Literature review: incident disclosure research, policy and legal reforms since 2008
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1. Executive Overview

This document provides a literature review of incident disclosure research, policy and legal reform documents published since 2008. The review takes into account Australian as well as international publications.

The last four years have seen an explosion of policy and literature on all aspects of incident disclosure. Over this time, three developments are apparent. First, as new policy is issued, implemented and evaluated, the principles for enacting incident disclosure are becoming increasingly detailed and refined. Second, publications increasingly encompass the various inter-disciplinary dimensions of incident disclosure, addressing its legal, ethical, moral, psychological, sociological, communicative and relational dimensions. Third, and most significant perhaps, the literature is becoming increasingly patient-centred and less risk-managerial.

These developments have been assisted by policy makers, researchers, practitioners and patients advocating more strategic approaches to quality and safety. Thus, jurisdictions have moved towards developing key performance indicators for implementing quality and safety goals and standards and for measuring quality and safety processes and outcomes. What typifies many of these goals, standards and measures is that they place patients at the centre of the health care system and the health care process. One manifestation of this is the growing support for engaging patients in various aspects of quality and safety improvement. Another is the growing interest in patient rights (viz. the Australian Charter of Patient Health Care Rights and the Perth Declaration 2009 of Patients for Patient Safety). Yet another is the push for greater openness to patients on the part of practitioners and services (viz. the UK’s Action versus Medical Accidents’ Duty of Candour proposal adopted by the UK Department of Health; Stratton 2011; also see IHI’s Respectful Management of Adverse Events white paper 2010, in the process of being redrafted at the time of writing).

While concern about disclosure centres on its legal risks and complexities, the prominence of legal barriers and the import of legal reform are being reassessed. First, and despite operating in a highly litigious environment, several US commentators are inclined to treat legal reform as harbouring limited relevance for their enactment of day-to-day incident disclosures (McDonald et al 2010; Massachusetts Coalition for the Prevention of Medical Errors 2006; Conway et al 2010). They favour framing disclosure instead as a type of service reparation that patient-consumers expect to issue forth automatically and naturally from the trust relation in which care is or should be anchored. In this, legal concerns are positioned as adjunct to the service’s primary obligations to the patient-consumer. Second, health care complaints commissions offer patients an alternative route potentially involving mediation and other non-legal solutions (Bismark et al 2011). While the complaints route is found to accomplish only a low percentage of the total of activities requested by complainants, it offers, at least in principle, the potential to circumvent legal-adversarial contests.
Third, analyses of law reform that is enacted in support of disclosure conclude that “disclosure laws do not require, and most apology laws do not protect, the key information that patients want communicated to them following an unanticipated outcome” (Mastroianni et al 2010: 1614). While enunciated in the US context, this claim indicates that the intended effects of legal reforms may not in fact be the ones realised. This, in turn, puts question marks around legislative reform as the means par excellence for enhancing and strengthening the practice of incident disclosure. Fourth, as recent Australian research has shown (Iedema et al 2011a), patients want to understand the specific intentions and in situ decision-making of their treating clinicians. That is, central to patients’ and families’ process of reconciliation with an unexpected outcome is understanding their clinicians’ intentions, decisions, statements, and actions. For them, that understanding requires kinds of information which, paradoxically, recent legal reform seeks to subject to stricter sequestration through broadening the remit of ‘qualified privilege’ (Studdert and Richardson 2010). The fraught nature of such solution may become apparent when we consider that “The further entanglement and enmeshing of day-to-day life into legal liability with the risk of potential litigation will lead to over-cautious, excessively sensitive, cramped and inhibited social relationships” (Moorehouse 2011: 105). Equally, we should acknowledge that legal solutions targeting the complex dynamics of incident disclosure operate on the idealist presumption that formal rules can and will adequately account for and contain the often unpredictable nature of people’s responses to personal harm, their feelings of grief and interpersonal grievance.

Fifth and last, commentators have begun to propose alternative models for redress to support incident disclosure. Propositions include the disclose-and-offer model such as COPIC’s 3R program, the early-settlement model as used in Michigan, and the ‘health court’ model. Each of these enables services, practitioners and patients to accomplish agreements out of court (Mello and Gallagher 2010; for discussion of these models see section 5.2 below, ‘Alternative Compensation Systems’). Yet other solutions promote clinician-support initiatives ranging from service-specific debriefs and staff counselling programs to national support programs such as Medically Induced Trauma Support Services or MITTS in the US. These programs emphasise the importance of talking openly about unexpected outcomes with trusted colleagues as a pre-cursor to openly and effectively discussing incidents with patients and others, such that they too may feel supported, respected and heard. While research is yet to establish the effectiveness of these alternatives and outline ways of enhancing their processes and outcomes, they are solutions that are not contingent on large-scale legal reform. They are solutions that afford immediate action oriented towards reconciling practitioners and patients to the need to address an unexpected outcome, towards enabling them to do so, and towards generating outcomes by circumventing adversarial processes.

Critical to the success of these alternatives is the effort expended on improving how clinicians regard disclosure, conduct disclosure, and support peers in doing disclosure. These efforts are rendered all the more important by their trifold aims: increased safety, greater satisfaction, and potential savings. Openness about incidents will enable clinicians to learn from what went wrong – an outcome that is almost as important for
patients as is clinicians’ respect for them as individual patients. Learning from incidents bears directly on the safety gradient of clinical work. All this is contingent on greater openness among stakeholders about the risks, problems and undesirable outcomes produced by health care. Openness may entrain self-healing and restore at least some degree of well-being for both clinicians and patients (Allan and McKIllop 2010). Last but not least, as Kraman and Hamm (2007), Boothman et al (2009), and Kachalia et al (2010) have shown, openness about unexpected outcomes leads to financial and other measurable resource savings. Alongside growing evidence of what patients and their families expect when things go wrong, the encouraging resource implications of disclosure may inform and perhaps transform insurers’ stance on openness about incidents (Lamo 2011).

In what follows we set out post-2008 developments in incident disclosure registered at the level of national and state policy, legal reform, theoretical modelling, research evaluation and communication training. Each section is accompanied by its own specific references to facilitate tracing of relevant sources.

1.1 Executive Overview: References


Lamo, N (2011) Disclosure of Medical Errors: The Right Thing to Do, But What is the Cost?


2. Methods

The methodological approach included a MeSH search for the following terms: Open disclosure, Disclosure, Incident disclosure, Adverse event / reporting / communication, Disclosure harmful errors, Patient Safety, Patient family communication, Doctors/hospital duty to advise, Doctors/hospital duty to of care, Medical negligence, iatrogenic, and Duty of candour. The following databases were searched: Medline, Cochrane Database, CINAHL, EBESCO and Academic Search Elite. Further, Department of Health and Government Regulator sites were searched in the US, UK, New Zealand, Canada, Scotland and Australia.

Medline alone yielded 30,585 articles in response to the term ‘disclosure’. Most of these were concerned with the disclosure of illness status to patients, family or others. Better results were obtained with the following search terms: ‘incident disclosure’, ‘open disclosure’, and ‘disclosure of medical error’. After searching Medline, Cochrane and CINAHL we reached saturation: aside from short commentaries and review articles not yet included, the same articles began to appear. We stopped our search when we reached 142 articles which we considered most relevant for the purpose of the present review. Articles were selected according to their date of publication so as not to overlap with our previous literature review (Iedema et al 2008), targeting articles published after 2008. Each section has its own list of references. A list of additional references is provided at the end of this document in a separate Appendix.

2.1 Methods: Reference

3. Incident Disclosure: Policy Developments

At the time of our last literature review there were incident disclosure policies in place in several jurisdictions (as set out on p 41 of our previous literature review; Iedema, Sorensen & Piper 2008: 41). Over the intervening four years, disclosure policy development has proceeded apace both nationally and internationally: more jurisdictions have implemented ‘Open Disclosure’ policies and some of those jurisdictions with policies in place at the time of our last review have revised their existing policies. The policies share a number of characteristics, including their aims, language and scope. All profile incident disclosure as the right thing to do. With regard to their articulation, the Canadian policies are the most patient-centred, having been drafted with more patient input than policies in other jurisdictions. The UK Being Open Policy is also highly patient-centered, although this policy anchors incident disclosure to risk management more than comparable policies. Policies largely agree on the scope of incident disclosure as pertaining to all unexpected outcomes involving harm, while certainly differing on whether to include disclosure of near-misses. Canada does not mandate the disclosure of near misses, whereas the New Zealand and UK policies do. The Canadian policy also differs from the other policies in the emphasis it places on the need to address organisational culture as well as error in relation to incidents.

3.1 International policy developments

3.1.1 New Zealand

In New Zealand, incident disclosure is framed as a consumer right. There is an ethical and legal duty placed on health service providers to openly disclose incidents (including near misses) to patients under the Code of Health and Disability Services Consumers’ Rights 1996. Incident disclosure is also a requirement of the Health and Disability Service Standards.

Disclosure policies have been developed by several District Health Boards in New Zealand. However, since our last literature review, the New Zealand Health and Disability Commissioner has issued a Guidance on Open Disclosure Policies and Practice in order to promote a clear and consistent approach to incident disclosure. This Guidance sets out:

- What Open Disclosure should include: Information about unintended harm and near misses; acknowledgement of the incident, an explanation of what happened, how it happened, why it happened and, where appropriate, what actions have been taken to prevent it happening again; a sincere apology using the word sorry; provision of the contact details and information about the local health and disability consumer advocate as well as options for making a
complaint, and the provision of information about the entitlement to compensation.

- **Why it’s important:** The legal, ethical and moral dimensions of Open Disclosure including the fact that Open Disclosure affirms consumers’ rights, fosters open and honest professional relationships and enables systems to change to improve service quality and consumer safety.

- **Who should be involved:** The service provider with whom the consumer has built rapport and in cases of significant harm a representative from management as well. Guidance is also given about who should be involved and how they should be involved if the incident occurred in a team environment. Additional guidance on team environment incidents is also provided by the Medical Council of New Zealand in *Disclosure of Harm: Good Medical Practice* (2008).

- **Where and when disclosure should take place:** Usually within 24 hours of the event occurring. There needs to be an acknowledgement of the limits of what is known and commitment to sharing further information as it becomes available. The *Guidance* also acknowledges the fact that Open Disclosure is not a single conversation, but a process of ongoing communication, ending only when the consumer feels that they have all the information and support they need.

- **How it should take place:** Including support for consumers and staff, consideration of cultural and ethnic identity; the requirement to document the open disclosure process in the consumer’s records; the need for ongoing staff training including training in effective communication skills, and

- **The relevant rights** under the *Code* (1996).

### 3.1.2 Canada

Various Canadian provinces have had Open Disclosure laws and/or policies in place for some time, including: Alberta, Calgary, Manitoba, Quebec, Nova Scotia, Ontario, Winnipeg, Saskatoon, and Saskatchewan. These policies and laws are comprehensively listed, compared and analysed by Gregory (2008), and will not be further commented on here.

Since our last review, the Canadian Patient Safety Institute (CPSI) endorsed the *Draft Disclosure Guidelines* and published the *Canadian Disclosure Guidelines* (2008). In order to promote a consistent approach to Open Disclosure the CPSI is currently in the process of revising the *Canadian Disclosure Guidelines* (2008). The Revised Guidelines are due for release in November 2011. The *Draft Revised Disclosure Guidelines* (2011) frame Open Disclosure as based on principles of patient safety, openness, transparency, accountability, trust, respect and compassion. The aim of the *Draft*
Guidelines is to evoke CPSI’s main guiding theme: “Ask.Listen.Talk. – Good healthcare starts with good communication”.

The Draft Disclosure Guidelines (2011) set out:

- **Guiding principles for Open Disclosure**: Patient-centered healthcare; patient autonomy; healthcare that is safe; leadership support; disclosure is the right thing to do; and honesty and transparency.

- **The ethical, professional and legal importance of Open Disclosure** for the patient and provider.

- **The need to build the foundation for Open Disclosure** (via a “just culture” rather than an “error” focused approach) including: Training and education for staff on open disclosure and communication; emotional support for staff (in the form of counseling, leave and the opportunity to share their experience with other staff), emotional and financial support for patients (in the form of reimbursement for expenses).

- **The Disclosure process** including: When disclosure should take place; the need for a sincere apology using the word “sorry” and avoidance of words including “negligence,” “fault,” or “failing to meet the standard of care”; the recognition that disclosure is an ongoing process and the different stages of disclosure (The approach to the disclosure process in these guidelines is purported to occur in two stages: (1) initial disclosure and (2) post analysis disclosure. During the initial disclosure, consideration should be given to the following: (a) participants in the disclosure discussions (b) when disclosure should take place (c) the setting and location of the disclosure (d) what to disclose, and (e) how will disclosure occur. During the initial disclosure, the guidelines suggest providing facts, explaining the care plan, avoiding speculation, expressing regret, outlining expectations, arranging follow-up, identifying a contact and documenting. During the second phase of disclosure, further facts and any actions taken are provided to the patient/family with an appropriate expression of regret. The information is documented); the role of leadership and management; preparing for initial disclosure; who should be part of the disclosure team; what to disclose; how to disclose; setting and location; and the documentation required.

- **Specific circumstances that need to be considered** including: Large scale disclosure (multiple patient disclosure and multiple jurisdiction disclosure); paediatric patients; patients with mental health issues; patients with communication issues including different ethnic and cultural backgrounds; and Open Disclosure in research settings.

- **The position in relation to near misses**: Near misses need only be disclosed depending on their circumstances. In general, if an event did not reach the patient, there may be no requirement to disclose. But if the event reached the patient...
patient, and there is potential for harm, the event should be disclosed. Even if it reached the patient but there is no potential for harm, the event generally should be disclosed.

- **Recommended readings** including: National and international policy frameworks and associated literature.

- **The recommended elements of a Disclosure policy** including: Policy statement/objectives; definitions of key terms: provision for patient support; provision for healthcare provider support and education; the disclosure process; and the need to consider the provision for particular circumstances applicable to the individual organization).

- **A checklist for the Disclosure process.**

- **A list of Disclosure principles provided by the Canadian Chapter of Patients for Patient Safety, and**

- **Guidelines for informing the media.**

In addition to the *Draft Disclosure Guidelines* (2011), the Canadian Medical Protective Association (2008) has published a number of guidelines including how to disclose adverse events; how to apologize, and how to learn from adverse events.

### 3.1.3 The United Kingdom

Since our last literature review the National Patient Safety Agency (NPSA) has revised and re-launched its Open Disclosure Policy entitled *Being Open: Communicating patient safety incidents with patients and their carers (Being Open)* (NPSA 2009). The NPSA couches the revised policy in terms of “a set of principles that healthcare staff should use when communicating with patients, their families and carers following a patient safety incident in which the patient was harmed.” The aims of the policy are to support a culture of openness, honesty and transparency.

Since the release of the original *Being Open* policy in 2005, the NHS in England and Wales has undergone significant changes that have altered the context, infrastructure and language of patient safety and quality improvement. For example, the 2009 document *the NHS Constitution for England* contains a pledge to patients in relation to complaints and redress: “The NHS also commits when mistakes happen to acknowledge them, apologize, explain what went wrong and put things right quickly and effectively.”

In addition, a review of the *Being Open* policy, undertaken in 2008, showed that more needed to be done to strengthen the implementation of *Being Open*. Based on the recommendations and feedback obtained through a listening exercise with healthcare
professionals and patients, the NPSA (2009) developed an updated *Being Open Framework* to demonstrate how to strengthen the culture of *Being Open* within healthcare organisations. The framework is couched in terms of the need for openness, compassion, improved communication, patient rights and reducing complaints and litigation.

The framework sets out:

- **What Being Open means** including: The benefits of Open Disclosure, the foundations of Open Disclosure including the need to acknowledge, apologize and explain when things go wrong (including near misses); conducting a thorough investigation into the incident and reassuring patients, their families and carers that lessons learned will help prevent the incident from recurring; providing support for those involved to cope with the physical and psychological consequences of what happened, and saying sorry.

- **The 10 principles required to embed a culture of Open Disclosure** including: Acknowledgement; truthfulness, timeliness and clarity of communication; apology recognizing patient and carer expectations; providing professional support; risk management and systems improvement requirements; multidisciplinary responsibility; clinical governance; confidentiality and continuity of care.

- **The Open Disclosure process** including: Acknowledgement that the process is more than a one-off event; it is a communication process with a number of stages and the duration of the process will depend upon the needs of the patient, their family and carers, and how the investigation into the incident progresses. Stage 1 includes incident detection and recognition. Stage 2 involves the preliminary health care team discussion. Stage 3 involves disclosing to the patient. Stage 4 includes follow up discussions with the patient and Stage 5 is the completion of the Open Disclosure process.

- **How to implement the policy in a way that will strengthen the culture of Open Disclosure.** In this regard, throughout 2010, the NHS required health care providers to review and strengthen local policies to ensure they were aligned with the *Being Open* framework; make a board-level public commitment to implementing the principles of *Being open*; nominate executive and non-executive leads responsible for leading the policy; identify senior clinical counselors to mentor and support fellow clinicians; develop and implement a strategy for training staff and provide ongoing support; raise awareness and understanding of the *Being open* principles and local policy among staff, patients and the public, making information visible to all.

- **Links to supporting tools** including: Fact sheets, e-learning tools and access to training workshops.
• Documentation requirements, and
• Specific patient characteristics that need to be considered.

In line with the re-launch of Being Open, a number of health service providers have reviewed or drafted Open Disclosure Policies, some of which are publicly available on the organisation’s website.

In addition, the National Institute for Health Research (NIHR) has funded a number of investigators to explore how the re-launched Being Open Policy will be implemented and whether or not it is working (Birks 2010). The research will be run from September 2011 until September 2013.

3.1.4 The United States

Healthcare facilities accredited by the Joint Commission must disclose outcomes of care to patients and their families to comply with the agency’s standards, and some state regulations also require disclosure of unanticipated outcomes. The Joint Commission Standard RI.2.90 states, “Patients and, when appropriate, their families are informed about the outcomes of care, treatment, and services that have been provided including unanticipated outcomes.” According to Joint Commission Standards, at a minimum, the patient and/or his or her family should be made aware of outcomes of care, services, or treatment that will affect current and future decisions regarding the patient’s care and unanticipated outcomes related to Joint Commission-defined sentinel events. This standard has been in place for Joint Commission-accredited facilities since July 2001. Likewise, the National Patient Safety Foundation (NPSF) adopted a Statement of Principle on Open Disclosure in 2001.

In addition to the accreditation requirements in place in the US, some states have implemented laws requiring healthcare organizations to disclose adverse events or unanticipated outcomes to patients (this will be discussed in more detail in section 4). For example, Florida, Nevada, New Jersey, and Pennsylvania regulations require that patients be notified of adverse events, and New Jersey passed a law in 2004 requiring all the state’s healthcare facilities to report medical errors that result in death, disability, or loss of bodily function to the state Department of Health and Senior Services.

Following on from the ASHRM (2003) monograph series of papers on Open Disclosure cited and summarized in our previous literature review, in 2006 the Harvard teaching hospitals, the Harvard School of Public Health, and the Risk Management Foundation collaborated to develop the white paper When things go Wrong: Responding to Adverse Events. The white paper provides guidance on communicating adverse events and supporting patient s and staff during the disclosure process.

Other organisations have also published policies and guidance on Open Disclosure including the ECRI Institute’s (2008) Disclosure of Unanticipated Outcomes. The ECRI
Publication sets out the elements of disclosure, who is responsible for disclosure, when and where disclosure is accomplished, when disclosure is not recommended, what to disclose, documenting disclosure, financial and legal implications of disclosure. The ECRI Guidance also provides a resource list setting out various American Health Providers publications and policies in relation to Open Disclosure. In addition an organisational checklist for Open Disclosure is provided. The Department of Veterans affairs (2008), Harvard Hospitals (2006) and the Institute for Health care Improvement (Conway et al 2010) provide similar resources.

3.1.5 Australia

In Australia the Australian Commission on Safety and Quality in Health Care has published and evaluated its National Open Disclosure Standard. The Standard and accompanying resources including the Evaluation of the Standard, Manager’s Handbook, a booklet for patients, a factsheet and frequently asked questions about Open Disclosure, an education module on adverse events in general practice and a number of related journal articles and other resources are available on the Commission’s website.

In addition, the Commission is reviewing the National Open Disclosure Standard at the time of writing. The project will develop a revised national open disclosure policy document that:

- Incorporates the latest evidence and research into open disclosure;
- Builds on Australian experience of implementing and practising open disclosure;
- Meet the needs of patients, families and carers and of health care professionals, facilities and services in relation to open disclosure.

The first steps in this process will be developing and disseminating a discussion paper (including a proposed, new open policy document) as the basis for extensive stakeholder consultation. The project is expected to conclude in late 2012.

Thanks to the Commission’s initiatives, all States and Territories now have Open Disclosure policies in place. Links to individual jurisdictions open disclosure policies and accompanying resources are provided on the Commission’s website.

3.1.6 Policy References

New Zealand

Literature review: incident disclosure research, policy and legal reforms since 2008


Canada


**United Kingdom**


United States


Australia


Australian Commission on Safety and Quality in Healthcare (2010) *Open Disclosure of Things that Go Wrong in Health Care: A Booklet for Patients Beginning an Open Disclosure Project* (available at:

4. Incident disclosure and the law

4.1 Clinicians’ fear of the legal consequences of Open Disclosure

It is widely accepted from international studies that clinicians fear the legal environment, or lack of protection from that environment, when charged with doing incident disclosure (Carrier, Reschovsky, Mello, Mayrell & Katz 2010). To verify whether this was the case in Australia, Studdert, Piper & Iedema (2010) conducted a National cross-sectional study of 51 experienced OD in mid 2009 to assess the attitudes of health professionals engaged in Open Disclosure to the legal risks and protections that surround this activity. The main outcome measures were the perceived barriers to Open Disclosure; the awareness of and attitudes toward medico-legal protections and recommendations for reform. The key finding was that 88% of respondents regarded fears about medico-legal risks as a major or moderate barrier to Open Disclosure. Views were mixed regarding the extent to which existing laws encourage health care professionals to conduct Open Disclosure. Respondents’ knowledge of the laws regarding Open Disclosure was limited and in some cases, incorrect.

Respondents suggested various legal reforms including strengthening and clarifying existing laws, particularly qualified privilege laws and apology laws; improving education and awareness of existing laws; overhauling the medical negligence system (introduce a no-fault/mixed compensation system, or adopt a mediation-collaborative law model of incident disclosure); and better aligning of the roles of other legal actors, such as coroners and complaints commissioners, with the culture and objectives of Open Disclosure. Other legal aspects of Open Disclosure that were raised as minor impediments included barriers to the early offer of compensation under the Medicare Legislation, the impact of Freedom of Information legislation, defamation laws, complaints procedures, and privacy and confidentiality laws (Studdert, Piper & Iedema 2010).

Based upon these findings and other research (Studdert & Richardson 2010) have made a number of recommendations in relation to changes to the law (detailed in section 4.2 below).

4.1.1 Legal fears: References


4.2 Will Open Disclosure Increase Litigation?

No strong empirical evidence exists to determine whether openly communicating about unanticipated outcomes of care increases clinicians’ exposure to medico-legal activity, decreases it, or leaves it unaffected (Studdert & Richardson 2010). According to Studdert & Richardson (2010) there are theoretical reasons to expect that Open Disclosure may stimulate litigation. On the other hand, there are no signs of spikes in medical negligence litigation, health care complaints or medical board actions in Australia over the last five years as interest in and enactment of Open Disclosure has increased. Also, several institutions in the US that have adopted progressive disclosure policies have reported favourable experiences (e.g. Boothman et al 2009).

In reviewing the existing literature and conducting a study involving hypothetical situations rather than real experiences, Taylor (2007) found that where the harm suffered by the patient is described as mild to moderate, full disclosure will either decrease the frequency of litigation or have no impact. Where harm is described as severe, the frequency of litigation with full disclosure appears to be unchanged. Conversely, the absence of disclosure or ineffective disclosure does increase the likelihood of litigation or claims irrespective of the category of harm. Taylor (writing in 2007) regards the question of Open Disclosure prompting litigation or claims as unanswered. The author recommends further empirical research involving patients and/or families who made the decision not to pursue claims or litigation after having received full disclosure, and conversely involving those who made the decision to pursue litigation (Taylor 2007).

Taylor (2007) also found that specific factors that have been determined as limiting litigation or claims following adverse events include: transparency; compassion; apology, and accountability. Important to note is Taylor’s finding that where patients/families chose to make a claim, litigate or pursue discipline through a professional body, the least important reported factor is financial compensation. Furthermore, factorial studies and related literature demonstrate that non-disclosure or ineffective disclosure will cause patients and/or families to turn to litigation. In many cases the reported purpose of litigation is to obtain something other than financial compensation. All of the factorial studies reviewed by Taylor (2007) suggest that respectful, honest and accurate communication following an adverse event is paramount to patients and families. This was of particular significance in cases of minor to moderate harm. In cases of severe harm caused by an adverse event, and if the patient had lost their ability to work or continue their business as a result, there was a link to the claim being made for financial compensation irrespective of disclosure.

More recently, Helmchen & Richards (2010) surveyed a representative sample of Illinois residents about their knowledge about medical errors, their confidence that their providers would disclose medical errors to them, and their propensity to sue and recommend providers that disclose medical errors and offer to remedy them. Of the 1018 respondents, 27% would sue and 38% would recommend the hospital after
medical error disclosure with an accompanying offer of remediation. Compared with the least confident respondents, those who were more confident in their providers' commitment to disclose were not likely to sue but significantly and substantially more likely to recommend their provider to others.

Related to this, evidence is emerging which demonstrates how Open Disclosure can have economic benefits. This evidence primarily relates to savings made via a reduction in litigation claims arising from medical errors. Instances include:

- The Mater Hospitals, Brisbane, Australia – the hospitals have noticed a significant reduction in claims with savings of nearly $2 million AUD over four years, and a substantial return on investment (Wu (2009a) cited in NPSA (2009)).

- A large, academic hospital in Singapore – there has been a reduction in the number of claims after implementing their system for handling serious incidents. In the past two years, they have had no cases proceed to litigation, with estimated savings of approximately $500,000 SGD per year (Wu (2009b) cited in NPSA 2009).

- The University of Michigan Hospital System – its full-disclosure program has halved the number of pending lawsuits resulting in a total average annual savings of $2US million (Boothman et al 2009; Kachalia et al 2010). The University of Michigan Health System’s experience suggests that a response by the medical community more directly aimed at mitigating patients need to call lawyers would more effectively reduce claims, without compromising meritorious defenses. More importantly, honest assessments of medical care give rise to clinical improvements that reduce patient injuries (Boothman et al 2009; Kachalia et al 2010). More specifically, Kachalia et al (2010) found that after full implementation of a disclosure-with-offer program, the average monthly rate of new claims decreased from 7.03 to 4.52 per 100,000 patient encounters (rate ratio [RR], 0.64 [95% CI, 0.44 to 0.95]). The average monthly rate of lawsuits decreased from 2.13 to 0.75 per 100,000 patient encounters (RR, 0.35 [CI, 0.22 to 0.58]). Median time from claim reporting to resolution decreased from 1.36 to 0.95 years. Average monthly cost rates decreased for total liability (RR, 0.41 [CI, 0.26 to 0.66]), patient compensation (RR, 0.41 [CI, 0.26 to 0.67]), and non-compensation-related legal costs (RR, 0.39 [CI, 0.22 to 0.67]).

- The Lexington Veterans Affairs Medical Center (Kraman & Hamm 1999; Kraman, Cranfill et al 2002; Wojcjeszak, Banja, Houk 2006).

- The COPIC Insurance company’s 3Rs program (Quinn Eichler 2008; Gallagher, Studdert & Levinson 2007), and

- The University of Illinois at Chicago’s Seven Pillars Process has, in the first two years post-implementation, led to more than 2,000 incident reports annually,
prompted more than 100 investigations with root cause analysis, translated into
close to 200 system improvements and served as the foundation of almost 106
disclosure conversations and 20 full disclosures of inappropriate or unreasonable
care causing harm to patients (McDonald, Helmchen, Smith, Centomani,
Gunderson, Mayer & Chamberlin (2010)).

An overview of the features of all of the abovementioned US programs is provided in
Schostok (2010). Despite the emerging evidence for the financial savings brought about
by incident disclosure coupled with early settlement offers, there exists scant literature
on the wider resource implications of incident disclosure. In this regard, Peto,
Tenerowicz, Benjamin, Morsi & Burger (2009) highlight the pressures placed upon
Baystate Health in implementing an organisation-wide Open Disclosure Policy. The
authors state that the implementation of a formal disclosure program has placed internal
pressure on the organisation to more promptly determine causality of adverse events
and to respond to patient/family requests for information and/or assistance. Some of the
resource intensive challenges in sustaining the program include the ability to promptly
investigate, to accurately determine liability, to communicate empathetically even if
unable to meet all patient/family expectations, and to ensure establishment of a just
culture. Similarly, Iedema et al 2008 comment on the considerable time and effort
required from clinical staff to conduct incident disclosure and produce a best-possible
outcome (Iedema et al 2008).

4.2.1 Rise in litigation: References

Approach to Medical Malpractice Claims? The University of Michigan Experience,
_J. Health & Life Sci. L._125.


Gallagher T, Studdert D & Levinson W (2007) Disclosing Harmful Medical Errors to
Patients _NEJM_ 356 (2) 2713-19.

Patients' Propensity to Sue and Their Assessment of Provider Quality?: Evidence
From Survey Data Medical Care _Med Care_ 48 (11) 955-961.

Disclosure Pilot Program_. Sydney, The Australian Commission on Safety and
Quality in Health Care.

(2010) Liability claims and costs before and after implementation of a medical error


4.3 Legal duty to disclose adverse events

Since our previous review of the literature which highlighted the different sources of the duties imposed upon health service providers to openly disclose adverse events (p 10-11), there has been a push, in some jurisdictions, to enshrine a legal duty to openly disclose adverse events in legislation. For example, in New Zealand a statutory duty of open disclosure exists under the *Code of Health and Disability Services Consumers’ Rights*, where each patient is treated as a consumer with a certain set of rights, including being informed about any adverse event. Several states in the US have made it a legal obligation for healthcare institutions to disclose serious unanticipated outcomes to patients, and Pennsylvania requires hospitals to notify patients in writing within seven days after a "serious event" (Gallagher, Studdert and Levinson 2007). The issue is gaining momentum in the United Kingdom (Shekar et al 2010) and Australia (UTS Centre for Health Communication Symposium ‘Duty of Candour?’, 19 February 2011). The push for a statutory “duty of candour” has been led largely by consumer groups such as Action Against Medical Accidents (AvMA) in the United Kingdom. The reasoning behind the need for a statutory duty of candour is the perceived need to address a culture of ‘cover up’ and a lack of public confidence in the public health care system (AvMA 2010).

4.3.1 Legal duty: References


4.4 Apology Laws

Following on from our previous literature review, not much has changed in the legal landscape in relation to apology laws: Whilst all Australian jurisdictions and an increasing number of overseas jurisdictions have enacted apology legislation, there is still considerable variation between the laws. Australian apology laws have been reviewed and analysed by Studdert & Richardson (2010), Browne (2008) and Vines (2005; 2007a). Vines (2007b) has also reviewed and analysed apology laws in place in England, Wales and Scotland.

Studdert & Richardson (2010) state that in relation to apology laws, The National Open Disclosure Standard includes an “expression of regret” as an appropriate element of a disclosure, defining it as “an expression of sorrow for the harm experienced by the patient.” Another term used to describe such a ‘regret’ apology is ‘partial apology’. A partial apology excludes admissions of responsibility from the apology statement.

All states and territories have apology laws— statutory provisions that protect statements of apology or regret made after “incidents” from subsequent use in various legal contexts. These laws were not enacted with Open Disclosure in mind; they apply to a much broader range of activities and predate Open Disclosure policy. The protection takes the form of restricting the inferences that may be drawn from apologies, the uses to which apologies may be put in civil proceedings, or both. They are generally contained in the civil liability legislation of each jurisdiction (Studdert & Richardson 2010).

Studdert & Richardson’s (2010) analysis of the apology laws revealed that their protective value is constrained by several factors:

1) Their variability across jurisdictions – Laws vary in a number of ways including the type of proceedings to which the shield applies. States may protect apologies from use in civil proceedings of any kind (TAS, WA), exclude certain types of civil liability claims (ACT, NSW) or limit the protection to proceedings in tort (SA) or personal injury damages claims (NT, VIC, QLD). Only the Victorian legislation explicitly covers medical board hearings.

2) The laws lack clarity in relation to incident disclosure activities.

3) Six jurisdictions (Qld, Vic, Tas, WA, NT, SA) exclude statements containing acknowledgements of fault or liability. While all Australian states and territories have apology legislation in place, the scope of protection provided in the legislation in each jurisdiction varies. A basic “I am sorry” will be protected in most circumstances in all jurisdictions. However, an apology including admission of responsibility (the ‘full apology’) is only protected in the Australian Capital Territory and New South Wales. So, the legislation in Australian jurisdictions varies in relation to the protection given to apologies, and in relation to whether the apology is relevant to any determination of fault and liability and whether it is
admissible as such.

4) The laws are also constrained by their inherently selective nature – they address only one element of incident disclosure, the apology. So, statements describing the event, its cause (“the treatment caused your injury”) and why it occurred (“this should not have happened”) are likely to be construed as separate and distinct statements from the apology, and so remain discoverable and admissible in legal proceedings.

Because of this variability and perceived lack of ability to express a full and sincere apology, clinicians do not feel protected during the open disclosure process (Studdert, Piper & Iedema 2010).

Interestingly, the academic literature on apology makes the point that the legal concerns about an apology constituting an admission of liability may be overstated. Thus, even if an apology constituted an admission of responsibility at the time it was given, legally that admission should not be seen as conclusive. The apology is one piece of evidence that has to be weighed up with all the other evidence in the case. It is for the courts to find whether on all the evidence in the case there is or is not legal liability. According to Vines (2005), the Courts, even outside of legislative protections, have been loath to find an apology accepting responsibility as evidence of fault in the absence of other evidence.

Several commentators have analysed existing apology laws in Canada (Bailey, Robertson & Hegedus 2007; Barr 2009; Borg 2009; Gregory 2008; MacDonald & Attaran 2009; O’Connell 2009; Schwartz 2009; Silversides 2008) and the US (Dresser 2008; Ebert 2008; Jesson L & Knapp P 2008-2009; Hyman, Liebman Schechter et al 2010; Lazare 2006; Pearlmutter 2011; Pelletier & Robson 2008; Pollock, Pesto, Sirridge et al. 2010; Robennolt 2009; Rubel-sieder 2008). Comment has also been made on the legal position in the UK (Fienmann 2009).

In relation to apology laws in the US, McDonnell &, Guenther (2008) reviewed the codified statutes of each of the 50 US states and the District of Columbia to determine the prevalence and characteristics of apology laws. They found that many states (36) have recently adopted apology laws and that, like those in existence in Australia, there is variability in these laws. The authors review some of the important differences in these laws and explore the potential impact of apology laws. For example of the 36 states with apology laws 28 states prevent expressions of condolence, sympathy or regret from being used against the physician in litigation. The remaining 8 states also protect admissions of fault. Within these 8 states there are further variations. For example, in Vermont, only oral statements are protected – written statements may be used as evidence at trial. However, the states of Florida, New Jersey, Nevada and Pennsylvania have enacted laws that not only protect admissions of fault, but also enforce the reporting of medical errors to patients.
The authors state that it is hoped that the laws will make physicians feel more comfortable in reporting mistakes and that this will lead to a reduction in medical errors. It is also hoped that improved communication between physician and patient will reduce the risk of litigation. However, as the majority of the laws is less than 10 years old (with two-thirds being less than 5 years old), McDonnell & Guenther (2008) conclude that it is too early to assess their effects. The authors comment: 'If further experience shows that disclosures and apologies can be fostered with apology laws, then improved physician–patient relationships, better patient understanding of their adverse outcomes, increased patient satisfaction, and medical error reduction might all be realized'. Results from the Studdert, Piper & Iedema (2010) study suggest that in Australia this is not the case, given that despite legal protections the majority of practitioners fear the medico-legal consequences of offering an apology following an adverse event.

In reviewing the laws in place in the US in 2010, Mastroianni, Mello & Sommer (2010) found that most of the apology laws have "major shortcomings" and may actually discourage open disclosure and apologies. MacDonald & Attaran (2009) reached a similar conclusion in relation to apology laws in place in Canadian provinces. As did Studdert & Richardson (2010), Mastroianni et al (2010) found that many of the shortcomings could be resolved by improved statutory design and communication about the legal requirements and protections. In contrast, Wei (2007) states that potential barriers to physicians' disclosure of medical mistakes may actually be rooted in professional norms that will remain outside the scope of law's influence.

4.4.1 Apology laws: References


Robennolt J (2009) Apologies and Medical Error Clinical Orthopaedics and Related Research 467 (2) 376-382.


4.5 Qualified Privilege Laws

Since our last review, Studdert & Richardson (2010) have conducted a detailed analysis of the qualified privilege laws currently in operation in Australia. In summary, they state that all Australian states and territories have statutes that anchor qualified privilege to a “quality assurance committee” (QAC), or similarly named entity. Such entities must be specifically “declared” by the relevant Minister before they may enjoy this limited form of privilege over the information they handle. The idea behind this protection is that quality peer review of mistakes, served by the processes of a root causes analysis or similar investigative process would not occur without the protection. That is, the reality is taken to be that some people will simply not be honest if the protection is not given – and accordingly the system cannot learn from its mistakes.

Critical to note is that none of the qualified privilege legislation addresses Open Disclosure directly. The potential point of intersection between the quality assurance activity (that attracts the privilege) and Open Disclosure is that some of the same information may be handled in both settings. Specifically, the same adverse event that forms the focus of QAC work may be (or may have been) the subject of an incident disclosure, raising 2 distinct questions:

1) Does qualified privilege law introduce prohibitions or barriers to the release of the subject matter of QAC work, such that persons conducting incident disclosure are inhibited from conveying the same or similar information to patients?
2) Does the protection provided to QAC information under qualified privilege laws extend to the provision of the same or similar information to patients in incident disclosure?

Generally speaking, the answer to both questions is “no.” The fundamental reason is that the connection between state qualified privilege statutes and Open Disclosure processes is quite weak. The principal consideration is that statutory privileges that attach to quality assurance activities (all states) and RCAs (QLD, SA) are not substantive legal barriers to full and candid incident disclosure. There are some restrictions however on the transfer of quality assurance and root cause information to people outside of the groups that produce it.

That said, all jurisdictions have lawful pathways that should enable the release of such information to patients to whose care the information relates. With respect to barriers to the release of incident information, the greater obstacle is likely to be non-legal — namely, the reluctance of hospitals, health services or clinicians directly or indirectly identified in the reports to agree to and facilitate the information release, springing from their concern that information may end up in court.

Qualified privilege places a limitation in most jurisdictions on persons’ ability to access and use a QAC’s primary investigation documentation for incident disclosure. However, two factors mitigate this limitation. One is the timing of an incident disclosure (potentially preceding the lengthy QAC investigation, particularly in the case of incidents where fault
is clearly evident). Another is the consideration that ‘protected’ QAC information will typically form only one component of the information considered relevant to the disclosure. That is, patients’ and families’ questions and requests for information may not or only marginally intersect with the remit of the QAC investigation.

Currently, qualified privilege law provides little or no protection for information conveyed in incident disclosures: Open Disclosure currently does not attract qualified privilege. Once incident information is disclosed as part of incident disclosure, therefore, that information may be used in litigation or other medico-legal actions. Studdert & Richardson (2010) suggest that law reform might consider privileging incident disclosure, assuming that in practice the disclosure process has fully agreed and clear communication boundaries. Gregory (2008) analyses equivalent legislation in place in Canadian provinces, but fails to pass judgment on whether qualified privilege provides an adequate mechanism for encouraging frontline practitioners to engage in incident disclosure.

4.5.1 **Qualified privilege: References**


5. Financial Dimensions of Incident Disclosure

5.1 The Insurance Implications of Open Disclosure

Whilst an increasing number of insurers publicly support Open Disclosure and have issued guidance for their members on how to enact Open Disclosure (Lamo 2011; Canadian Medical Protective Association 2009; Edwards-Smith; INVIVO; NHS Litigation Authority 2009; Nisselle 2008), fears remain about the insurance implications and support given to health professionals from their insurer (Studdert, Piper & Iedema 2010).

The main issue impacting upon insurance is the potential for incident disclosure to trigger an admission clause in the insurance contract. An insurance contract may provide a clause that prevents the insured from making an admission of liability, or from compromising a claim without the consent of the insurer. In many cases, the insurance contract will provide that the insurer may refuse to pay a claim in respect of certain acts (including for example breach of an admissions clause). An apology admitting fault made in the course of an incident disclosure process may therefore be perceived as triggering this clause and result in the insurer refusing to indemnify and/or provide legal representation or assistance in relation to any court or other proceedings arising from the incident (Piper 2011). The problem with admissions clauses arguably stems from the degree of ambiguity and inconsistency in the application of apology laws to open disclosure.

5.1.1 Insurance implications: References


Medical Defence Union. MDU encourages doctors to say sorry of things go wrong. MDU, May 2009 (available at: www.themdu.com/Search/hidden_Article.asp?articleID=1982&contentType=Media%20rele
ase&articleTitle=MDU+encourages+doctors+to+say+sorry+if+things+go+wrong&userType= , accessed 23 August 2011).


5.2 Alternative compensation systems

Emerging evidence reporting favorable experiences of institutions in the US that have adopted early disclosure and offer programs (e.g. Boothman et al 2009) coupled with the literature on the role and content of apologies has led to increasing debate on the appropriate system(s) for providing redress and compensation to victims of adverse events (Croxson 2010; Dauer 2011). Most of this literature comes from the US. For example, Kachalia & Mello (2011) discuss the provision in the Patient Protection and Affordable Care Act in March 2010 that authorises $50 million for states and health care systems to test new approaches to the resolution of medical-injury disputes. This authorisation supplemented the $23 million that the Agency for Healthcare Research and Quality (AHRQ) awarded in 2010 for projects to advance new approaches to medical-injury compensation and patient safety. Kachalia & Mello (2011) review what is known about the effectiveness of various strategies for liability reform and the implications for the future direction of reform.

Barringer, Studdert, Kachalia & Mello (2008) discuss the historical experience of administrative medical injury compensation proposals in the US. More recently, Mello & Brennan (2009), Payne (2011), and Mello, Kachalia & Studdert (2011) set out the reasoning behind the specialist ‘health courts’ currently being piloted in the US.

Mello, Kachalia & Studdert (2011) state that in the US patients injured by medical negligence are required to seek compensation through lawsuits, an approach that has drawbacks related to fairness, cost, and impact on medical care. Several countries, including New Zealand, Sweden, and Denmark, have replaced litigation with administrative compensation systems for patients who experience an avoidable medical injury. Sometimes called "no-fault" systems, such schemes enable patients to file claims for compensation without using an attorney. A governmental or private adjudicating organization uses neutral medical experts to evaluate claims of injury and does not require patients to prove that health care providers were negligent in order to receive compensation. Information from claims is used to analyze opportunities for patient safety improvement. The systems have successfully limited liability costs while improving injured patients’ access to compensation. American policymakers may find many of the elements of these countries’ systems to be transferable to demonstration projects in the U.S.

Mello and Gallagher (2010) outline three models that currently incorporate and encourage disclosure. The first is the reimbursement model as adopted by COPIC, the Colorado Medical Insurance Company. The reimbursement model involves an offer of reimbursement for out of pocket expenses of up to US$25,000. Offers are made without prior establishment of provider negligence, but they are not made in expectation that the patient waives the right to sue. The reimbursement model excludes cases of evident substandard care, fatal injuries and cases where a lawyer has become involved. The second model is the ‘early-settlement model’. Here there are no limits on the amount of compensation awarded, but acceptance of compensation means the patient forecloses on their right to sue. The third model is that of the ‘health court’. Health courts are
populated by experts who determine the avoidability of the injury linked to the amount to be awarded for economic losses and suffering. Health courts do not expect patients to waive their right to sue. Their principal concerns are rapid compensation and ensuring that learning occurs among those involved in the incident (Mello et al 2010). Carrier, Reschovsky, Mello et al (2010) note that physicians’ fears are not assuaged by traditional tort reforms such as capping damages, but that they may be reassured by the introduction of health courts.

Payne (2010) summarizes the features of ‘health courts’ as they are currently being piloted in the US. Specialist Health Courts appoint full-time judges dedicated to healthcare cases appointed through a non-partisan screening commission. Judges select neutral experts from a panel in each area of medicine, replacing the ‘hired gun’ experts that may confuse and prolong disputes. Patients are reimbursed for all medical costs and lost income, and a fixed fee that would be predetermined according to a schedule for specific types of injuries. In June 2007 the AMA adopted a policy that set out principles for health courts. They are designed to serve as guidelines for state medical associations, local governments, insurers, and hospitals. The principles cover structure, selection, and training of judges and experts, damages and medical error reporting. The AMA’s William A Hazel described the courts as “a promising reform that merits more investigation,” and a feasible alternative to California’s 1975 Medical Injury Compensation Reform Act which includes a $250 000 cap on non-economic damages (cited in Payne 2010).

The issue of alternative compensation systems has also been debated in Canada (Gilmour 2006; Taylor 2008). In addition, Scotland (Scottish Government 2011) plans on introducing a no-fault scheme for medical injury and England has legislated for a compensation scheme for medical negligence, although it has yet to be implemented in practice (Redress Act 2006 (UK)).

Various other commentators set out the schemes in place in other jurisdictions. For example, Johansson (2010) provides an overview of the Swedish administration system for compensation of patient injuries. Since 1975 Sweden has had a patient insurance system to compensate patients for health-related injuries. The system was initially based on a voluntary patient insurance solution, but in 1997 it was replaced by the Patient Insurance Act. The current Act covers both physical and mental injuries. Although about 9,000-10,000 cases are processed in Sweden annually, compensation is paid in barely half of these cases. In the Swedish patient injury claim processing system, the Patient Claims Panel is the authority that plays an important role in ensuring fair and consistent application of the Act. Wallis & Dovey (2011), Bismark, Dauer, Paterson et al (2006), and Manning (2010) analyze aspects of the New Zealand compensation system. Croxson (2010) provides a brief overview of features of the systems in place in New Zealand and the US.

Closer to home, and focusing on health care complaints commissions’ achievement in negotiating pre-legal solutions to incidents, Bismark, Spittal, Gogos, Gruen & Studdert (2011) found that many patients accessing the Complaints Commission of an Australian
jurisdiction were dissatisfied with their experience and suggest several ways to address this issue. Noteworthy in with regard to compensation for incidents is that, in August 2011, the Australian Government released the Productivity Commission’s report into long-term care and support for Australians with disability. The report recommends a National Disability Insurance Scheme to provide all Australians with insurance for the costs of support if they or a family member acquire a disability. Further, the report recommends the establishment of a National Injury Insurance Scheme that would provide lifetime support for people acquiring a catastrophic injury from an accident. These schemes appear to cover all causes of catastrophic injury or disability, including those due to medical “accidents” and is based upon motor accident compensation schemes currently in place (Productivity Commission 2011). Arguably, the release of this report and the international work in relation to appropriate compensation systems adds impetus to the need to extend the debate on appropriate mechanisms to regulate and provide redress for all medical accidents and errors in Australia.

5.2.1 Alternative compensation: References


6. Incident disclosure communication

6.1 The incident disclosure gap

Recent research confirms that there is a gap between incidents that require disclosure and incidents that are disclosed (Iedema et al 2011; Weissman et al 2008). Consensus is forming that only around 30% of incidents are disclosed. The remaining 70% remain undisclosed and potentially contested as requiring disclosure, channeled through complaints (Bismark et al 2011), and still subject to disclosure requests from patients and families, at times mediated with the help of the media or political representation. Lopez et al (2009) found that disclosure “was more likely if the [incident] required additional treatment and less likely if the [incident] was preventable” (Lopez et al 2009: 1892). Further, if errors were not apparent to the patient, doctors would be less inclined to disclose them. At the same time, doctors were less likely to provide information about errors when they did decide to disclose them. Important too was the finding that disclosure made patients raise their rating of the service and of the quality of the care provided (Lopez et al 2009: 1892).

Despite mounting evidence of ‘the disclosure gap’, questions about the legitimacy of patient-based assessments of incidents persist (Dauer 2011). Research as shown however that patients are justifiably concerned about problems and risks in their care (Friedman et al 2008). Their experiences of quality of care and incidents have been shown to positively associate with experts’ assessments of what constitutes an incident, or what Dauer might regard as ‘the objective dimensions of incidents’ (Lopez et al 2009). That evidence aside, health services continue to call into question the right of consumers to question service standards and outcomes, and the means they choose to do so. Overall, and assisted by the view that medical expertise should be allowed to trump lay persons’ personal experience, the way that health services, clinical risk managers and policy makers classify incidents consistently favours biomedical criteria over socio-psychological criteria.

Thus, incident severity in the Canadian Disclosure Guideline is framed in biomedical terms (Disclosure Working Group 2011b). Similarly, the International Incident Classification System proposed by Runciman and colleagues promote the view that problems and failures in care can be satisfactorily and exhaustively labeled using single outcome-based incident definitions (Runciman et al 2009) - an approach that sits uncomfortably with patients’ and families’ accounts of unexpected care outcomes (Iedema et al 2008). In these publications, patients’ and families’ perspective on incidents is portrayed as incurring an unduly broadened definition of health care incident. Patients’ and families’ ‘broadening’ of incident definitions would be on the basis of what Dauer (2011) describes as ‘subjective’ elements. Such ‘subjective’ elements however have an indelibly ‘objective’ function for patients and families, as they help illuminate the complexity and dynamics of incident events (viz. the ‘incident cascade’) on the one hand, and help clarify the mode of involvement of specific individuals and their perceived role in the unexpected outcome, on the other hand (Iedema et al 2011a).
The gap that researchers have identified between things that go wrong and what is disclosed, therefore, is not merely one that calls for more information, but is also one that calls for different kinds of information compared to what is favoured by established incident definitions, reporting conventions and investigation approaches. Seen from that angle, the gap at issue here results from clinicians and consumers entertaining radically different understandings about what should be talked about in the wake of an unexpected outcome.

Important here is that for consumers the treatment process occurs principally on the basis of a trust. This is particularly so because the patient is expected to offer up and expose their body to the probing gaze and ‘magical capacities’ of the clinician (Good 1994). For clinicians, trust is not an end point in the patient relationship, but is its point of departure. From there, care for them inevitably branches out across a range of rationalities besides interpersonal trust, including organizational, economic, technological, professional and reputational reasoning, concerns and interests. A gap is further implied as medicine cools its stance towards patient-clients through ‘detached concern’. Detached concern is construed as the prerequisite par excellence to the efficacy and ‘objectivity’ of medical and surgical intervention (Lief and Lief 1963). The practice of clinical-medical reasoning and the stance of detached concern may jeopardise however the clinician’s engagement with and appreciation for the patient’s own disease experience and treatment expectations. Such practice and stance may particularly be at odds with patients’ awareness of the in situ processes of clinical care, and their sense that these processes only too frequently lapse into risky behaviours, problematic decisions, and undesirable outcomes (Iedema et al 2009; Iedema et al under review).

The foregoing is seen to add weight to the proposal that patients’ and families’ assessments of quality and safety of their care should be taken into account when determining whether clinical care has resulted in unexpected outcomes (Iedema et al 2011a). Moreover, patients and families (unlike most clinicians) tend to spend a lot of time observing the processes and trajectories of care (Millman et al 2011). They are therefore in a unique position to speak about its quality and outcomes (Millman et al 2011, Conway et al 2010). Their participation becomes all the more significant when we consider that, the immense achievements of health care notwithstanding (Bliss 2010), the nett benefit of health care may no longer outbalance the direct and indirect harm that it entrains (Kilo and Larson 2009). It is not surprising, in light of these factors, that calls are growing for patients’ and family members’ experiences of health care to be given a more important role to play in how we achieve quality and enhance safety (Truog et al 2011).

6.2 Incident disclosure: current state of play

Commentators are increasingly inclined to regard disclosure as a relational achievement rather than as a skill that a person obtains or appropriates (Truog et al 2011). The point here is that communicating disclosure is unlikely to follow a set route,
and that the communicator needs to invent ways of going on depending on the kind of patient, the type of incident, the level of severity of the harm, the other stakeholders involved, and so forth. In short, the growing emphasis on the relational dimensions of open communication is fuelled by the realisation and acknowledgment that disclosure is deeply unpredictable. This unpredictability is not due to the patient’s ‘subjective’ response to an incident; rather, this unpredictability is inherent in all situations that involve life and death decisions, emotions, professional uncertainty, organizational complexities, cultural and linguistic specificities, and incident particularities (its varying nature, causation and severity).

This caveat of inherent unpredictability notwithstanding, Truog et al (2011) offer a comprehensive list of ‘things to do’ when disclosing an incident (Truog et al 2011: 74ff). Similarly, Iedema et al (2011a) set out a list of 30 incident disclosure points derived from patients’ and family members’ experiences of incidents and of health services ways of responding to these incidents. For reasons of space, these lists are not reproduced here. Consensus however is that a disclosure needs to be prepared for among the relevant clinicians, and the patient/family needs to be told a disclosure may be necessary; the disclosure is to allow a frank exchange of views and experiences rather than an information session, without straying beyond what is known about what happened (where ‘what is known’ is not simply circumscribed by what clinicians regard as fact, but also by what the patient (family) regards as important and noteworthy); the disclosure communication event involves an explanation, an apology, a plan for the patient and a plan for improvement; closure is achieved when all stakeholders express being ready for closure, and an offer of involvement in monitoring improvement and improvement outcomes is made to those affected (McDonald et al 2010; Conway et al 2010; Truog et al 2011; Iedema et al 2011).

While set language cues are helpful for enabling novices to initiate incident disclosure, patients and families will expect sincerity from those that do the disclosing. Sincerity manifests in the clinician as being oriented not towards themselves and their organization in the first instance, but to the patient and their family (Wheeler and Johnston 2009; NSW Ombudsman 2007). Disclosure training using actor-patients is useful for clinicians needing to learn to understand the type of language that is appropriate for disclosure discussions, but they also need to develop their own approach to sharing bad news, navigating through disappointment, anger, and blame, and steering the conversation from rumination and recrimination through to reparation and a productive outcome (Truog et al 2011; Iedema et al 2009).

In cases where disclosure occurs not to one patient (or family), but to large numbers of patients, the communication approach is rather different in complexity and dynamics (Dudzinski et al 2010). Here, the timing of publication of the need for disclosure is critical, because the incident is likely to be picked by the media (Delaney 2009). How individual patients are communicated with will be closely scrutinised by media representatives, and patients’ responses to such communication are likely to be publicised as well (Delaney 2009). In these instances, the clinical significance of the error may mean even less compared to that in the case of the individual patient. Thus,
the South Australian incident where sub-ideal radiological treatment was discovered to have occurred several years ago was declared at the time to have involved an insignificant deviation in radiological strength by the hospital. This assessment was used to justify non-disclosure at the time, a judgment confirmed several years later by the external investigator (Delany 2009). The non-disclosure decision was met with furore however when reported in the local newspaper: the hospital had decided not to mass-disclose the incident when it was uncovered without considering the views and interests of those (potentially) affected.

Another aspect of disclosure communication that is coming increasingly to the fore is that it frequently implicates not individual clinicians, but teams of clinicians. Where much of the US literature has privileged the doctors as the purveyors of incident disclosure, it has more recently begun to engage nurses with the task (Shannon et al 2009). Nurses have begun to complain about being excluded from disclosure communication, putting them in a precarious position, wedged between the patient (their family), and the doctor (Shannon et al 2009).

6.2.1 Communicating disclosure: References


Weissman, JS, Schneider, EC, Weingart, SN, Epstein, AM, David-Kasdan, J,

6.3 The role and content of apologies

As noted in our previous literature review (Iedema, Sorensen & Piper 2008), the literature outlines the ethical, moral, cultural and psychological aspects at play in relation to apologies in healthcare. This literature concludes that patients and their carers may not be assuaged by a ‘partial apology’ or expression of regret, and that they may expect a full apology that contains an acceptance of responsibility. This conclusion creates a tension between what patients and families want and the more limited expression of regret that forms the basis of most apology laws (Karla, Massey, Mulla 2005; Belinger 2003; 2004; 2005; Wojcieszak, Banja & Houk 2006; and Woods 2007 cited in Iedema, Sorensen & Piper 2008).

Generally, of course, good communication following an adverse event reduces the likelihood of complaints and litigation (Fallowfield 2010; Bluebond-Langer, Rodriguez & Wu 2010), but whether good communication incurs the offer of a full apology remains dependent on incident causation, patient (family) literacy and socio-economic background, and the legal environment within which the communication takes place. These latter factors make it difficult if not impossible to prescribe one particular apology over another. What is clear however is that if responsibility for the unexpected outcome is clearly evident, and services or practitioners fail to acknowledge this in how they phrase their apology, the patient (family) is unlikely to derive much satisfaction from a partial apology, and is more likely to take the matter further in order to force those responsible to acknowledge fault (Vincent et al 1994). To achieve restorative justice, patients and families are known to seek involvement from the media, political representatives, or a court of law.

In light of the foregoing it is not surprising that an increasing amount of literature is emerging on the role and content of apologies in relation to health care incident. Vines has published on the restorative justice function of apology laws (2007a). Similarly Alberstein & Davidovitch (2011) explore both the legal, and the cultural and collective, aspects of the role of apology in health care. In exploring the psycho-legal dimensions of apologies Allan (2007; 2008) and Allen and McKillop (2010) state that there is preliminary support from the psychological and physiological literature that disclosure can moderate the recovery and health of patients after an adverse incident, provided that the disclosure incorporates an admission of responsibility. In this regard, Slocum, Allan and Allan (2011) conceptualize apology as a process that consists of one or more of three components: affect, affirmation, and action. Each of these components has two categories; one that reflects a self-focus on the part of the wrongdoer, and the other a self–other focus. What will be accepted as a good enough apology appears to depend on the severity of the consequences of the wrong, the level of responsibility attributed to the wrongdoer, and the perceived wrongfulness of the behavior.

Vrabl (2009) sets out the role of apology in maintaining trust. Similarly, Bismark (2009), Armstrong (2009) and Cohen (2010) explain that in the aftermath of an adverse event, an apology can not only help restore trust to the patient-provider relationship, but also bring comfort to the patient, and forgiveness to the health practitioner. Wu, Stokes &
Pronovost (2009) found that patients will probably respond more favorably to physicians who apologise and accept responsibility for medical errors than those who do not apologise or give ambiguous responses and, in this regard, patient perceptions of what is said may be more important than what is actually said (see too Yardley et al 2010).

Lazare & Sherman (2011) state that whilst apologising to patients and their families for medical mistakes is an increasingly accepted practice, often overlooked is the need for clinicians or services to apologise to other members of the treatment team or patients for humiliations inflicted in medical practice, independent of medical mistakes. Their article presents empirical data based on a sample of 355 subjects and analyses what the offended party seeks in an apology and the magnitude of the importance of each of these desires. The restoration of dignity in response to humiliation emerges as one of the most important functions of apologies. Finally, this article identifies 15 healing forces of apology, a combination of which is necessary for healing any given incident that is experienced as an offence.

6.3.1 Apology: References


Yardley, I, Yardley E & Wu A (2010) How to Discuss Errors and Adverse Events with Cancer Patients *Current Oncology Reports* 12(4) 253-260.
6.4 Establishing accountability

Recognition has grown of the need to balance systems thinking and the ‘no blame’ approach to incident communication with appropriate means of establishing accountability and culpability for unexpected outcomes. While the term ‘no blame’ may have served to give clinicians confidence that their better intentions would not be called into question and that they would not be scape-goated as a result of things having gone wrong (Dekker 2008), confidence is now growing that it is time to introduce the notion that accountability for inappropriate conduct can be appropriately computed and publicly established. Equally, Wachter and Pronovost (2009) argue that the ‘no blame’ principle has been pushed to the point where it protects those who should have been made accountable. In their view, clinicians should no longer expect to escape culpability when culpability for an unsafe act is indeed at issue. This shift in thinking is critical to incident disclosure, since patients and families expect the disclosure discussion to touch on precisely these issues: who is personally accountable and to what degree (Iedema et al 2011).

Echoing patients’ and families’ priorities, this trend towards a more nuanced form of accountability determination has important implications for incident disclosure. Thus, Boothman et al (2009) are clear that when an incident occurs and it is found to have resulted from inappropriate clinical, medical, administrative or managerial decisions and/or actions, this will be openly acknowledged to the patient who is harmed, and/or to their family, and it will be reflected in the ‘full’ apology that is offered. Here, open acknowledgement of an error and a full apology are considered appropriate, even when the legal context offers limited to no protection for such apologies and admissions (Mastroianni et al 2010). Similarly, McDonald et al (2010) build Reason’s culpability algorithm (Reason 2000) into their University of Illinois incident disclosure model as one of its seven pillars, recognising that this is a central component to effective incident disclosure.

That said, few of the disclosure models or algorithms proposed lend as yet sufficient credence to patients’ or family members’ views of accountability or culpability. This is despite evidence that patients’ ratings of the quality of care received show an association with incident occurrence (Lopez et al 2009); despite evidence that patients have knowledge of problems, risks and incidents in health care (Iedema et al forthcoming), and despite growing evidence of the need for patient-assisted incident reporting (Millman et al 2011).

The lack of confidence in patients’ perspective on unexpected outcomes in their care runs parallel with the commonly held view on the part of providers that patients’ response and reparative expectation is but an “untidy psychological process”. Thus, Edward Dauer insists on contrasting “the subjective expectations of the patient and the objective measures in the medico-legal system” (Dauer 2011: 736). Patients’ subjective perspective on incidents positions their responses and reparative expectations as inherently unpredictable, and therefore as inherently problematic: “there is little that is intrinsic or inevitable about people’s needs and expectations following an injurious
event” (Dauer 2011: 735). Lacking empirical evidence for this view, Dauer remains suitably vague on the point of whence medico-legal understandings of incidents derive these special privileges of certainty, tidiness, and objectivity.

Indeed, Dauer regards the cultural and linguistic specificity of patients’ backgrounds as sufficient reason to downplay the reliability of their stances, questioning whether “patients’ expectations … are authentic” (Dauer 2011: 736). Worse still, he regards patients’ willingness to accept an apology as currency in the process of reparation following an incident as evidence of their ‘unreliable subjectivity’: “the effects of disclosure and apology [show that] patients’ perceptions are malleable”. Inherent in Dauer’s view are several deeply concerning assumptions: that the medico-legal perspective on and approach to addressing incidents is tidy and rigourous; that clinicians’ approaches to incident investigation remain unaffected by the unreliable “permutations” that typify patients’ expectations and responses, and that the justification for disclosure is that ‘patients’ malleability’ should be exploited to circumvent extended legal processes! Not surprisingly, Dauer’s final three-fold catalogue of principal objectives of disclosure (restoration of a patient’s pre-event condition; accountability for providers; learning from incidents) lacks a critical fourth: display of service/practitioner humility and restoration of the patient’s dignity by acknowledging and acting on patients’ questions about, insights into, and expectations regarding particular service processes and individual behaviours (Iedema et al 2011).

The trend towards involving patients in post-incident processes, including investigation (McDonald et al 2010), practice improvement (Conway et al 2010) and outcomes monitoring (Iedema et al 2011) reassures us that many now acknowledge that patients’ responses and expectations cannot be dismissed as ‘subjective’, ‘malleable’, and ‘lacking intrinsic-ness and inevitability’. On the contrary, as Conway and colleagues suggest for example, patients’ input into the post-incident process “increases its credibility” (Conway et al 2010: 11). Thus, it is natural that consumers should expect growing involvement in their care, and that they expect openness when things go wrong. Some may even expect to be involved in making sure incidents do not re-occur. We are fortunate to now have several examples of patients adding value to how clinicians approach service reparation and improvement outcomes monitoring (Iedema et al 2011).

6.4.1 Establishing accountability: References


6.5 Near Misses and Disclosure

Disclosure of near misses is generally seen as ‘beyond the call of duty’, as this might involve clinicians in little else than communicating about problems in care at the expense of caregivers’ achievements (Disclosure Working Group [Canada] 2011a). While the term ‘near miss’ remains of questionable application in health care (Disclosure Working Group [Canada] 2011b), its significance is that it separates events that cause harm to the patient from ones that do not. For that reason, ‘near misses’ are seen to have organisational, clinical and/or medical significance only, therefore not warranting disclosure.

However, in a recent publication Wu et al (2011) explain that the situation around ‘near misses’ is somewhat more complex than this. A critical consideration is that patients’ and families’ situated experience of incidents may create a significant difference between their assessment of incident severity and that attributed to the incident by clinicians, risk managers and patient safety officers. On that basis, providers should take care with independently attributing the classification of ‘near miss’, and assuming that the patient and family are not in need of a discussion about what happened and what resulted. It may be that while the event appeared to constitute a ‘near miss’ to the provider(s), it did in fact produce suffering or harm in the eyes of the patient or family, as stories recorded by Ledema and colleagues frequently attest (Ledema et al 2011a/b). Instead of regarding patients’ and families’ interpretation as lacking intrinsic-ness and inevitability, as is Dauer’s (2011) inclination, providers should dialogue with patients and families to reassure themselves that everyone is in agreement that they came to no harm, and that the ‘near miss’ is indeed a matter for the clinical team to address independently, rather than requiring full and formal disclosure to the patient and/or family.

The above bears on discussions in the literature that operate on the assumption that providers’ assessment of incidents and classification of their severity are self-sufficient (e.g. Gallagher et al 2009; Truog et al 2011). Research into patients’ and families’ experiences of incidents has shown that such assessments and classifications can be incomplete, dismissive of patients’ and families’ experiences, and even ‘objectively’ wrong, to (reluctantly) use Dauer’s term. Questions about assessments can be raised from a ‘subjective’ perspective (with assessments not recognising that patients [and families] may experience severe and extended mental suffering as a result of an inappropriate discharge, a dismissed concern, or ignored self-diagnosis), and from an ‘objective’ perspective, due to actual harm going unrecognised, being ignored, being downplayed or deliberately being denied by providers. With incident not being reported as frequently as they should, checking back with patients and families is surely important.

In this context we may refer to Denham’s discussion about the ‘five rights’. Denham recognises that the five clinical-technical ‘rights’ (‘treatment to the right patient, with the right drug, at the right times, with the right dose, using the right route’) should be complemented with the five ‘cultural rights’ or ‘TRUST: ‘Treatment that is just, Respect,
Understanding and compassion, Supportive care, and Transparency and the opportunity to contribute to learning’ (Denham 2007: 107). While the intent of Denham’s TRUST model is to reassure clinicians involved in incidents that they have rights, it also has application to the patient’s role in the determination of near misses. That is, when the impact of a ‘near miss’ is assessed, the patient should be granted the opportunity to confirm such assessment, and the provider should not assume that their ‘objective’ assessment can proceed from the principle that the patient’s confirmation of such assessment is dispensable.

6.5.1 Near misses: References


Conclusion

The domain of incident disclosure has seen a rapid increase in interest from policy makers, researchers, clinicians, consumers and even insurers. The above literature review provides but a snapshot of some of the more notable works published in this domain. Nevertheless we are able to deduce some important conclusions from the literature review. Three conclusions are outlined here.

First, incident disclosure is recognized to realise patient-centredness. Without adequate communication about unexpected outcomes, and without that communication being structured as open and democratic dialogue, patients are unlikely to derive the feeling their interests and concerns are heard. Since it is their bodies that are ‘on the line’, and some rare exceptions aside, non-disclosure is no longer feasible or ethical.

Second, incident disclosure is increasingly realised to encompass more than ‘just’ disclosure of an incident. Thus, disclosure is seen as indicator of safety culture. Going beyond obligation to the patient (or their family), open discussion about unexpected outcomes manifests practitioners’ and services’ resilience in the face of problems and failures. It demonstrates their capacity for learning, and it evidences a humility towards those who seek care.

Third, incident disclosure is regarded as requiring innovative ways of thinking about (the need for) legal reform. Useful examples can be found in the domains of family law and public accident and disability insurance. There, we have complemented adversarial and complaints models with elaborate conciliation processes and public insurance arrangements. These arrangements provide important starting points for rethinking the ways in which we currently frame health care incident responses, and for re-evaluating our approach to legal reform.
Appendix: Incident Disclosure - Additional references


43. Editorial (2011) "Disclosure-with-offer program provides more transparent culture." in *Strategies for nurse managers.*


79. Lloyd, R (2008) Treasury Managed Fund - Scheme Structure Including Contract of
Literature review: incident disclosure research, policy and legal reforms since 2008


96. Obama, B (2009) "Obama Verbatim on Open Disclosure. These remarks are excerpted from a speech by President Obama on Jan. 22, as he welcomed senior staff and cabinet secretaries to the White House." Washington D.C.

71:150-516.
113. Senate Statement (2009) "Statement of Gerald m. Cross, MD, FAAFP Acting under secretary for health, Veterans Health Administration Department of Veterans Affairs before the Committee on Veterans’ Affairs United States Senate." in *The Committee on Veterans’ Affairs United States Senate*. Washington DC.


