclosure. This chapter examines protecting the confidentiality of patients and providers, and discusses the tension between this and other principles of open disclosure as described in the current Standard.

8.1 Patient confidentiality

The Standard is very clear about the importance of confidentiality, particularly for the patient. Section 3(d) defines a patient's support person with the main intention of protecting incident information from being released to unauthorised third parties. Section 7.8 of the Standard addresses privacy and confidentiality more generally during open disclosure and the investigation of related incidents.¹⁰

There is a risk that confidentiality can be used as a shield to block the release of information to the patient's support person. Research indicates that patients greatly benefit from the presence of support people during the disclosure process, be they guardians, official or unofficial carers, loved ones or family members.⁹⁸ In a small but significant number of cases, a harmed patient will be unable to provide consent for release of information to a third party who is not a next of kin or nominated support person through proper legal mechanisms. It is therefore important to establish a preferred support person early in an episode of care, and a revised Standard will need to reflect this requirement.

The need to identify a support person early in the episode of care reinforces the importance of the consent process in incident management and that, in practice, open disclosure starts with effective and open communication at first contact. Conversations about what to do if the unexpected happens can have additional benefits. They may stimulate dialogue about potential clinical incidents, help build rapport between provider and patient, improve clinical outcomes¹³⁵ and assist communication following a harmful incident.^{48, 76}

8.2 Provider confidentiality

Protecting information about healthcare providers is an important consideration during open disclosure and incident management. Managing undue blame, retribution and reputational damage are priorities for healthcare organisations. Any evidence of scapegoating and undue blame is counterproductive and will undermine system learning from incidents.

However, confidentiality must be balanced with open information exchange, transparency and accountability. A 'no blame' culture should retain some level of individual accountability, with commentary emerging on the need for health services to develop 'just cultures' to achieve the right balance between openness and confidentiality.^{301–306}

While the majority of harmful incidents are caused by a confluence of system factors and human error, individual actions also contribute. Inevitably, some incidents occur due to actions precipitated by an individual mistake, oversight or (unintended) negligence. Others are caused by deliberate yet non-malicious deviations from accepted best practice, guidelines or policy. However, evidence suggests that the great majority of harmful incidents contain no moral culpability on the part of providers.^{J, 307}

8.2.1 Provision of information during open disclosure

In terms of open disclosure, recent evidence suggests that patients expect, and benefit from, clarification of individual actions that led to a harmful incident and to what degree these determined the result.^{19(p41)} Open disclosure dialogue should include acknowledgment and apology for any inappropriate clinical, administrative or managerial decisions and actions that contributed to harm (even if these are made in good faith).²⁹⁰

A clear distinction should be made between the contents of open disclosure discussions (which provide the patient with insight into decision-making during the incident) and the results of formal investigations (such as root cause analyses which provide information on system failures). While patients will have an interest in formal investigation outcomes, especially the steps taken to prevent incident recurrence, system 'facts' should be kept separate from information on individual actions. This is to some extent necessitated by the fact that outcomes of formal investigation are usually only available some time after open disclosure commences.

There is an observed tendency to protect information from being shared with patients for fear of litigation, yet evidence would suggest that fears may be misplaced, and that opacity is counter-productive in a legal sense.^{99, 101, 103} Qualified privilege (QP) statutes protect information gathered during an investigation process by an officially 'declared' committee or entity. There are, however, pathways for patients to obtain such information if they desire. Generally speaking, the remit of QP does not cover the contents of open disclosure conversations (see sections 2.4.3 and 3.4.1).

Also, it is important that the need for information by patients is balanced with protection of personal information about healthcare providers involved in a harmful incident. This pertains to information that is not relevant to the incident, its management and subsequent open disclosure.

It may be the case that open disclosure itself addresses the tensions outlined here and integrates openness, free flow of information and transparency within a culture that balances fairness and accountability. This may be especially relevant to fears of harmed parties 'going public' with information. It may even apply to cases where a clear individual culpability is established. In this regard open disclosure may, again, complement organisational risk management.

J Situations where deliberate and malicious intent is established fall outside of the scope of the current and revised Standard. Organisations should clearly distinguish between unacceptable behaviour warranting disciplinary action, and behaviour that, even if it leads to harm, falls within boundaries that are understandable given the complexity and interdependency of modern health care on a range of factors and events.

8.3 Documentation

There was conflicting information. There was an acknowledgment there was an incident with the patient. That was done poorly from a clinical disclosure by a junior staff member with conflicting information. And that was actually then in itself the incident in that that's what really caused the anxiety for the patient. Support personnel^[86(p26)]

Clear documentation is a key component of open disclosure, and is relevant in relation to confidentiality. The current Standard describes documentation requirements in Section 11. The available evidence identifies a need to improve documentation processes and ensure a clear documentation trail of incidents, initial management and the open disclosure process.¹¹

Open disclosure documentation should include:^{11, 22, 48, 156}

- putting in place an open disclosure documentation management process that includes tracking all relevant incident information including the medical record, a record of the open disclosure process, and incident investigation information
- ensuring the medical record is up-to-date prior to the first open disclosure meeting, including a comprehensive account of the adverse event as it is initially understood. In the case of death due to an incident, a copy of the medical record should remain accessible to all those who will be involved in the open disclosure process
- keeping a record of the open disclosure process; recording all relevant patient, family and support person contact details, all discussions, all information provided, logistical details, and all plans proposed and agreement and commitments made
- ensuring documentation is made available to the patient, family and carer(s) without contravening legal constraints
- developing and maintaining a comprehensive file note which is kept separate from the medical record
- providing a written report in appropriate language at the end of any investigations.

These practices will enable a clear and consistent message to be conveyed to patients — avoiding situations described in the quote above — and establish a robust platform for balancing transparency and accountability with confidentiality and protection.

8.4 Implications for a revised national Standard

The current Standard contains competing priorities between confidentiality and other principles of disclosure. There is a need for openness and transparency when providing information to a harmed patient and their support person but consent must be sought early from patients to permit release of information to support persons in the event of harm.

Recommendation 6.1: The revised Standard should outline the importance of formally seeking support person nominations early in the episode of care in case of subsequent open disclosure and incident management.

Balancing justified accountability with protection of staff from undue blame is an important consideration. Patients expect information on individual decision-making as well as system accountability during post-incident management. Evidence suggests that the most effective

strategy for protecting providers and organisations from legal exposure is transparent and active communication. This is ethically supported, can ameliorate negative perceptions and lessen the impulse to engage in 'revenge-taking behaviour' by patients.¹⁶⁹

Recommendation 6.2: The revised Standard should advocate for best practice open disclosure that openly and transparently provides all available information to patients and support persons.

Recommendation 6.3: The revised Standard should address the need to balance patients' need for information with protecting the personal information about healthcare professionals involved in a harmful incident (information that is not related to the incident or the ensuing open disclosure).

Clear documentation is a vital component of sound open disclosure practice.

Recommendation 6.4: The revised Standard should outline documentation requirements that provide patients and providers with consistent and complete information during the open disclosure process.

References

10. Australian Council for Safety and Quality in Health Care. *Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care*. Canberra, 2003.
11. Iedema R, Allen S, Britton K, Piper D, Baker A, Gribich C, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The '100 patient stories' qualitative study. *British Medical Journal* 2011;343(d4423).
19. Piper D, Iedema R. *Literature review: Incident disclosure policy, legal reform and research since 2008*. Sydney: Centre for Health Communication (University of Technology Sydney) and ACSQHC (Australian Commission on Safety and Quality in Health Care), 2011.
22. Gallagher TH. A 62-year-old woman with skin cancer who experienced wrong-site surgery. *Journal of the American Medical Association* 2009;302(6):669–677.
48. Truog RD, Browning DM, Johnson JA, Gallagher TH. *Talking with patients and families about medical error: A guide for education and practice*. Baltimore: Johns Hopkins University Press, 2011.
76. Woods MS. *Healing words: The power of apology in medicine*. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations, 2007.
86. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. *Final report: Evaluation of the National Open Disclosure pilot program*. Sydney: The Australian Commission on Safety and Quality in Health Care (ACSQHC), 2008.
98. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. The National Open Disclosure Pilot: Evaluation of a policy implementation initiative. *Medical Journal of Australia* 2008;188(2008):397–400.
99. Studdert D, Richardson MW. *Legal aspects of open disclosure: A review of Australian law*. *Medical Journal of Australia* 2010;193(5):273–276.
101. Brown D. *Open disclosure: Morally right, but is it legally safe?* Medico-Legal Society of NSW Inc Scientific Meeting. Sydney, 2008.
103. Vines P. The power of apology: Mercy, forgiveness or corrective justice in the civil liability arena? *University of New South Wales Faculty of Law Research Series* 2007;2007(30):1–29.
135. Hojat M, Louis DZ, Marham FW. Physicians' empathy and clinical outcomes for diabetic patients. *Academic Medicine* 2011;86(3):359–364.

156. Helmchen LA, Richards MR, McDonald TB. Successful remediation of patient safety incidents: A tale of two medication errors. *Health Care Management Review* 2011;April–June 2011.
169. Allan A, McKillop D. The health implications of apologizing after an adverse event. *International Journal on Quality in Health Care* 2010;22(2):126–131.
290. Boothman R, Blackwell AC, Campbell DA, Commiskey E, Anderson S. A better approach to medical malpractice claims? The University of Michigan experience. *Journal of Health and Life Sciences Law* 2009;2(2):125–159.
301. Christakis NA. Don't just blame the system. *British Medical Journal* 2008;336(7647):747.
302. Wachter RM, Pronovost PJ. Balancing 'no blame' with accountability in patient safety. *New England Journal of Medicine* 2009;361(14):1401–1406.
303. Walton M. Creating a 'no blame' culture: Have we got the balance right? *Quality and Safety in Health Care* 2004;13:163–164.
304. Joint Commission. *Behaviors that undermine a culture of safety*. Sentinel event alert, Washington DC: Joint Commission, July 9 2008.
305. Goldmann D. System failure versus personal accountability: The case for clean hands. *New England Journal of Medicine* 2006;355:121–123.
306. Marx D. *Patient safety and the 'just culture': A primer for health care executives*. New York: Columbia University, 2001.
307. Merry AF, McCall Smith A. *Errors, medicine and the law*. Cambridge, UK: Cambridge University Press, 2001.



Open disclosure implementation

Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology, expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

9 Open disclosure implementation

Open disclosure involves difficult feelings, emotions and personal interactions and cuts across professional and academic lines. It 'harbours an unusual energy',^{300(p99)} and it is perhaps not surprising that progress on embedding it in the routine operation of health systems has been slower than other safety and quality initiatives.^{21, 48, 300} Health care is a unique endeavour in terms of its complexity, its moral functions and broader social obligations.^{271, 308} The culture and tenets of modern medicine, which value empiricism, rationality and objective detachment, may at times run counter to the principles of open disclosure.

This chapter examines some of the barriers to open disclosure, as well as its aims and its benefits. As resource scarcity is often cited as a major factor behind its lagging implementation, a discussion on the economics of open disclosure follows. The chapter concludes with an outline of several successful open disclosure programs in Australia and overseas.

9.1 Summary of barriers and enablers

The barriers to enacting and institutionalising disclosure are complex and multi-factorial. Provider barriers to open disclosure include a lack of confidence in communication skills, fear of litigation or loss of reputation, and avoidance of difficult emotional confrontations on the part of clinicians. Institutional barriers include a lack of transparency and a culture that promotes unrealistic expectations of practitioners. A lack of resources, particularly time, to carry out open disclosure is also often cited as an impediment. Patient barriers can include a desire not to participate in disclosure processes or to be confronted with sometimes complex detail and discussion.

9.1.1 Barriers

Iledema and colleagues distil open disclosure barriers into four domains:¹²

- 1 Insufficient insight into consumer experience and understanding of incidents:
 - lack of insight into consumers' perceptions of what constitutes an incident
 - uncertainty about consumers' capacity to understand clinical complexity, medical technicalities, and the system's dimensions of failure
- 2 Uncertainty about disclosing incident information:
 - lack of capacity in dealing with complex emotions and family dynamics
 - doubts about cultural appropriateness and effectiveness of incident disclosure
- 3 Uncertainty about communicating incidents with colleagues and within the organisation:
 - challenges of dealing with resistant or distressed colleagues
 - doubts about how admission of unexpected outcomes aligns with concepts of professionalism and quality improvement

4 Uncertainties about medico-legal implications of disclosure:

- doubts about aligning disclosure with qualified privilege
- uncertainty about insurers' stance on incident disclosure.

Allan and Munro also examined barriers to open disclosure policy and practice. Their findings align with those of Iedema and colleagues and are grouped into five clusters:²⁰

- 1 Individual: includes fear of litigation, disciplinary, reputational and financial concerns
- 2 Interpersonal: lack of confidence and communication ability; conflict avoidance
- 3 Organisational or cultural: lack of institutional support and leadership; 'club culture'
- 4 Meta-level: priority with protecting the organisation rather than enhancing quality of patient care
- 5 Professional: misunderstanding of the needs and expectations of patients.

Underpinning these are more fundamental cultural and institutional impediments which go to the core of modern medical practice and how providers are educated and socialised. These were discussed in more detail in Chapter 6, and are articulated by Walshe and Shortell.²²⁰

9.1.2 Enablers

Barriers to cultural change are not insurmountable. It is noteworthy that it was once unusual for clinicians to discuss openly with patients serious diagnoses and prognoses of terminal illness or end-of-life care but this is now accepted professional behaviour.^{85, 251} Potential solutions to barriers are equally complex and interwoven with healthcare culture more broadly. Within the clinical microsystem, the enablers of open disclosure can be distilled to two points:

- Healthcare professionals must be supported to enact open disclosure.
- Healthcare professionals must be supported to cope with the effects of harmful incidents and with the process of open disclosure.

The necessary support can be provided through the development of skills, education and collaborative practice.

Education and development

Education and development of clinical and administrative staff is the key enabler of open disclosure at individual and system levels. It is a potential driver of the requisite cultural transformation necessary for open disclosure to 'take hold' in everyday clinical practice.^K Ideally, training and education:

- focuses on communication and 'active listening' skills
- includes learning about patient preferences, preferably utilising real patient stories and experiences
- begins during medical training and education
- canvasses the legal aspects of open disclosure
- includes scenarios in which disclosure can be experienced and practised.

K See Chapter 6 for more detailed discussion of education, training and development.

Patient involvement

Patients and their support persons play a key role in health care and in open disclosure. A patient who is engaged in the clinical aspects of their treatment, and aware of potential risks and consequences, will be better placed to take part in their treatment and in communication of a harmful incident. To enable this, patients must be informed of their rights and responsibilities should an unexpected event occur and encouraged to participate actively in all aspects of their care. Patients may have different preferences and requirements and should be given the choice of close involvement in decision-making in relation to their care.

Potential enablers of open disclosure implementation and uptake are summarised in Table 5.

9.2 The economics of open disclosure

Thorough economic analysis of open disclosure practice is lacking. Previous studies have tended to isolate particular aspects, such as the effect of disclosure on malpractice litigation or on medical 'productivity'.^{292, 309–312} Before discussing the economics^L of open disclosure, it is worth revisiting some findings from the research and literature outlined throughout this report:

- A small but significant proportion of healthcare interventions result in patient harm.
- Patients value the 'extra-clinical' dimension of their health care (communication, respect and dignity) in addition to clinical aspects.
- Health services and governments around the world are moving towards a citizen- and patient-centred model of service provision where the views and preferences of consumers are key policy drivers and determinants of public value.
- Patients expect a prompt and honest explanation, and an apology, when things go wrong. A perceived lack of openness and remorse following an adverse event is cited as a key motivator for pursuing legal remedies.
- Clinicians benefit from open disclosure in a number of ways including through reduced burn-out and job dissatisfaction, and lessening the post-incident tendency to practise potentially inefficient defensive medicine.
- Acquiring 'soft' skills to conduct open disclosure can improve communication and interaction among staff, and between staff and patients.

Open disclosure should be viewed as a legitimate part of health care. Available evidence suggests that disclosure should be a continuation of an episode of care and that providers and organisations should factor open disclosure into routine processes and budgets to look after people harmed by their care. With harmful incidents occurring in at least one in ten episodes of care, this is a potentially significant consideration both in activity and in benefit.

There is also the question of what is valued in health care or, more accurately, on whose values resource allocation decisions are based. Patients expect clinical care with humanity, especially when things go wrong. If it is accepted that the purpose of a healthcare service is to serve its patients, then resources should be allocated to improve the necessary skills and to manage post-harm care consistent with patient preferences.

^L 'Economics' is defined here as the enquiry into optimal allocation of scarce resources between a range of competing areas to generate the maximum benefit to stakeholders and to society. This allocation should be seen in terms of the 'margin' (i.e. where the next portion or quantum of resources should be invested).

Table 5 Summary of potential open disclosure enablers

Enablers	Their role
Individual practitioners	<p>Participating in training and education</p> <p>Engaging with patients about treatments and interventions, known risks, complications and potentially adverse outcomes</p> <p>Mentoring and supporting junior staff</p>
Health services management	<p>Promoting open disclosure as part of patient-centred and high quality care</p> <p>Integrating open disclosure with risk management and quality improvement</p> <p>Promoting policy and implementation of open disclosure to staff</p> <p>Supporting staff involved in open disclosure</p> <p>Providing staff with open disclosure training including simulation or role-play</p> <p>Measuring and evaluating open disclosure practice and reporting on it</p>
Health services executive leadership	<p>Explicitly supporting open disclosure practice and its role in high quality care</p> <p>Framing incidents as learning opportunities</p> <p>Emphasising the value of the patient experience in quality improvement</p> <p>Requesting regular data and results of open disclosure as part of routine performance monitoring</p>
Teaching institutions	<p>Incorporating open disclosure theory and practical skills into curricula</p>
Professional associations and learned colleges	<p>Including open disclosure in official charters</p> <p>Making open disclosure part of clinician responsibility to patients</p> <p>Making open disclosure part of ongoing certification and a continuing professional development requirement</p>
Insurers and the legal profession	<p>Engaging in organisational open disclosure policy-making</p> <p>Educating clients on open disclosure</p> <p>Integrating insurance policies with open disclosure practice, especially apology, including incentives and requirements to enact open disclosure in insurance policies</p>
Consumer groups	<p>Promoting open disclosure and patient involvement more generally</p> <p>Educating healthcare professionals on patient involvement</p>
Individual patients, families, carers, guardians	<p>Should they choose to do so:</p> <ul style="list-style-type: none"> • participating in their care as members of the team • considering all information provided by hospital staff • asking questions
Policy makers	<p>Acknowledging publicly the importance of open disclosure and apology following harm</p> <p>Mandating the implementation of best practice open disclosure</p> <p>Working with jurisdictional counterparts, healthcare stakeholders and insurers and the legal profession to remedy the effect of legislative inconsistency, including:</p> <ul style="list-style-type: none"> • aligning relevant legislation • canvassing alternative compensation schemes

9.2.1 Priority setting

In modern medicine, certain types of progress are embraced, sometimes at significant financial cost and sometimes for a 'meagre contribution' to health outcomes.^{313, 314} Taking up high-cost, technological innovations and associated changes in practice can provide marginal improvement to health outcomes while contributing to escalating health costs and resource scarcity. Some commentators suggest, in relation to some biomedical innovations, that 'the net benefit of health care may no longer outbalance the direct and indirect harm that it entrains.'^{19(p41)}

Open disclosure represents a profound and positive change in practice and care. It incurs costs (money, time and effort) but is a change backed by evidence to produce better outcomes for patients and healthcare professionals as well as the institution as a whole.

Compared with some biomedical innovations, open disclosure can be instituted at a smaller cost and has the potential to improve the quality of organisational communication and efficiency, suggesting that it is worthwhile for investment in open disclosure to be prioritised.

9.2.2 Return on investment

Health care is a public institution. Its funders are taxpayers, plus insured or fee-paying consumers. As de facto shareholders, citizens and consumers expect value for money and a return on their investment. This includes an expectation of the appropriate management of harmful incidents. Patients prefer honesty and transparency when the unexpected occurs and that, in turn, assists individual clinical outcomes and collective trust in health care.

The emerging value of the extra-clinical dimensions of care is captured by Rabow and colleagues, who write that 'it has become increasingly apparent that biomedical science alone is insufficient to address human illness, experiences of suffering, loss, recovery and healing.'^{133(p310)} The literature suggests that systematic implementation of open disclosure may accrue additional benefits such as improving team dynamics and inter-professional communication and communication with patients. This can, in turn, also improve clinical performance and outcomes and improve patient satisfaction. There is the potential for direct savings through reduced medico-legal exposure. The consequences of poorly managed incidents on staff can include a range of negative effects such as defensive practice and high staff turnover.

Open disclosure is an ethical practice which assists health services manage, and learn from, harmful incidents. Its implementation can be framed as a pragmatic business decision from which benefits can extend beyond its enactment.

In summary, disclosure programs should be:

- viewed as an ordinary part of care budgets, resources and time
- prioritised for health resource allocation
- framed as a sound structural and human capital investment which, especially at the margin, may offer a 'best buy' for public and private organisations.

9.3 Measuring and evaluating open disclosure

An important part of the development and implementation of the revised Standard will be guidance on tracking and measuring the extent and quality of open disclosure practice both within individual health services and across the Australian healthcare system.

Measurement can serve several ends. It is a key part of quality improvement at the organisational and clinical microsystem level. Measurement processes can establish internal and system-level benchmarks for performance. Measurement and reporting can serve as a useful incentive for improvement. This does not necessarily involve publication of results. However, public reporting is a possible driver of accountability, transparency and improvement.³¹⁵

Tables 6 and 7 list suggested outcome and process measures for evaluating open disclosure practice. The use of staff and patient surveys at the completion of open disclosure is recommended as a key evaluation and feedback tool, and source of valuable data. Other methods advocate integrating the clinical incident reporting systems with disclosure (see Section 9.4 and Appendix).

The revised Standard should strongly recommend implementing systems to monitor, evaluate and improve the quality of open disclosure processes. This should include the use of internal performance measurement. In the future, open disclosure may be included in jurisdictional and inter-jurisdictional performance reporting. There is growing emphasis on transparency and public reporting as part of current healthcare reforms in Australia.^M Open disclosure may be reported in a similar way in the future.

Table 6 Suggested open disclosure outcome measures

Outcome measures	Suggested benchmark
Percentage of reported clinical incidents disclosed	90%
Percentage of sentinel events formally disclosed	100%
Percentage of open disclosure vs open disclosure requests through:	
• patient initiations	TBC
• complaints	TBC
Percentage of staff or providers trained in open disclosure	
General	90%
Specialised	10% (multi-professional)
Results of staff feedback to training / development	100% confident; 80% very confident
Results of staff feedback to open disclosure	100% satisfied; 80% highly satisfied
Results of patient feedback / satisfaction surveys	100% satisfied; 80% highly satisfied
• following a sentinel event	90% satisfied; 70% highly satisfied

M The MyHospitals website recently commenced hospitals-level publication of *Staphylococcus aureus* bacteraemia rates.

Table 7 Suggested open disclosure process measures

Process measures
The health service has an official open disclosure policy based on the revised Standard that: <ul style="list-style-type: none">• contains the steps for open disclosure described in the Framework• contains provisions for ongoing support for the patient and loved ones or carers• contains provisions for ongoing support of staff involved in open disclosure and clinical incidents, including a 'debrief' with suitably qualified staff
The health service has an identified open disclosure support officer in place with a capacity to respond to clinical incidents
The health service has an official and regular program for open disclosure training and education including, where appropriate, role-playing and simulation with structured feedback, which includes: <ul style="list-style-type: none">• open disclosure as part of orientation of all clinical and management staff• basic open disclosure education for all staff with regular refresher workshops• comprehensive training for selected individuals from various professions
The health service has a standardised survey for patients, family and support persons involved in open disclosure to elicit impressions and satisfaction with the open disclosure process
The health service has a standardised survey for staff involved in open disclosure to elicit impressions and satisfaction with the open disclosure process
The health service can trigger open disclosure through a variety of methods including: <ul style="list-style-type: none">• complaints• clinical incident notification• case note review• general observation• patient request
The patient, family and carer are provided with open disclosure information in an appropriate format
The health service has a record of all communications made about healthcare incidents that are discussed with patients, families and carers
The health service has official counselling and support service for staff involved in clinical incidents and consequent open disclosure processes

9.4 Implications for a revised national Standard

Recommendation 7.1: The revised Standard should recommend implementing systems to monitor, evaluate and improve the quality of open disclosure processes including:

- internal process measures
- data collected from patients and staff to measure and inform open disclosure improvements
- feedback to clinical staff about open disclosure performance and improvement activities.

9.5 Open disclosure implementation frameworks

Open disclosure research has produced frameworks and models on how to approach disclosure implementation in a health service or facility. These are outlined below.

9.5.1 The 4-A Framework

The 4-A Framework is a model for implementing and managing open disclosure in a healthcare organisation. It consists of the following components: awareness, accountability, ability, action. The model is summarised in the following table.

Table 8 The 4-A Framework to assist organisational open disclosure (adapted from Gallagher 2007⁸⁹)

Awareness	Heighten awareness of open disclosure and its importance through education, promotion and leadership. This may include: <ul style="list-style-type: none">• conducting clinical-microsystem-level needs assessment and organisation-wide surveys• identifying gaps in practice — engage consumers and patients to provide their views and experiences directly to staff• sharing information and experiences, especially those of senior staff• including senior staff in workshops• providing comprehensive education for staff• make open disclosure part of official induction and orientation
Accountability	Create accountability, thereby promoting a transparent system Clearly delineate who is accountable and have a clear reporting structure Define accountabilities and responsibilities in policy Use structure, process and outcome measures (e.g. number of staff trained, percentage adverse events openly disclosed, clinician and patient satisfaction)
Ability	Furnish and build into the organisation the ability and confidence to disclose Integrate open disclosure with other clinical governance and quality improvement policies especially risk, clinical incident management and complaints Establish a comprehensive training and education strategy Train some experts and provide basic awareness to ALL staff Educate a cohort of staff to be open disclosure consultants Provide around-the-clock support for patients and staff Foster a collegiate, team approach 'Normalise' open disclosure — make it routine
Action	Convert the ability into action Engage leadership in 'top down' support Actively champion open disclosure Provide simulation to develop and maintain confidence and skills Instil realistic expectations among staff Link open disclosure with other improvement activity

9.5.2 National Quality Forum guideline

In 2006 the National Quality Forum endorsed a 'safe practice guideline' for open disclosure. The key elements are shown in Table 9.

Table 9 Key elements of the National Quality Forum safe practice guideline⁹¹**Content to be disclosed:**

- Facts about the event
- Error or system failure, if known
- Results of event analysis to support informed decision making by the patient
- Regret for the unanticipated outcome
- Formal apology if unanticipated outcome is caused by error or system failure

Institutional requirements

Integrate disclosure, patient safety and risk management activities

Establish disclosure support systems:

- provide background disclosure education
- ensure that disclosure coaching is available at all times
- provide emotional support for healthcare workers, administrators, patients, and families
- use performance improvement tools to track and enhance disclosure

9.5.3 'T.R.A.C.K.'

The T.R.A.C.K acronym was proposed by Truog and colleagues for five core relational values that enable sound open disclosure. These are transparency, respect, accountability, continuity and kindness. An adapted version is presented in the table below.

Table 10 The T.R.A.C.K. framework (adapted from Truog 2007⁴⁸)

Value	Definition	Optimal patient and staff outcome
Transparency	Being frank, open and obvious	'I've had timely access to the information and input I needed'
Respect	Esteem for the intrinsic value of a person	'I've been valued as a human being by the people helping me' 'I've been respected throughout the process by my colleagues and management'
Accountability	Being answerable or called to account for intent, decision and actions	'The right people have assumed responsibility for their actions'
Continuity	Continuous and connected actions and activity over a period of time	'The care I've received makes sense and fits together'
Kindness	Acting in a caring, considerate and compassionate manner	'I've been treated with warmth, empathy and compassion'

References

12. Iledema R, Allen S, Sorensen R, Gallagher TH. What prevents incident disclosure, and what can be done to promote it? *Joint Commission Journal on Quality and Patient Safety* 2011;37(9):409–417.
19. Piper D, Iledema R. *Literature review: Incident disclosure policy, legal reform and research since 2008*. Sydney: Centre for Health Communication (University of Technology Sydney) and ACSQHC (Australian Commission on Safety and Quality in Health Care), 2011.
20. Allan A, Munro B. *Open disclosure: A review of the literature*. Perth: Edith Cowan University, 2008.
21. O'Connor E, Coates HM, Yardley IE, Wu AW. Disclosure of patient safety incidents: A comprehensive review. *International Journal on Quality in Health Care* 2010;22(5):371–379.
48. Truog RD, Browning DM, Johnson JA, Gallagher TH. *Talking with patients and families about medical error: A guide for education and practice*. Baltimore: Johns Hopkins University Press, 2011.

85. Iedema R, Jorm C, Wakefield J, Ryan C, Sorensen R. A new structure of attention? Open disclosure of adverse events to patients and families. *Journal of Language & Social Psychology* 2009;28(2):139–157.
89. Gallagher TH, Denham CR, Leape LL, Amori G, Levinson W. Disclosing unanticipated outcomes to patients: The art and practice. *Journal of Patient Safety* 2007;3(3):158–165.
91. Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *New England Journal of Medicine* 2007;356(2007):2713–2719.
133. Rabow MW, Remen RN, Parmelee DX, Inui TS. Professional formation: Extending medicine's lineage of service into the next century. *Academic Medicine* 2010;85(2):310–317.
220. Walshe K, Shortell S. When things go wrong: How health care organizations deal with major failures. *Health Affairs* 2004;23(23):109–118.
251. Levinson W, Gallagher TH. Disclosing medical errors to patients: A status report in 2007. *Canadian Medical Association Journal* 2007;177(3):265–267.
271. Silverman HJ. Organizational ethics in health care: Proactively managing the ethical climate to ensure organizational integrity. *HEC Forum* 2000;12(3):202–215.
292. Studdert DM, Mello MM, Gawande AA, Brennan TA, Wang YC. Disclosure of medial injury to patients: An improbable risk management strategy. *Health Affairs* 2007;26(1):215–226.
300. Iedema R. Attitudes toward error disclosure need to engage with systems thinking. *The Joint Commission Journal on Quality and Patient Safety* 2010;36(3):99–100.
308. Cleveland C. *Sacred space: Stories from a life in medicine*. Philadelphia, PA: American College of Physicians, 1998.
309. Sloan FA, Shadle JH. Is there empirical evidence for 'defensive medicine'? A reassessment. *Journal of Health Economics* 2009;28(2):481–491.
310. Kessler DP, McLellan MB. How liability law affects medical productivity. *Journal of Health Economics* 2002;21:931–955.
311. Baicker K, Fisher ES, Chandra A. Malpractice liability costs and the practice of medicine in the medicare program. *Health Affairs* 2007;26(3):841–852.
312. Baicker K, Chandra A. The effect of malpractice liability on the delivery of health care. *Frontiers in Health Policy Research: Forum for Health Economics & Policy*, 2005.
313. Fuchs V. The doctor's dilemma — what is 'appropriate' care? *New England Journal of Medicine* 2011;365(7):585–587.
314. Kilo C, Larson E. Exploring the harmful effects of health care. *Journal of the American Medical Association* 2009;302(1):89–91.
315. Leape L. *Transparency and public reporting are essential for a safe health care system*. New York, NY: The Commonwealth Fund, 2010.



Appendix: Examples of open disclosure programs and strategies

Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology, expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

Appendix: Examples of open disclosure programs and strategies

While systematic implementation has proved challenging, open disclosure has been implemented successfully in a variety of healthcare organisations around the world. These include large, multi-centre health services and smaller facilities, as well as both public and private organisations. Some medical indemnity insurers have instituted open disclosure programs. It should be noted that open disclosure is a component of the programs instituted in these examples.

The Mater Hospital Group, Australia

There are many open disclosure success stories in Australia. Mater Health Services Brisbane is among them.

Mater recognises that openly discussing adverse events and near misses with patients and their families is an integral component of Mater's mission and values, and is openly committed to the principles of open disclosure and the promotion of a safety culture that values transparency, honesty and respect.

Mater's Clinical Safety and Quality Unit (CSQU) was formed in 2002. The CSQU's role is broad, and includes responsibility for medico-legal advice relevant to open disclosure. The Mater's approach to open disclosure has included the introduction of inhouse medico-legal counsel to the Mater campus in September 2003, and inhouse claims management in January 2004. These staff members play an important role in staff education, early liaison with patients and their families and, where indicated, early resolution of complaints, claims and compensation.

Other steps that Mater has introduced and are integral to comprehensive implementation of open disclosure include:

- Engagement of an external contractor in May 2004 to advise CSQU on how Mater might design and implement a communications and training package to educate and engage all clinicians in the roll out of open disclosure practices and clinical incident management.
- Subsequent engagement of the same contractor to assist with the training of senior clinical colleagues as leaders and mentors in open disclosure and clinical incident communication and management. This centred on development of advanced clinical communication skills to enable appropriate, open and honest conversations with patients and their families following serious adverse events.
- Development of a service-wide *Open Disclosure Policy* that was comprehensively promoted across the entire health service.

For the majority of reported clinical incidents, open disclosure now takes place as a matter of course, initiated by the clinicians involved in patient care. Mater recognises that ensuring early and comprehensive disclosure with the patient in relation to an event fosters a good rapport with the patient and their family and which ultimately will have a positive influence on patient clinical care and the rapid resolution of the patient's concerns.

During the past few years, Mater has received a considerable amount of positive feedback from patients and families on its approach to open disclosure. The advantageous interaction between patient safety, adverse events and adverse financial outcomes has emerged since the inception of the program.

COPIC Insurance Company '3Rs' Program

COPIC insures physicians in Colorado. In 2000, COPIC adopted a voluntary early intervention program for harmful incidents that do not involve death or clear negligence. The '3Rs' program focuses on:

- recognising an unanticipated event
- responding promptly
- resolving the issue.

COPIC trains and supports physicians in communicating openly with patients following harm. Financial assistance is available on a 'no fault' basis. Approximately half of COPIC's physicians participate. This cohort experiences slightly (not significantly) lower claims than the other half. Incidents handled through the program are resolved more 'amicably' than if they were litigated.^{48, 91, 291}

University of Michigan Hospital

Michigan's 'full disclosure and offer' program was instituted in 2001. It consists of three basic components: compensate patients quickly and fairly; defend cases considered to be without merit; and study all harmful incidents to determine how procedures could be improved. The program has halved the number of pending lawsuits resulting in a total average annual savings of US\$2 million.^{235, 290}

Following implementation, the average monthly rates of new claims and lawsuits, and the median time from claim reporting to resolution all decreased significantly. Average monthly rates decreased significantly for total liability, patient compensation, and non-compensation related legal costs.^{74, 77, 235}

University of Illinois Medical Centre's Seven Pillars Process

The University of Illinois at Chicago's Seven Pillars Process, a Michigan-style disclosure program, was implemented in 2006. The process is another good example of integrating risk management, system improvement and open disclosure. The seven pillars are:

- 1 incident reporting
- 2 investigation
- 3 communication and disclosure
- 4 apology and remediation

- 5 system improvement
- 6 data tracking and performance evaluation
- 7 education.¹⁵⁵

In the first two years post-implementation, the process led to more than 2000 incident reports annually, prompted more than 100 investigations with root cause analyses, translated into nearly 200 system improvements and served as the foundation of 106 disclosure conversations and 20 full disclosures of inappropriate or unreasonable care causing harm to patients.¹⁵⁵

References

- 48. Truog RD, Browning DM, Johnson JA, Gallagher TH. *Talking with patients and families about medical error: A guide for education and practice*. Baltimore: Johns Hopkins University Press, 2011.
- 74. Kraman SS, Hamm G. Risk management: Extreme honesty may be the best policy. *Annals of Internal Medicine* 1999;131(12):963–967.
- 77. Kraman SS, Cranfill L, Hamm G, Woodard T. Advocacy: The Lexington Veterans Affairs Medical Center. John M. Eisenberg patient safety awards. *Joint Commission Journal for Quality Improvement* 2002;28(12):646–650.
- 91. Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *New England Journal of Medicine* 2007;356(2007):2713–2719.
- 155. McDonald TB, Helmchen LA, Smith KM. Responding to patient safety incidents: The ‘seven pillars’. *Quality and Safety in Health Care* 2010;19:e11.
- 235. Kachalia L, Kaufman S, Boothman R. Liability claims and costs before and after implementation of a medical error disclosure program. *Annals of Internal Medicine* 2010;153:213–221.
- 290. Boothman R, Blackwell AC, Campbell DA, Commiskey E, Anderson S. A better approach to medical malpractice claims? The University of Michigan experience. *Journal of Health and Life Sciences Law* 2009;2(2):125–159.
- 291. Quinn RE, Eichler MC. The 3Rs program: The Colorado experience. *Clinical Obstetrics and Gynecology* 2008;51:709–718.

Bibliography

1. Mohr J, Batalden P, Barach P. Integrating patient safety into the clinical microsystem. *Quality and Safety in Health Care* 2004;13(suppl 2):ii34–ii38.
2. WHO (World Health Organization). *The international classification for patient safety*. Geneva: WHO, 2009.
3. Joint Commission. Sentinel event policy and procedures 2011. (Accessed November 2011, at http://www.jointcommission.org/Sentinel_Event_Policy_and_Procedures)
4. Conway J, Federico F, Stewart K, Campbell M. *Respectful management of serious clinical adverse events* (2nd ed.). Cambridge, Massachusetts: Institute for Healthcare Improvement, 2011.
5. WHO (World Health Organization). *World alliance for patient safety*. Geneva: WHO, 2004.
6. Institute of Medicine. *To err is human: Building a safer health system*. Washington DC, 2000.
7. Leape L. Institute of Medicine medical error figures are not exaggerated. *Journal of the American Medical Association* 2000;284(1):95.
8. Wilson R, McL., Harrison BT, Gibberd RW, Hamilton JD. An analysis of adverse events from the quality in Australian health care study. *Medical Journal of Australia* 1999;170:411–415.
9. Wilson R, Runciman WB, Gibberd RW, Harrison B, Newby L, Hamilton J. The quality in Australian health care study. *Medical Journal of Australia* 1995;163(9):458–471.
10. Australian Council for Safety and Quality in Health Care. Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care. Canberra, 2003.
11. Iedema R, Allen S, Britton K, Piper D, Baker A, Gribich C, et al. Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The '100 patient stories' qualitative study. *British Medical Journal* 2011;343(d4423).
12. Iedema R, Allen S, Sorensen R, Gallagher TH. What prevents incident disclosure, and what can be done to promote it? *Joint Commission Journal on Quality and Patient Safety* 2011;37(9):409–417.
13. Iedema R, Allen S, Britton K, Gallagher TH. What do patients and relatives know about problems and failures in health care? *BMJ Quality and Safety* 2011;doi 10.1136/bmjqs-2011-000100.
14. ACSQHC (Australian Commission on Safety and Quality in Health Care). Independent research into patient and provider views and experiences with open disclosure: University of Technology, Sydney, 2011.
15. Ovreteit J. Understanding the conditions for improvement: Research to discover which context influences affect improvement success. *BMJ Quality and Safety* 2011;20(Suppl 1):i18–i23.
16. Ovreteit J, Shekelle P, Sydney M, McDonald K, Hempel S, Pronovost P, et al. How does context affect interventions to improve patient safety? An assessment of evidence from studies of five patient safety practices and proposals for research. *BMJ Quality and Safety* 2011.;20:604–610 doi:10.1136/bmjqs.2010.047035
17. Millar A. Is money spent on quality improvement better spent on clinical care? — yes. *Medical Journal of Australia* 2011;194(12):640.
18. Iedema R, Sorensen R, Piper D. Open disclosure: Review of the literature. Sydney: ACSQHC (Australian Commission on Safety and Quality in Health Care), 2008.
19. Piper D, Iedema R. *Literature review: Incident disclosure policy, legal reform and research since 2008*. Sydney: Centre for Health Communication (University of Technology Sydney) and ACSQHC (Australian Commission on Safety and Quality in Health Care), 2011
20. Allan A, Munro B. *Open disclosure: A review of the literature*. Perth: Edith Cowan University, 2008.
21. O'Connor E, Coates HM, Yardley IE, Wu AW. Disclosure of patient safety incidents: A comprehensive review. *International Journal on Quality in Health Care* 2010;22(5):371–379.

22. Gallagher TH. A 62-year-old woman with skin cancer who experienced wrong-site surgery. *Journal of the American Medical Association* 2009;302(6):669–677.
23. Runciman WB, Merry AF, Tito F. Error, blame, and the law in health care — an antipodean perspective. *Annals of Internal Medicine* 2003;138(12):974.
24. Productivity Commission. Disability care and support: Report no. 54. 2011. (Accessed on 15 May 2012 at http://www.pc.gov.au/__data/assets/pdf_file/0012/111270/disability-support-volume1.pdf http://www.pc.gov.au/__data/assets/pdf_file/0013/111271/disability-support-volume2.pdf)
25. Sinclair CM. *The report of the Manitoba pediatric cardiac surgery inquest: An inquiry into twelve deaths at the Winnipeg Health Sciences Centre in 1994*. Winnipeg: Provincial Court of Manitoba, 2000.
26. Kennedy I. *Learning from Bristol: The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995*. London: Department of Health, 2001.
27. Douglas N, Robinson J, Fahy K. *Inquiry into obstetric and gynaecological services at King Edward Memorial Hospital 1990–2000*. Perth: Government of Western Australia, 2001.
28. Donaldson L. *An organisation with a memory: Report of an expert group on learning from adverse events in the NHS*. Norwich, UK: NHS Stationery Office, 2000.
29. Kohn LT, Corrigan JM, Donaldson MS. *To err is human: Building a safer health system*. Washington DC: National Academy Press, 1999.
30. Brennan TA, Leape LL, Laird MM, Nan M, Hebert L, Localio AR, et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard medical practice study. *New England Journal of Medicine* 1991;324:370–376.
31. Leape LL. Error in medicine. *Journal of the American Medical Association* 1994;272(23):1851–1857.
32. Classen D, Resar R, Griffin F, Federico F. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Affairs* 2011;30(4):581–589.
33. Hauck K, Zhao X, Jackson T. Adverse event rates as measures of hospital performance. *Health Policy* 2012;104(2):146–154.
34. Zwaan L, de Bruijne M WC, Thijs A, Smits M, van der Wal G. Patient record review of the incidence, consequences and causes of diagnostic adverse events. *Archives of Internal Medicine* 2010;170(12):1015–1021.
35. Levinson DR. *Hospital incident reporting systems do not capture most patient harm*. Washington, DC: US Department of Health and Human Services, Office of the Inspector General, Report No. OEI-06-09-00091, 2012.
36. ABS (Australian Bureau of Statistics). Patient experiences in Australia 2009. Australian Bureau of Statistics. (Accessed November 2011, at <http://www.abs.gov.au/ausstats/abs@.nsf/Products/4839.0.55.001~2009~Chapter~Harm+and+harmful+side-effects?OpenDocument>)
37. Christiaans-Dingelhoff I, Smits M, Zwaan L. To what extent are adverse events found in patient records reported by patients and healthcare professionals via complaints, claims and incident reports? *Health Services Research* 2011;11(49) doi:10.1186/1472-6963-11-49.
38. Sari ABA, Sheldon TA, Cracknell A, Turnbull A. Sensitivity of routine systems for reporting patient safety incidents in an NHS hospital: Retrospective patient case note review. *British Medical Journal* 2007;334(79):79–81.
39. Daniels JP, Hunc K, Cochrane D, Carr R, Shaw NT, Taylor A, et al. Identification by families of pediatric adverse events and near misses overlooked by health care providers. *Canadian Medical Association Journal* 2012; 184(1):29–34.
40. de Feijter JM, de Grave WS, Muijtjens AM, Scherpbier AJJA, Koopmans RP. A comprehensive overview of medical error in hospitals using incident-reporting systems, patient complaints and chart review of inpatient deaths. *PLoS ONE* 2012;7(2):e31125.
41. Robotham J.. How could this happen? Hospital blunder turns a family's joy into heartbreak. Sydney: *Sydney Morning Herald*, 1 August 2010.

42. Editorial. State falters at first test of hospital reform. Melbourne: *The Age* 19 August 2011.
43. Merry AF, Peck DJ. Anaesthetists, errors in drug administration and the law. *NZ Medical Journal* 1995;108(185–187).
44. Kronman AC, Paasche-Orlow M, Orlander JD. Factors associated with disclosure of medical errors by housestaff. *BMJ Quality and Safety* 2011;doi:10.1136/bmjqs-2011-000084.
45. Gallagher T, Waterman A, Garbutt J, Kapp J, Chan D, Dunagan W, et al. US and Canadian physicians' attitudes and experiences regarding disclosing errors to patients. *Archives of Internal Medicine* 2006;166(15):1605–1611.
46. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *Journal of the American Medical Association* 2003;289(8):1001–1007.
47. Espin S, Levinson W, Baker R, Lingard L. Error or 'act of God'? A study of patients' and operating room team members' perceptions of error definition, reporting, and disclosure. *Surgery* 2006;139(1):6–14.
48. Truog RD, Browning DM, Johnson JA, Gallagher TH. *Talking with patients and families about medical error: A guide for education and practice*. Baltimore: Johns Hopkins University Press, 2011.
49. Gallagher TH, Lucas MH. Should we disclose harmful medical errors to patients? If so, how? *Journal of Clinical Outcomes Management* 2005;12(5):253–259.
50. Iezzoni LI, Rao SR, DesRoches CM, Vogeli C, Campbell EG. Survey shows that at least some physicians are not always open or honest with patients. *Health Affairs* 2012;31(2):383–391.
51. Valentine N, Darby C, Bonsel GJ. Which aspects of non-clinical quality of care are most important? Result from WHO's general population surveys of 'health system responsiveness' in 41 countries. *Social Science and Medicine* 2008;66:1939–1950.
52. Blendon R, DesRoches C, Brodie M, Benson M, Rosen A, Schnieder E, et al. Views of practising physicians and the public on medical errors. *New England Journal of Medicine* 2002;347(24):1933–1940.
53. Kenagy JW, Berwick DM, Shore MF. Service quality in health care. *Journal of the American Medical Association* 1999;281:661–665.
54. Garbutt J, Waterman AD, Kapp JM, Dunagan WC, Levinson W, Fraser V, et al. Lost opportunities: How physicians communicate about medical errors. *Health Affairs* 2008;27(1):246–255.
55. ACSQHC (Australian Commission on Safety and Quality in Health Care). *Patient-centred care: Improving quality and safety through partnerships with patients and consumers*. Sydney: ACSQHC, 2011.
56. Bodenheimer T. Coordinating care — a perilous journey through the health care system. *New England Journal of Medicine* 2008;358(10):1064–1071.
57. Haggerty JL, Reid RJ, Freeman GK, Starfield BH, Adair CE, McKendry R. Continuity of care: A multidisciplinary review. *British Medical Journal* 2003;327(7425):1219–1221.
58. Lewis GH, Vaithanathan R, Hockey PM, Hirst G, Bagian J. Counterheroism, common knowledge, and ergonomics: Concepts from aviation that could improve patient safety. *The Milbank Quarterly* 2011;89(1):4–38.
59. Gawande A. *The checklist manifesto: How to get things right*. New York: Metropolitan Books, 2010.
60. Gawande A. 'Cowboys and pit crews' speech to Harvard medical graduates 26 May 2011.
61. Morey JC, Simon R, Jay GD. Error reduction and performance improvement in the emergency department through formal teamwork training: Evaluation results of the med teams project. *Health Service Research* 2002;37:1553–1581.
62. Nugus P, Greenfield D, Travaglia J. How and where clinicians exercise power: Interprofessional relations in health care. *Social Science and Medicine* 2010;71:898–909.
63. Espin SL, Lingard LA. Time as a catalyst for tension in nurse–surgeon communication. *Association of Operating Room Nurses Journal* 2001;74(5):672–682.

64. Fischer M, Ereaut G. *Can changing clinician–patient interactions improve healthcare quality? A scoping report for the health foundation*. London: Health Foundation, 2011.
65. Pronovost P. Navigating adaptive challenges in quality improvement. *BMJ Quality and Safety* 2011;20(7):560–563.
66. Braithwaite J, Skinner CA, Doerin ML. A values-based health system. *Medical Journal of Australia* 2011;194(5):259–262.
67. Cannon J, Berwick DM. A new frontier in patient safety. *Journal of the American Medical Association* 2011;305(21):2221–2.
68. Foye R, Ovretveit J, Shekelle P. The role of theory in research to develop and evaluate the implementation of patient safety practices. *BMJ Quality and Safety* 2011;20:453–459.
69. Espin S, Lingard L, Baker GR, Regehr G. Persistence of unsafe practice in everyday work: An exploration of organizational and psychological factors constraining safety in the operating room. *Quality and Safety in Health Care* 2006;15(3):165–170.
70. Peterkin A. Guidelines covering disclosure of errors now in place at Montreal Hospital. *Canadian Medical Association Journal* 1990;142(1990):984–985.
71. Berwick D. What patient-centered care should mean: Confessions of an extremist. *Health Affairs* 2010;28(4):w555–w565.
72. Wachter RM. The end of the beginning: Patient safety five years after ‘to err is human’. *Health Affairs* 2004;November 2004:W4/534–545.
73. Massachusetts Coalition for the Prevention of Medical Errors. *When things go wrong: Responding to adverse events (a consensus statement of the Harvard hospitals)*, 2006.
74. Kraman SS, Hamm G. Risk management: Extreme honesty may be the best policy. *Annals of Internal Medicine* 1999;131(12):963–967.
75. Berwick D. *Escape the fire: Lessons for the future of health care*. New York: Commonwealth Fund, 2002.
76. Woods MS. *Healing words: The power of apology in medicine*. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations, 2007.
77. Kraman SS, Cranfill L, Hamm G, Woodard T. Advocacy: The Lexington Veterans Affairs Medical Center. John M. Eisenberg patient safety awards. *Joint Commission Journal for Quality Improvement* 2002;28(12):646–650.
78. National Patient Safety Agency. *Being open: Communicating patient safety incidents with patients, their families and carers*. London: NHS (National Health Service), 2009.
79. Canadian Patient Safety Institute. *Canadian disclosure guidelines*. Edmonton, AB: Canadian Patient Safety Institute, 2008.
80. DVA (Department of Veterans Affairs). *Disclosure of adverse events to patients (VHA directive 2008-002)*. Washington: DVA, Veterans Health Administration, 2008.
81. National Patient Safety Agency. *Being open. Communicating patient safety incidents with patients and their carers*. Whitehall, London: NHS (National Health Service), 2005.
82. Disclosure Working Group. *Canadian open disclosure guidelines: Being open and honest with patients and families*. Edmonton, AB: Canadian Patient Safety Institute, 2011.
83. Health & Disability Commissioner. *Code of health and disability services consumers’ rights New Zealand*. 1996. (Accessed November, 2011, (Accessed 15 May 2012 at <http://www.hdc.org.nz/the-act--code/the-code-of-rights>)
84. Health & Disability Commissioner. *Guidance on open disclosure policies*. Wellington, New Zealand: Health & Disability Commissioner, 2009.
85. Iedema R, Jorm C, Wakefield J, Ryan C, Sorensen R. A new structure of attention? Open disclosure of adverse events to patients and families. *Journal of Language & Social Psychology* 2009;28(2):139–157.

86. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. *Final report: Evaluation of the National Open Disclosure pilot program*. Sydney: The Australian Commission on Safety and Quality in Health Care (ACSQHC), 2008.
87. Pace WD, Staton EW. Improving the disclosure of medical incidents: A genuine apology is only the first step in the process. *British Medical Journal* 2011;342:d4340.
88. Gallagher TH. *Disclosing harmful errors to patients: Recent developments and future directions*. Open Disclosure Seminar. Sydney: University of Technology Sydney, 2009.
89. Gallagher TH, Denham CR, Leape LL, Amori G, Levinson W. Disclosing unanticipated outcomes to patients: The art and practice. *Journal of Patient Safety* 2007;3(3):158–165.
90. Gallagher TH, Garbutt JM, Waterman AD, Flum DR, Larson EB, Waterman BM, et al. Choosing your words carefully: How physicians would disclose harmful medical errors to patients. *Archives of Internal Medicine* 2006;166(August 14–28):1585–1593.
91. Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *New England Journal of Medicine* 2007;356(2007):2713–2719.
92. Wu A, Huang IC, Stokes S, Pronovost P. Disclosing medical errors to patients: It's not what you say, it's what they hear. *Journal of General Internal Medicine* 2009;24(9):1012–1017.
93. Hopgood C, Peck C, Gilbert B, Chappell K, Zou BL. Medical errors - what and when: What do patients want to know? *Academic Emergency Medicine* 2002;9:1156–1161.
94. Duclos CW, Eichler M, Taylor L, Quintela J, Main DS, Pace W, et al. Patient perspectives of patient-provider communication after adverse events. *International Journal for Quality in Health Care* 2005;17(6):479–486.
95. Rathert C, Brandt J, Williams ES. Putting the 'patient' in patient safety: A qualitative study of consumer experiences. *Health Expectations* 2011;doi:10.1111/j.1369-7625.2011.00685.
96. Fisseni G, Pentzek M, Abholz HH. Responding to serious medical error in general practice — consequences for the GPs involved: Analysis of 75 cases from Germany. *Family Practitioner* 2008;25(1):9–13.
97. Hopgood C, Tamayo-Sarver JH, Weiner B. Patient race/ethnicity, age, gender and education are not related to preference for or response to disclosure. *Quality and Safety in Health Care* 2008;17:65–70.
98. Iedema R, Mallock N, Sorensen R, Manias E, Tuckett A, Williams A, et al. The National Open Disclosure Pilot: Evaluation of a policy implementation initiative. *Medical Journal of Australia* 2008;188(2008):397–400.
99. Studdert D, Richardson MW. Legal aspects of open disclosure: A review of Australian law. *Medical Journal of Australia* 2010;193(5):273–276.
100. Studdert D, Piper D, Iedema R. Legal aspects of open disclosure II: Attitudes of health professionals — findings from a national survey. *Medical Journal of Australia* 2010;193(6):351–355.
101. Brown D. *Open disclosure: Morally right, but is it legally safe?* Medico-Legal Society of NSW Inc Scientific Meeting. Sydney, 2008.
102. Vines P. Apologising to avoid liability: Cynical civility or practical morality? *Sydney Law Review* 2005;27(3):483–505.
103. Vines P. *The power of apology: Mercy, forgiveness or corrective justice in the civil liability arena?* University of New South Wales Faculty of Law Research Series 2007;2007(30):1–29.
104. RACGP (Royal Australian College of General Practitioners). *Regaining trust after an adverse event. An education module on managing adverse events in general practice*. Melbourne: RACGP, ISBN 978-0-86906-292-0, 2008.
105. Paterson R. *The review team for the review of future governance arrangements for safety and quality in health care. National arrangements for safety & quality of health care in Australia: The report of the review of future governance arrangements for safety and quality in health care*. Canberra: Australian Health Ministers' Conference, 2005.

106. ACSQHC (Australian Commission on Safety and Quality in Health Care). *National Safety and Quality Health Service (NSQHS) Standards*. Sydney, 2011.
107. Mazor KM, Greene SM, Roblin D. More than words: Patients' views on apology and disclosure when things go wrong in cancer care. *Patient Education and Counseling* 2011(August 6).
108. Okamoto S, Kawahara K, Algren M. Transformative possibilities of communication in medical error cases in Japan. *International Journal on Quality in Health Care* 2011;23(1):26–35.
109. Nie J-B. The 'cultural differences' argument and its misconceptions: The return of medical truth-telling in China. In: Rudnick A, editor. *Bioethics in the 21st century*. Shanghai: InTech, 2011:103–120.
110. Clinton HR, Obama B. Making patient safety the centerpiece of medical liability reform. *New England Journal of Medicine* 2006;354(2006):2205–2208.
111. Dauer EA. Medical injury, patients' claims and the effect of government responses in Anglo-American legal systems. *BMJ Quality and Safety* 2011;9:735–737.
112. Golann D. Dropped medical malpractice claims: Their surprising frequency, apparent causes, and potential remedies. *Health Affairs* 2011;30(7):1343–1350.
113. Vincent CA, Young M, Phillips A. Why do people sue doctors? A study of patients and relatives taking legal action. *Lancet* 1994;343:1609–1613.
114. Taylor J. *The impact of disclosure of adverse events on litigation and settlement: A review for the Canadian patient safety institute*. Ottawa: Canadian Patient Safety Institute, 2007.
115. Bismark M, Dauer E, Paterson R, Studdert D. Accountability sought by patients following adverse events from medical care: The New Zealand experience. *Canadian Medical Association Journal* 2006;175(2006):889–894.
116. Schwappach DLB, Koeck CM. What makes an error unacceptable? A factorial survey on the disclosure of medical errors. *International Journal for Quality in Health Care* 2004;16(4):317–326.
117. Wu AW. Medical error: The second victim. *British Medical Journal* 2000;320(7237):726–727.
118. Peto RR, Tenerowicza LM, Benjamin EM, Morsi DS, Burger PK. One system's journey in creating a disclosure and apology program. *Joint Commission Journal on Quality and Patient Safety* 2009;35(10):487–496.
119. Finkelstein D, Wu AW, Holtzman N, et al. When a physician harms a patient by medical error: Ethical, legal, and risk-management considerations. *Journal of Clinical Ethics* 1997;8:330–335.
120. Sweet MP, Bernat JL. A study of the ethical duty of physicians to disclose errors. *Journal of Clinical Ethics* 1997;8(4):341–318.
121. Hingorani M, Wong T, Vafidis G. Patients' and doctors' attitudes to amount of information given after unintended injury during treatment: Cross sectional, questionnaire survey. *British Medical Journal* 1999;318(7184):640–641.
122. Kaldjian LC, Jones EW, Rosenthal GE. Facilitating and impeding factors for physicians' error disclosure: A structured literature review. *Journal on Quality and Patient Safety* 2006;32(4):188–198.
123. Engel KG, Rosenthal M, Sutcliffe KM. Residents' responses to medical error: Coping learning and change. *Academic Medicine* 2006;81:86–93.
124. Garbutt J, Brownstein DR, Klein EJ. Reporting and disclosing medical errors: Paediatricians' attitudes and behaviors. *Archives of Paediatric Adolescent Medicine* 2007;161:179–185.
125. Kaldjian LC, Jones EW, WU BJ, et al. Disclosing medical errors to patients: Attitudes and practices of physicians and trainees. *Journal of General Internal Medicine* 2007;22:988–996.
126. White AA, Gallagher TH, Krauss MJ, Garbutt J, Waterman AD, Dunagan WC, et al. The attitudes and experiences of trainees regarding disclosing medical errors to patients. *Academic Medicine : Journal of the Association of American Medical Colleges* 2008;83(3):250–256.
127. Evans SB, Yu JB, Chagpar A. How radiation oncologists would disclose errors: Results of a survey of radiation oncologists and trainees. *International Journal of Radiation Oncology Biology Physics* 2012.

128. Medical Board of Australia. Good medical practice: A code of conduct for doctors in Australia. Canberra: Medical Board of Australia, 2011. (Accessed on 15 May 2012 at <http://www.medicalboard.gov.au/Codes-Guidelines-Policies.aspx>)
129. Lopez L, Weissman JS, Schneider EC. Disclosure of hospital adverse events and its association with patients' ratings of the quality of care. *Archives of Internal Medicine* 2009;169:1888–1894.
130. Weissman JS, Schneider EC, Weingart SN, Epstein AM, David-Kasdan J, Feibelman S, et al. Comparing patient-reported hospital adverse events with medical record review: Do patients know something that hospitals do not? *Annals of Internal Medicine* 2008;149(2):100–108.
131. Schoen C, Osborn R, Huynh PT, Doty M, Zapert K, Peugh J, et al. Taking the pulse of health care systems: Experiences of patients with health problems in six countries. *Health Affairs* 2005;Web Exclusive W5–509.
132. Loren DJ, Klein EJ, Garbutt J, Krauss MJ, Fraser V, Dunagan WC, et al. Medical error disclosure among pediatricians: Choosing carefully what we might say to parents. *Archives of Pediatrics & Adolescent Medicine* 2008;162(10):922–927.
133. Rabow MW, Remen RN, Parmelee DX, Inui TS. Professional formation: Extending medicine's lineage of service into the next century. *Academic Medicine* 2010;85(2):310–317.
134. Hojat M, Vergare MJ, Maxwell K. The devil is in the third year: A longitudinal study of erosion of empathy in medical school. *Academic Medicine* 2009; 84(9):1182–1191.
135. Hojat M, Louis DZ, Marham FW. Physicians' empathy and clinical outcomes for diabetic patients. *Academic Medicine* 2011;86(3):359–364.
136. Peabody F. The care of the patient. *Journal of the American Medical Association* 1927;88(12):882.
137. Prictor M, Hill S. Does communication with consumers and carers need to improve? In: Hill S, editor. *The knowledgeable patient: Communication and participation in health - a Cochrane handbook*. Oxford, UK: Wiley-Blackwell Publishing Ltd, 2011.
138. Young-Xu Y, Neily J, Mills PD, Carney BT, West P, Berger DH, et al. Association between implementation of a medical team training program and surgical morbidity. *Archives of Surgery* 2011;146(12):1368–1373.
139. Hull L, Arora S, Aggarwal R, Darzi A, Vincent C, Sevdalis N. The impact of nontechnical skills on technical performance in surgery: A systematic review. *Journal of the American College of Surgeons* 2012;214(2):214–230.
140. Ambady N, LaPlante D, Nguyen T, Rosenthal R, Chaumeton N, Levinson W. Surgeons' tone of voice: A clue to malpractice history. *Surgery* 2002;132(1):5–9.
141. Braithwaite J, Iedema R, Jorm C. Trust, communication, theory of mind and the social brain hypothesis: Deep explanations for what goes wrong in health care. *Journal of Health Organisation and Management* 2007;21(4/5):353–367.
142. Shannon SE, Foglia MB, Hardy M, Gallagher TH. Disclosing errors to patients: Perspectives of registered nurses. *Joint Commission Journal on Quality and Patient Safety* 2009;35(1):5–12.
143. Jeffs L, Espin S, Rorabeck L. Not overstepping professional boundaries: The challenging role of nurses in simulated error disclosure. *Journal of Nursing Care Quality* 2011;26(4):320–327.
144. Loren DJ, et al. Risk managers, physicians, and disclosure of harmful medical errors. *Joint Commission Journal on Quality and Patient Safety* 2010;36(March 2010):101–108.
145. Chamberlain CJ, Koniaris LG, Wu AW, Pawlik TM. Disclosure of 'nonharmful' medical errors and other events: Duty to disclose. *Archives of Surgery* 2012;147(3):282–286.
146. Weingart S, Zhu J, Chiappetta L. Hospitalized patients' participation and its impact on quality of care and patient safety. *International Journal on Quality in Health Care* 2011;23(3):269–277.
147. Weingart SN, Pagovich O, Sands DZ, Li JM, Aronson MD, Davis RB, et al. What can hospitalized patients tell us about adverse events? *Journal of General Internal Medicine* 2005;20(9):830–836.

148. Peat M, Entwistle V, Hall J, et al. Scoping review and approach to appraisal of interventions intended to involve patients in patient safety. *Journal of Health Service Research and Policy* 2010;15(Suppl. 1):17–25.
149. Rathert C, Huddleston N, Pak Y. Acute care patients discuss the patient role in patient safety. *Health Care Management Review* 2011;36:134–144.
150. Wu AW. Is there an obligation to disclose near-misses in medical care? In: Sharpe VA, editor. *Accountability: Patient safety and policy reform*. Washington DC: Georgetown University Press, 2004:135–142.
151. Disclosure Working Group. *Canadian disclosure guidelines*. Edmonton, AB: Canadian Patient Safety Institute, 2008.
152. Wu A, Iedema R, Gallagher TH. Disclosing close calls to patients and their families. In: Wu A, editor. *The value of close calls in improving patient safety: Learning how to prevent and mitigate patient harm*: Joint Commission Resources, 2010.
153. Sorensen R, Iedema R, Piper D, Manias E, Williams A, Tuckett A. Disclosing medical error to patients: Can practice inform policy? *Health Expectations* 2009;13:148–159.
154. Weiss PM, Koch S, Lara-Torre E, Scarrow PK. To air the error: Lowering the barriers to successful disclosure conversations. *The Female Patient* 2011;36:17–21.
155. McDonald TB, Helmchen LA, Smith KM. Responding to patient safety incidents: The ‘seven pillars’. *Quality and Safety in Health Care* 2010;19:e11.
156. Helmchen LA, Richards MR, McDonald TB. Successful remediation of patient safety incidents: A tale of two medication errors. *Health Care Management Review* 2011;April–June 2011.
157. Madden B, Cockburn T. Bundaberg and beyond: Duty to disclose adverse events to patients. *Journal of Law and Medicine* 2007;14(2007):501–527.
158. Lamb RM, Studdert DM, Bohmer RMJ, Berwick DM, Brennan TA. Hospital disclosure practices: Results of a national survey. *Health Affairs* 2003;22(2):73–83.
159. ACSQHC (Australian Commission on Safety and Quality in Health). Australian safety and quality framework for health care. Sydney: ACSQHC, 2010. (Accessed January 2012, at <http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/NSQF>)
160. Iedema R, Jorm C, Wakefield J, Ryan C, Dunn S. Practising open disclosure: Clinical incident communication and systems improvement. *Sociology of Health & Illness* 2009;31(2):262–277.
161. Robbennolt J. Attorneys, apologies and settlement negotiation. Social Science Research Network, 2008. (Accessed 15 May 2012, at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1275419)
162. Wheeler C. *Apologies liability and the public sector*. Sydney: NSW Ombudsman, 2009.
163. Keeva S. Does law mean never having to say you’re sorry? *ABA Journal* 1999;64.
164. Bibas S, Bierschbach R. Integrating remorse and apology into criminal procedure. *Yale Law Journal* 2004;114:85.
165. Alberstein M, Davidovitch N. Apologies in the healthcare system: From clinical medicine to public health. *Duke Law Review* 2011;74:151–175.
166. Lazare A. Apology in medical practice. *Journal of the American Medical Association* 2006;296(11):1401–1404.
167. Bismark M. The power of apology. *New Zealand Journal of Medicine* 2009;122(1304):96–106.
168. Berlinger N. Avoiding cheap grace. *Hastings Center Report* 2003;33(6):28–36.
169. Allan A, McKillop D. The health implications of apologizing after an adverse event. *International Journal on Quality in Health Care* 2010;22(2):126–131.
170. Lundahl BW, Taylor MJ, Stevenson R, Roberts KD. Process-based forgiveness interventions: A meta-analytic review. *Resources of Social Work Practice* 2009;18(5):465–478.

171. Worthington EL, Scherer M. Forgiveness is an emotional focussed coping strategy that can reduce health risks and promote health resilience: Theory, review and hypothesis. *Psychology and Health* 2004;19:385–405.
172. Taft L. Apology subverted. Commodification of apology. *Yale Law Journal* 2000;109:1135.
173. Wojcieszak D, Saxton JW, Finkelstein MM. *Sorry works! Disclosure, apology and relationships prevent medical malpractice claims*. Indiana: Bloomington, 2006.
174. Berlinger N. *After harm: Medical error and the ethics of forgiveness*. Baltimore: Johns Hopkins Press, 2005.
175. NSW (New South Wales) Parliament. *Proceedings before the General Purpose Standing Committee No. 2. Inquiry into review of complaints handling within New South Wales Health*. Sydney: NSW Parliament, 2006.
176. Riess H. Empathy in medicine — a neurobiological perspective. *Journal of the American Medical Association* 2010;304(14):1604–5.
177. Street R, Makoul G, Arora N, Epstein RM. How does communication heal? Pathways linking clinician–patient communication to health outcomes. *Patient Education & Counseling* 2009;74:295–301.
178. Wears RL, Wu A. Dealing with failure: The aftermath of errors and adverse events. *Annals of Emergency Medicine* 2002;39:344–346.
179. Armstrong D. The power of apology: How saying sorry can leave both patients and nurses feeling better. *Nursing Times* 2009;105(44):16–19.
180. Cohen ML. The power of apology. *Family Practice Management* 2010;17(1):40.
181. Wu A, Folkman S, McPhee S, Lo B. How house officers cope with their mistakes. *Western Journal of Medicine* 1993;159:565–569.
182. Lester H, Tritter JQ. Medical error: A discussion of the medical construction of error and suggestions for reforms of medical education to decrease error. *Medical Education* 2001;35:855–861.
183. Lazare A. *On apology*. New York: Oxford University Press, 2004.
184. Taft L. Apology and medical mistake. *Annals of Health Law* 2005;66:14.
185. McDonald T, Smith K, Chamberlin W, Centomani N. Full disclosure is more than saying ‘I’m sorry’. *Focus on Patient Safety* 2008;11:1–3.
186. Tavuchis N. *Mea culpa: A sociology of apology and reconciliation*. Stanford, MA: Stanford University Press, 1991.
187. Robson R, Pelletier E. Giving back the pen: Disclosure, apology and early compensation discussions after harm in the healthcare setting. *Healthcare Quarterly* 2008;11(Special Issue):85–90.
188. Brown J. The role of apology in negotiation. *Marquette Law Review* 2004;87:665.
189. O’Hara E, Yarn D. On apology and consilience. *Washington Law Review* 2002;77:1121.
190. Latif E. Apologetic justice: Evaluating apologies tailored toward legal solutions. *Boston University Law Review* 2001;81:289.
191. Fallowfield L, Jenkins V. Communicating sad, bad, and difficult news in medicine. *The Lancet* 2004;363(9405):312–319.
192. Iedema R. Creating safety by strengthening clinicians’ capacity for reflexivity. *BMJ Quality and Safety* 2011;20(Suppl 1):i83–i6.
193. Liebman CB, Hyman CS. A mediation skills model to manage disclosure of errors and adverse events to patients. *Health Affairs* 2004;23(4):22–32.
194. Allan A. *Implementing the Australian open disclosure standard: The legal situation in Western Australia*. Perth: Edith Cowan University, 2008.
195. Eisenberg D. When doctors say ‘we’re sorry’. *Time Magazine*, 2005.

196. *Dovuro Pty Ltd v Wilkins*. HCA 51; 215 CLR 317; 201 ALR 139; 77 ALJR 1706, 2003.
197. Williams B. *Moral luck*. Cambridge: Cambridge University Press, 1981.
198. Helmreich JS. Does 'sorry' incriminate? Evidence, harm and the meaning of apologies. *Cornell Journal of Law and Public Policy* 2012;21(3):567.
199. Smith P. Sorry mess over apologies. *Australian Doctor* 2007;10 January.
200. Ho B and Liu E. Does sorry work? The impact of apology laws on medical malpractice. 2010. (Accessed November 2011, at <http://ssrn.com/abstract=1744225>)
201. Rees C. Iatrogenic psychological harm. *Archives of Disease in Childhood* 2011. .doi:10.1136/archdischild-2011-300362
202. Boseley S and Campbell D. Negligence claims against GPs rising. *The Guardian*, 29 July 2011. (Accessed November 2011, at <http://www.guardian.co.uk/society/2011/jul/29/negligence-claims-gps-rising>)
203. Edgcumbe D. Patients' perceptions of hospital cleanliness are correlated with rates of methicillin resistant staphylococcus aureus bacteraemia. *Journal of Hospital Infection* 2009;71(1):99–101.
204. Isaac T, Zaslavsky AM, Cleary PD, Landon BE. The relationship between patients' perception of care and measures of hospital quality and safety. *Health Services Research* 2010;45(4):1024–1040.
205. Duckett S. Health care reform: Are we ready for the next big thing? *Medical Education* 2009;90(12):687–688.
206. Berwick D. *The moral test: Keynote presentation at the 23rd IHI annual national forum on quality improvement in health care*. Orlando, FL, December 2011.
207. Department of Health. *The operating framework for the NHS in England 2012/13*. Whitehall, London: National Health Service (NHS), 2011.
208. Australian Government. MyHospitals website. (Accessed November 2011, at <http://www.myhospitals.gov.au>)
209. Healthscope, 2011. MyHealthscope — accreditation, quality & safety: Measures of hospital performance. (Accessed 15 May 2012, at <http://www.healthscopehospitals.com.au/index.php/myhealthscope>)
210. Donabedian A. *Explorations in quality assessment and monitoring: The definition of quality and approaches to assessment*. Ann Arbor, MI: Health Administration Press, 1980.
211. Mooney G. Beyond health outcomes: The benefits of health care. *Health Care Analysis* 1998;6(2):99–105.
212. Campbell SM, Roland MO, Buetow SA. Defining quality of care. *Social Science and Medicine* 2000;51:1611–1625.
213. Hojat M. Ten approaches for enhancing empathy in health and human services culture. *Journal of Health and Human Services Administration* 2009;31:412–450.
214. Taylor BB, Marcantonio ER, Pagovich O, Carbo A, Bergmann M, Davis RB. Do medical inpatients who report poor service quality experience more adverse events and medical errors? *Medical Care* 2008;46(2):224–8.
215. Larson CO, Nelson EC, Gustafson D, Batalden P. The relationship between meeting patients' information needs and their satisfaction with hospital care and general health status outcomes. *International Journal for Quality in Health Care* 1996;8(5):447–456.
216. Greaves F, Pape UJ, King D, Darzi A, Majeed A, Wachter RM, et al. Associations between web-based patient ratings and objective measures of hospital quality. *Archives of Internal Medicine* 2012;172(5):435–436.
217. Little M, Jordens CFC, McGrath C, Montgomery K, Lipworth W, Kerridge I. Informed consent and medical ordeal: A qualitative study. *Internal Medicine Journal* 2008;38:624–8.

218. Iedema R, Sorensen R, Manias E, Tuckett A, Piper D, Mallock N, et al. Patients' and family members' experiences of open disclosure following adverse events. *International Journal for Quality in Health Care* 2008;20(6):421–432.
219. Kuzel AJ, Woolf SH, Gilchrist VJ, Engel JD, LaVeist TA, Vincent C, et al. Patient reports of preventable problems and harms in primary health care. *Annals of Family Medicine* 2004;2(4):333–340.
220. Walshe K, Shortell S. When things go wrong: How health care organizations deal with major failures. *Health Affairs* 2004;23(23):109–118.
221. Mooney G. *Challenging health economics*. New York: Oxford University Press, 2009.
222. Entwistle VA. Hurtful comments are harmful comments: Respectful communication is not just an optional extra in health care. *Health Expectations* 2008;11:319–320.
223. Huyard C. What, if anything, is specific about having a rare disorder? Patients' judgements on being ill and being rare. *Health Expectations* 2009;12:361–370.
224. Phillips, Y. Fetus mum sues hospital. *The Sunday Times*, 21 August 2011.
225. Cantor MD, Barach P, Derse A, Maklan CW, Wlody GS, Fox E. Disclosing adverse events to patients. *Joint Commission Journal on Quality and Safety* 2005;31(1):5–12.
226. Burroughs T, Waterman A, Gallagher TH. Patients' concerns about medical errors during hospitalization. *Joint Commission Journal on Quality and Patient Safety* 2007;33:5–14.
227. Joint Commission. *Comprehensive accreditation manual: The official handbook*. Oakbrook Terrace, IL: Joint Commission, 2011.
228. Health Quality Council of Alberta. *Disclosure of harm to patients and families: Provincial framework*. Calgary, AB: Health Quality Council of Alberta, 2006.
229. ACSQHC (Australian Commission on Safety and Quality in Health Care). *Australian charter for health care rights*. Sydney: ACSQHC, 2008.
230. Newell SM, Jones DA, Hatlie MJ. Partnership with patients to improve patient safety. *Medical Journal of Australia* 2009;92(2):63–64.
231. Cunningham W, Wilson H. Complaints shame and defensive medicine. *BMJ Quality and Safety* 2011;Doi 10.1136/bmjqs.2011.051722.
232. Berg JW, Appelbaum PS, Lidz CW, Parker LS. *Informed consent: Legal theory and clinical practice* (2nd ed). New York, NY: Oxford University Press, 2001.
233. Cassell EJ, Leon AC, Kaufmann SG. Preliminary evidence of impaired thinking in sick patients. *Annals of Internal Medicine* 2001;134(12):1120–23.
234. Gogos AJ, Clark RB, Bismark MM, Gruen RL, Studdert DM. When informed consent goes poorly: A descriptive study of medical negligence claims and patient complaints. *Medical Journal of Australia* 2011;195:340–344.
235. Kachalia L, Kaufman S, Boothman R. Liability claims and costs before and after implementation of a medical error disclosure program. *Annals of Internal Medicine* 2010;153:213–221.
236. Mello MM, Gallagher TH. Malpractice reform — opportunities for leadership by health care institutions and liability insurers. *New England Journal of Medicine* 2010;362:1353–56.
237. Schwappach DLB, Boluarte TA. The emotional impact of medical error involvement on physicians: A call for leadership and organisational accountability. *Swiss Medical Weekly* 2008;October 14.
238. Wu AW, Steckelberg RC. Medical error, incident investigation and the second victim: Doing better but feeling worse? *BMJ Quality and Safety* 2012.
239. Nash L, Daly M, Johnson M. Psychological morbidity in Australian doctors who have and have not experienced a medico-legal matter: Cross-sectional survey. *Australia and New Zealand Journal of Psychiatry* 2007;41(11):917–925.
240. Terry J, Wu A, Conway J. The second victim. 2011. GE Healthcare. (Accessed November 2011, at <http://nextlevel.gehealthcare.com/videos/webcasts/the-second-victim.php>)

241. Ghalandarpoorattar SM, Kaviani A, Asghari F. Medical error disclosure: The gap between attitude and practice. *Postgraduate Medical Journal* 2012;88(1037):130–133.
242. Appleby J, Raleigh V, Frosini F, Bevan G, Gao H, Lyscom T. *Variations in health care: The good, the bad and the inexplicable*. London: The King's Fund, 2011.
243. Runciman WB. Is money spent on quality improvement better spent on clinical care? — no. *Medical Journal of Australia* 2011;194(12):641.
244. Leape LL, Berwick DM. Five years after to err is human: What have we learned? *Journal of the American Medical Association* 2005;293(2005):2384–2390.
245. McLennan S, Beitat K, Lauterberg J, Vollmann J. Regulating open disclosure: A German perspective. *International Journal for Quality in Health Care* 2012;24(1):23–27.
246. Raghunathan K. Checklists, safety, my culture and me. *BMJ Quality and Safety* 2012.
247. Graber DR, Kilpatrick AO. Establishing values based leadership and value systems in healthcare organisations. *Journal of Human Services Administration* 2008;31(2):179–197.
248. Lamb R. Open disclosure: The only approach to medical error. *Quality and Safety in Health Care* 2004;13(2004):3–5.
249. Wei M. Doctors, apologies and the law: An analysis and critique of apology laws. *Journal of Health Law* 2007;40(1):107–159.
250. Sorry Works! Coalition. Analysis: Why docs won't say they're sorry. 2006. (Originally accessed November 2011 at <http://www.sorryworks.net/article37.phtml>, accessed 15 May 2012 at <http://webcache.googleusercontent.com/search?q=cache:SDZAw7no8uoJ:www.sorryworks.net/article37.phtml+&cd=1&hl=en&ct=clnk&gl=au&client=firefox-a>)
251. Levinson W, Gallagher TH. Disclosing medical errors to patients: A status report in 2007. *Canadian Medical Association Journal* 2007;177(3)(3):265–267.
252. Hilfiker D. Facing our mistakes. *New England Journal of Medicine* 1984;310(118).
253. Banja J. *Medical error and medical narcissism*. Sudbury MA: Jones and Bartlett, 2005.
254. Johnstone MJ. Clinical risk management and the ethics of open disclosure. Part 1. Benefits and risks to patient safety. *Australian Emergency Nursing Journal* 2008;11(88–94).
255. Hafferty WF. *Into the valley: Death and the socialization of medical students*. New Haven, CT: Yale University Press, 1991.
256. Fein SP, Hilborne LH, Spiritus EM, Seymann GB. The many faces of error disclosure: A common set of elements and a definition. *Society of General Internal Medicine* 2007;22:755–761.
257. Bismark MM, Spittal MJ, Studdert DM. Prevalence and characteristics of complaint-prone doctors in private practice in Victoria. *Medical Journal of Australia* 2011;195(6):25–28.
258. Buntine JA. Prevalence and characteristics of compliant-prone doctors in private practice in Victoria. *Medical Journal of Australia* 2011;198(6):325.
259. Nance J. *Why hospitals should fly: The ultimate flight plan to patient safety and quality care*. Bozeman, MT: Second River Healthcare Press, 2008.
260. Bell S, Delbanco T, Anderson-Shaw L, McDonald TB, Gallagher TH. Accountability for medical error. *Chest* 2011;140(2):519–526.
261. Liang BA. A system of medical error disclosure. *Quality and Safety in Health Care* 2002;11(1):64–68.
262. Donabedian A. The quality of medical care. *Science* 1978;200:856–864.
263. Kotter JP, Heskett JL. *Corporate culture and performance*. New York, NY: Free Press, 1992.
264. Kotter JP. Leading change: Why transformational efforts fail. *Harvard Business Review* 1995;March–April:59–67.
265. Lee P, Allen K, Daly M. A 'communication and patient safety' training programme for all healthcare staff: Can it make a difference? *BMJ Quality & Safety* 2011.

266. Reason J. Human error: Models and management. *British Medical Journal* 2000;320(768).
267. Bonvicini KA, Bylund CL, Carroll G, ROuse RA, Goldstein MG. Impact of communication training on physician expression of empathy in patient encounters. *Patient Education Counseling* 2009;75(1):3–10.
268. DEEWR (Department of Education, Employment and Workplace Relations). *Leadership, culture and management practices of high performing workplaces in Australia*. Report prepared by Boedker C, Cogin J, Langford P, Meagher K, Mouritsen J, Runnalls M, Sheldon P, Simmons S and Vidgen R, DEEWR. Sydney: Society for Knowledge Economics, 2011. (Accessed November 2011, at http://www.ske.org.au/download/SKE_2011_Literature_Review_Diagnostic_Instruments_January_10Jan2011FINAL.pdf)
269. Fritz J, Arnett RC, Conkel M. Organizational ethical standards and organizational commitment. *Journal of Business Ethics* 1999;20(4):289–299.
270. Chen DT, WSerhane PH, Mills AE. The role of organisational ethics in critical care medicine. *Critical Care Medicine* 2007;35(2 suppl):S11–S17.
271. Silverman HJ. Organizational ethics in health care: Proactively managing the ethical climate to ensure organizational integrity. *HEC Forum* 2000;12(3):202–215.
272. Rathert C, Phillips W. Medical error disclosure training: Evidence for values based ethical environments. *Journal of Business Ethics* 2010;97:491–503.
273. Iedema R, Jorm C, Lum M. Affect is central to patient safety: The horror stories of young anaesthetists. *Social Science and Medicine* 2009;69(12):1750–1756.
274. Halbach J, Sullivan L. *Medical errors and patient safety: A curriculum guide for teaching medical students and family practice residents*. MedEdPORTAL; 2005. (Accessed November 2011, at <http://services.aamc.org/30/mededportal/servlet/s/segment/mededportal/?subid=101>)
275. Halbach JL, Sullivan LL. Teaching medical students about medical errors and patient safety: Evaluation of a required curriculum. *Academic Medicine* 2005;80:600–606.
276. Gunderson A, Smith KM, Mayer DB, McDonald T, Centomani N. Teaching medical students the art of medical error full disclosure: Evaluation of a new curriculum. *Teaching and Learning in Medicine* 2009;21(3):229–232.
277. Gillies RA, Speers SH, Young SE, Fly CA. Teaching medical error apologies: Development of a multi-component intervention. *Family Medicine* 2011;43(6):400–406.
278. Newton BW, Barber L, Clardy J, Cleveland E, O'Sullivan P. Is there hardening of the heart during medical school? *Academic Medicine* 2008;83(3):244–209.
279. National Quality Forum. *Safe practices for better health care — 2009 update: A consensus report*. Washington DC, 2009.
280. Reason J. Beyond the organizational accident: The need for 'error wisdom' on the frontline. *Journal of Quality and Safety in Health Care* 2004;13:28–33.
281. Weick K. Reduction of medical errors through mindful interdependence. In: *Medical error*. Sutcliffe K, Rosenthal M (eds). San Francisco, CA: Jossey-Bass, 2004:177–199.
282. Weick K. Creativity and the aesthetics of imperfection. In: *Creative action in organisations*. Ford C, Gioia D (eds). Thousand Oaks CA: Sage, 1995:187–192.
283. Schulman PR. General attributes of safe organisations. *Quality and Safety in Health Care* 2004;13(suppl ii):ii39–ii44.
284. Bohmer RM. The four habits of high-value health care organizations. *New England Journal of Medicine* 2011;365(22):2045–2047.
285. Standards Australia. *ISO 31000: Risk management — principles and guidelines*. Sydney: Standards Australia Limited, 2009.
286. Millman A, Pronovost P, Makary MA, Wu A. Patient assisted incident reporting (PAIR): Including the patient in patient safety. *Journal of Patient Safety* 2011;7:106–108.

287. Australian Government. *A national health and hospitals network for Australia's future: delivering the reforms*. Canberra: Australian Government 2011. (Accessed 15 May 2012 at [http://www.yourhealth.gov.au/internet/yourHealth/publishing.nsf/Content/DeliveringTheReforms/\\$FILE/DeliveringTheReforms.pdf](http://www.yourhealth.gov.au/internet/yourHealth/publishing.nsf/Content/DeliveringTheReforms/$FILE/DeliveringTheReforms.pdf))
288. Weick K, Sutcliffe KM. *Managing the unexpected: Assuring high performance in the age of complexity*. San Francisco: Jossey-Bass, 2001.
289. Sepucha KJ, Fowler FF, Mulley AG. Policy supports for patient-centred care: The need for measurable improvements in decision quality. *Health Affairs* 2004;54:1–9.
290. Boothman R, Blackwell AC, Campbell DA, Commiskey E, Anderson S. A better approach to medical malpractice claims? The University of Michigan experience. *Journal of Health and Life Sciences Law* 2009;2(2):125–159.
291. Quinn RE, Eichler MC. The 3Rs program: The Colorado experience. *Clinical Obstetrics and Gynecology* 2008;51:709–718.
292. Studdert DM, Mello MM, Gawande AA, Brennan TA, Wang YC. Disclosure of medial injury to patients: An improbable risk management strategy. *Health Affairs* 2007;26(1):215–226.
293. Wakefield J, Jorm C, Ryan C. Open disclosure: Details matter — a response to studdert et al 2007. *Health Affairs* 2007;26(3):903–904.
294. Kraman SS, Hamm G. Bad modelling? *Health Affairs* 2007;26(3):903.
295. Studdert D, Mello MM, Gawande A, Brennan TA. Disclosure: The authors repond. *Health Affairs* 2007;26(3):904–905.
296. Department of Health WA (Western Australia). *Western Australian strategic plan for safety and quality in health care*. Perth: Department of Health WA, 2008.
297. Lamo N. Disclosure of medical errors: The right thing to do but what is the cost?: Lockton Insurance Companies Newsletter, Kansas City, MO: Lockton Companies, LLC, 2011:1–7.
298. RACGP (Royal Australian College of General Practitioners). *Standards for general practices* (4th edn). South Melbourne: RACGP, 2010.
299. RACGP (Royal Australian College of General Practitioners). *Standards for general practices*, 4th edition — key changes. South Melbourne: RACGP, 2010. (Accessed February, 2012, at http://www.racgp.org.au/Content/NavigationMenu/PracticeSupport/StandardsforGeneralPractices/Standards4thEd_KeyChanges.pdf)
300. Iedema R. Attitudes toward error disclosure need to engage with systems thinking. *The Joint Commission Journal on Quality and Patient Safety* 2010;36(3):99–100.
301. Christakis NA. Don't just blame the system. *British Medical Journal* 2008;336(7647):747.
302. Wachter RM, Pronovost PJ. Balancing 'no blame' with accountability in patient safety. *New England Journal of Medicine* 2009;361(14):1401–1406.
303. Walton M. Creating a 'no blame' culture: Have we got the balance right? *Quality and Safety in Health Care* 2004;13:163–164.
304. Joint Commission. *Behaviors that undermine a culture of safety*. Sentinel event alert, Washington DC: Joint Commission, July 9 2008.
305. Goldmann D. System failure versus personal accountability: The case for clean hands. *New England Journal of Medicine* 2006;355:121–123.
306. Marx D. *Patient safety and the 'just culture': A primer for health care executives*. New York: Columbia University, 2001.
307. Merry AF, McCall Smith A. *Errors, medicine and the law*. Cambridge, UK: Cambridge University Press, 2001.
308. Cleveland C. *Sacred space: Stories from a life in medicine*. Philadelphia, PA: American College of Physicians, 1998.

309. Sloan FA, Shadle JH. Is there empirical evidence for 'defensive medicine'? A reassessment. *Journal of Health Economics* 2009;28(2):481–491.
310. Kessler DP, McLellan MB. How liability law affects medical productivity. *Journal of Health Economics* 2002;21:931–955.
311. Baicker K, Fisher ES, Chandra A. Malpractice liability costs and the practice of medicine in the medicare program. *Health Affairs* 2007;26(3):841–852.
312. Baicker K, Chandra A. The effect of malpractice liability on the delivery of health care. *Frontiers in Health Policy Research: Forum for Health Economics & Policy*, 2005.
313. Fuchs V. The doctor's dilemma — what is 'appropriate' care? *New England Journal of Medicine* 2011;365(7):585–587.
314. Kilo C, Larson E. Exploring the harmful effects of health care. *Journal of the American Medical Association* 2009;302(1):89–91.
315. Leape L. *Transparency and public reporting are essential for a safe health care system*. New York, NY: The Commonwealth Fund, 2010.



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Open disclosure: an open discussion with a patient about an incident(s) that resulted in harm to that patient while receiving health care. The elements of open disclosure are an apology or expression of regret, a factual explanation of what happened and the potential consequences, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.

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