AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Open Disclosure:
A Review of the Literature

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Executive Summary

This report presents a review of the open disclosure literature. This literature is obtained through searching national and international policy, legal research, empirical studies, and other related publications. Criteria for inclusion are that work is published within the last 5 years, and it makes an important contribution to the field in so far that is evident from its citations and innovative perspective.

The literature available to date shows that open disclosure is of rising concern to policy makers, legal experts and academic researchers alike, given the steep rise in open disclosure related publications over the last five years. The policy literature is rapidly expanding with jurisdictions across the English-speaking world in the process of producing their own forms of disclosure regulation and research. But because of the legal, economic and performative complexity of disclosure, our knowledge of the practice and effects of disclosure remains limited. Particularly vexing questions include what is the appropriate scope and force of privilege; what is the role of processes such as Alternative Dispute Resolution (ADR), and what is the compensatory value of error?

What is further evident is that there is as yet a paucity of non-hypothetical enquiry into open disclosure, with most studies relying on case study scenarios rather than investigating subjects' actual experiences of open disclosure.

Finally, given the moral importance that attaches to 'being open' about adverse events affecting patients' own bodies, debates are intensifying about the relative importance of ethical principles of openness vis-à-vis pragmatic considerations of the extent to which disclosure leads to legal liability and economic risk.

Modelled on the Canadian Patient Safety Institute's overview of Open Disclosure published last year (Canadian Patient Safety Institute, 2006), our document is structured as follows. Following brief background and methodology sections, we present our review in the form of summaries / commentaries on recent publications. The review itself is arranged according to the following headings: *legal materials, empirical studies, ethical writings* and *debate*. Following a brief Conclusion, the final section of the review contains our full bibliographic record of open disclosure related publications. *National and international policy and related documents* are included in an appendix.

Background and Introduction

Origins of Open Disclosure

In 1987, in response to rising legal bills due to litigation following adverse events, the Veteran Affairs Hospital in Lexington, USA, began to trial a radical plan: “to maintain a humanistic, care-giving attitude with those who had been harmed, rather than respond in a defensive and adversarial manner”. Recalling its inception, Woods writes: “As the policy was implemented and ethical issues regarding disclosure arose, the risk management committee had some tough decisions to make. Ultimately committee members decided the hospital had an obligation to reveal all the details of its investigations to patients and family members affected by errors or negligence, even if they otherwise would not have known that a mishap had occurred” (Woods, 2007: 81). Just over ten years later, the practice of apologizing for errors and complications was shown to have led to a drop in court cases and claims (Kraman, Cranfill, Hamm, & Woodard, 2002 ; Kraman & Hamm, 1999). Open Disclosure now forms part of health policy reform across the USA, Canada, Australia, New Zealand and the U.K.

Principles underpinning Open Disclosure

Open Disclosure involves clinicians in signalling to the patient and/or the patient’s family that an adverse event has occurred. The U.K.’s National Patient Safety Agency policy entitled “Being Open – Communicating patient Safety incidents with patients and their carers” (National Patient Safety Agency, 2005; UK Department of Health, 2005) highlights open communication as a principle that is central to its realisation: “openness and honesty can help prevent events form becoming formal complaints and litigation claims” because “[b]eing open when things go wrong is clearly fundamental to the partnership between patients and those who provide their care” (National Patient Safety Agency, 2005). Open Disclosure policy frames these moral-ethical principles within a legal liability discourse however that sets limits on precisely how disclosure and its attendant apology are articulated and enacted in situ. In general, the force of the constraints embedded in policy reflects the degree of admissibility of clinicians’ disclosures and apologies in a jurisdiction’s courts of law.

♦ Main challenges

How staff enact the openness that is advocated in Open Disclosure policy is thus contingent on the degree of legal protection given to disclosures and apologies. The challenge here is that staff needs to come to terms with the uneven and often shifting legal landscapes that impact on them and their work. In Australia, for example, partial apologies ('We are sorry this happened') are nationally advocated, even though apology legislation in New South Wales and the Australian Capital Territory (ACT) is such as to prevent full apologies ('We are sorry we made a mistake') from being admissible in court. Another challenge that lies at the heart of Open Disclosure is the requirement that clinicians disclose adverse event information to people who are physically injured and likely to be psychologically affected by those adverse events. The affective intensity of this is likely to produce situations where risk managerial and legal prudence become tangled with personal feelings and social dynamics.

A third prominent theme centres on disjunctions between what patients expect following incidents and what the doctors involved would be prepared to provide (Gallagher, Garbutt, Waterman, Flum, Larson, Waterman et al., 2006; Gallagher & Lucas, 2005). Research suggests this gap results from consumers' views favouring Open Disclosure to be deployed more frequently than do doctors'; for consumers an apology is desirable where for doctors apologizing remains a source of (legal) concern; consumers expect full disclosure of what happened while doctors would "choose their words carefully", and where consumers valued truth and compassion, the doctors valued truth, objectivity and professionalism.

Finally, research of actual Open Disclosure meetings is not available and may never be possible due to the sensitive nature of such meetings and of the issues discussed (but see Iedema, Jorm, Wakefield, Ryan, & Dunn, under review). Much research therefore reports on how clinicians *would* or *should* respond if finding themselves in the situation of having to share with patients and their families information about adverse events, and how patients (families) *may* respond in return (Chan, Gallagher, Reznick, & Levinson, 2005; Liebman & Hyman, 2004; Mazor, Reed, Yood, Fischer, Baril, & Gurwitz, 2006). Clearly, it is crucial that we enhance our understandings about how staff and consumers experience adverse events (e.g. Manser & Staender, 2005) and how they communicate about adverse events (Duclos, Eichler, Taylor, Quintela, Main, Pace et al., 2005; Iedema, Mallock, Sorensen, Manias, Tuckett, Williams et al., in press).

Method for searching and selecting material

In our search of the literature, two approaches were used, one for searching general literature, and the other for searching legal references. The processes used for each are briefly described below.

Process for searching general literature

Medline(ovid), Embase, Cochrane Database of Systematic Reviews, EBSCO, Academic Search Elite, databases were searched. Because this is a new field, and articles with the key word 'open disclosure' were few, we searched terms that may be associated with open disclosure but for which a different key word may have been used, such as adverse event, adverse events reporting, patient involvement, shared decision making and patient safety. We then extended our search to terms such as iatrogenic, doctors/hospital and duty; doctors/hospital and negligence, doctors/hospital and duty to advise; doctors/hospital and duty to warn; doctors/hospital and duty of care; medical negligence. These terms were then cross-matched with Australia to ascertain local references.

Process for searching the legal literature

LexisNexis, Austlii, Canlli, Ballii and Google were searched for relevant legal journal articles, cases and legislation on open disclosure. Search terms used included: open disclosure, adverse event, iatrogenic, doctors/hospital, duty of disclosure, duty of candour, duty to advise, duty of care, negligence, and medical negligence. Searches combined terms as well as searched them individually. The general search outlined above also revealed some legal literature. The Bibliographies of some of the literature revealed further relevant references. The resulting legal literature was grouped into the following sub-themes:

- The legal context
- The regulatory context
- Compensation and accountability
- Duty to disclose
- Qualified privilege
- Apology and law

As a result of our searches, a bibliographic database of over 500 references was developed, with articles directly relating to, or having indirect but relevant reference to the issue. Of these, 50 articles and policies were selected for review, chosen to give a rounded appreciation of the subject. In making this choice, we sought to not duplicate the Canadian literature review (Canadian Patient Safety Institute, 2006). We have kept closely to the open disclosure theme, and where key word search resulted in articles that dealt specifically with related themes but did not allude to disclosure (e.g. patient safety) they were not included.

Review and presentation template

The selected articles were grouped into major themes for review and presentation. Some articles cover multiple themes that we have used to link the review. The themes chosen include:

- The legal literature
- The ethics of disclosure
- The academic research literature (empirical studies that report on the impact of implementation on patients, on professionals and on specialties, including communication issues, and articles that propose methods for implementing open disclosure in health services)
- Debate
- Policy literature (appendix).

The review is grouped into Australian literature, where this is available, and then international literature. A generic template was devised to guide and structure the presentation of the material. This template consisted of:

- Outline of the presenting problem/context
- Actions arising or taken as a result of the problem, as defined
- Method of actions, where given
- Results
- Recommendations.

Structure of the report

Our report is structured into two main sections. Section one presents the literature review. Section two presents a bibliography of relevant literature.

Section 1:
Literature Review

A number of prominent domains are evident from our review, such as policy, law, empirical studies and moral exhortations. However, like the open disclosure process itself, these themes are overlapping and multi-dimensional. A possible reason for this is that open disclosure is not just a moral and ethical issue; the process also operates in an established, but dynamic, legal environment and the best way forward for all those involved is not yet clear. Thus, as the process evolves the effects it has on its participants and the health system are still being understood, analysed and expounded.

♦ The legal literature

The 2002 Corrs Chambers Westgarth *Open Disclosure Project: Legal Review* (Corrs Chambers Westgarth, 2002) provides the most comprehensive analysis of the law relating to Open Disclosure available at the time of publication. There is a need for the *Legal Review* to be updated as there have been several changes in the law since its publication. For example, post-review many jurisdictions have adopted legislation protecting apologies. The *Legal Review* also considered the applicability of the various Fair Trading Acts and Trade Practices Act to Open Disclosure. Since the *Legal Review*, there have been considerable legislative changes in several Australian jurisdictions removing the right of patients to sue doctors under this legislation. The case law has also progressed in the area of a clinician's duty to advise a patient of an adverse event, (Wighton v Arnot [2005] NSWSC 637 (1 July 2005).

One of the issues identified as potentially facilitating open disclosure by the *Legal Review* was the "linking" of the Open Disclosure Standard to a statute, namely the professional registration statutes throughout Australia. Or, alternatively, such statutes could expressly provide that failure to inform patients of adverse events may constitute a matter which attracts professional censure. Since the writing of the *Legal Review*, this has occurred in a minority of jurisdictions. However, the linking of the Open Disclosure Standard to statutes has not occurred.

Several matters raised in the *Legal Review* have not been addressed. For example, the *Legal Review* made the point that there was confusion over the nature and extent of the coverage of privilege legislation, which has not been addressed in any detail in the literature. Further, the *Legal Review* discusses the merits of Alternative Dispute Resolution (ADR) as a form of protection for information exchanged during the open disclosure process, citing the *Health Services (Conciliation and Review) Act* 1987 (Vic), as a potential model for consideration. There is a lack of Australian literature examining the applicability of both mediation principles to inform communication issues in open disclosure, as well as informing the wider regulation of the open disclosure process in the legal context in which it operates.

In this regard, Alternative Dispute Resolution (ADR) processes such as "Collaborative law" (Lande, 2003) may need to be considered in relation to open disclosure and the legal issues it raises. "Collaborative law" is a process where both sides of a dispute attend a meeting with their lawyers and each side has the benefit of hearing not only the other side's story but also the legal advice given to them. The issue also has the potential to facilitate "corrective justice" as set out by Vines (2005), and address privilege issues, in that collaborative law generates little in the way of documentation and the parties are required by the Participation Agreement signed by them at the outset of the matter, to make full, frank and honest disclosure of all relevant documents in their possession or control. These documents are tabled at the four-way meetings of the settlement team but no notices for discovery, subpoenas or pleadings are prepared or filed. The settlement negotiations are privileged and confidential. Also, the recent changes to the *Family Law Act* requiring compulsory mediation may well be instructive.

Whilst the literature is beginning to examine issues relating to compensation (Corbett, 2006) and accountability (Bismark, Dauer, Paterson, & Studdert, 2006) for medical error and the type of legal and regulatory environment required to deliver both appropriately, there are many systems in other jurisdictions that have not been examined in the literature, and that have the potential to inform the position in Australia.

The review below highlights four main themes as being prominent in the current literature:

- The general legal context of open disclosure
- The broader regulatory context and the role of law to compensate victims of medical error within that context
- Questions about whether a legal duty is imposed upon medical practitioners and health service providers to openly disclose adverse events or not, and if so, the legal source of that duty
- legal issues associated with certain aspects of the process itself, namely access to documents in the event of litigation and apology.

The legal context

Corrs Chambers Westgarth (2002) Open Disclosure Project: Legal Review. Sydney: Clinical Practice Improvement Unit, North Sydney Health, pp 1-73.

The Legal Review provides a legal analysis of the relevant stakeholders, and how they affect the legal analysis in open disclosure, as well as addressing the concern surrounding open disclosure causing increased litigation. The legal issues surrounding apology, privilege, misleading and deceptive conduct, the negligence liability of health care providers and institutional liability are also presented. The Role and status of Standards, Alternative Dispute Resolution (ADR), and how the law may facilitate Open Disclosure is also discussed.

The regulatory context

Gallagher, T.H., Studdert, D., & Levinson W., (2007) Disclosing harmful errors to patients, *The New England Journal of Medicine*, 356(26), 2713-2719.

This journal article sets out the regulatory approaches to open disclosure in the United States, and, in so doing, highlights the tensions faced by all jurisdictions in finding suitable methods to regulate open disclosure. According to Gallagher et al the aim of regulators in the U.S. is to bridge the gap between patient expectations in relation to disclosure of adverse events and clinical practice. The article provides an overview of the major open disclosure laws, standards, and programs in place as at June 2007. In comparison with the position in Australia, the American National Joint Commission on Accreditation of Healthcare Organizations (JHACO) Open Disclosure Standard links open disclosure to the accreditation status of hospitals. The article notes that the National Quality Forum (NQF) endorsed a safe practice guideline on the disclosure of serious unanticipated outcomes to patients in November 2006. The NQF guideline is significant as it frames disclosure as a core component of system-focused, high-quality health care rather than as a risk-management tool. Both the Joint Commission's standard and the NQF framework differ in operation from the Australian Standard in that they are linked to an underlying enforcement mechanism in the form of the 29 purchasing coalitions in the Leapfrog group using the NQF guidelines in their pay-for-performance ('P4P') programs. In addition more than 1300 hospitals representing more than half the nation's hospital beds submit information regarding their compliance with the guidelines to the Leapfrog group, which then publishes the information on the internet. According to Gallagher et al, this combination of direct financial incentives and visibility to consumers has the potential to catalyse the development of sophisticated disclosure programs, and is a more promising method of regulation than legislation. The authors comment that mandatory disclosure related legislation has been enacted by seven states at the time of publication, and 34 states have adopted apology laws that protect specific information conveyed in open disclosure. They further state that enforcement is a major challenge in relation to the regulation of open disclosure as it requires comprehensive reporting and monitoring systems and this is not reflected in the laws relating to open disclosure, as only Pennsylvania specifies and sanctions for non-compliance. In addition, U.S. apology laws, like their Australian counterparts, are not uniform and most, like the majority of Australian jurisdictions, only protect an expression of regret and not an admission of liability.

In Australia, open disclosure operates in a legal environment that traditionally looks to compensate victims of adverse events via the tort, fault-based principles of negligence, via litigation; safety and quality processes such as open disclosure must grapple with how to meet their aims of improving safety and quality in a legal environment that in many ways is incompatible with how open disclosure needs to work. Accordingly, the literature is beginning to focus on the broader regulatory issues surrounding safety and quality processes like open disclosure, such as the need to move away from the traditional fault-based legal approach to medical injury to a more systems-based approach where those responsible for improving patient safety would be responsible for building systems of compensation into their regulatory initiatives.

Corbett A. (2006) Regulating compensation for injuries associated with medical error. University of Sydney Law Review 28, pp 259-296.

Whilst Corbett's article does not specifically focus on Open Disclosure per se, it is instructive in relation to the academic literature on the regulation of medical error and patient safety more generally, and compensation for that error in particular. Corbett argues that there has been a shift in regulatory focus in health care from a concern of remedying individual instances of fault to a concern with remedying systematic failures. This shift has revealed an extraordinarily complex 'regulatory space'. Whilst not specifically mentioned, Open Disclosure is an obvious part of this regulatory space.

Corbett examines the issue of regulating compensation for injuries suffered from adverse events. He describes the issue as being multi-dimensional in that is concerned with creating a system that makes use of a large number of mechanisms that are integrated so that each of the mechanisms interact to increase the capacity of the system to achieve its regulatory outcomes: The issue of compensation occurs within a 'regulatory space' where the operation and competition of various regulatory regimes influence regulatory impact. Accordingly regulators must determine the boundaries of the systems of regulation, i.e. which institutions, laws, policies, practices and conduct need to be explicitly included in the regulatory initiative in order to achieve the public policy goal.

Corbett argues that the current tort based negligence system for compensating patients for medically related injury is unfair as well as being ineffective in improving levels of safety: it fails to deter unsafe practices and relatively few people who are injured can gain access to it. More importantly, tort law focuses on fault and inhibits participation of medical practitioners in safety initiatives, whereas patient safety initiatives adopt a systematic approach – these approaches are less than compatible.

Corbett therefore argues for the transfer of responsibility for developing rights to compensation to people who have responsibility for improving patient safety: Those responsible for improving patient safety should be required to build systems of compensation into particular regulatory initiatives. That is, the system of compensation should be a part of the system of regulation that is aimed at reducing the level of occurrence and severity of adverse events rather than being incompatible with it. Ultimately, compensation should be a form of 'enterprise liability' where a health care institution makes a decision about the appropriate level of investment needed to improve patient safety – a right to compensation arises when a particular adverse event was preventable and where there were mechanisms in place to reduce the probability of that particular adverse event.

Compensation and accountability

Related to the regulation of safety and quality initiatives such as open disclosure is the issue of compensation for medical error. The fault-based legal system awards monetary damages for medical negligence. The literature reveals that there may be a need to broaden the basis for compensation.

Bismark, M., Dauer, E., Paterson, R., & Studdert, D., (2006) Accountability sought by patients following adverse events from medical care: The New Zealand experience, *CMAJ*, 175(8), 889-894.

This journal article reviews compensation claims submitted to the Accident Compensation Corporation (ACC), New Zealand's national no-fault insurer following injuries associated with admission to a public hospital and complaint letters submitted to the National Health and Disability Commissioner (HDC) to determine the forms of accountability sought by injured patients. The ACC and HDC are New Zealand's two medico-legal paths for medical injury. The authors' argument for undertaking the study is that in countries where litigation is the dominant avenue for obtaining redress for perceived problems with care, patients have little choice other than alleging negligence and suing for monetary damages – accordingly these are extremely difficult environments in which to disentangle the different forms of accountability sought by those pursuing medico-legal action. In New Zealand the task is simpler as patients have a choice between monetary (ACC) and non-monetary compensation (HDC; these processes involve advocacy, investigation and mediation). Bismark et al found that of 154 patients, 50% sought corrective action to prevent similar harm to future patients (45% system change and 6% review of involved clinician's competence) and 40% wanted more satisfying communication (34% explanation and 10% apology). The odds that patients would seek compensation were significantly increased if they were in their prime working years or had a permanent disability as a result of their injury. When injuries resulted in death, the odds of a compensation claim to the ACC were about one-eighth of those of a complaint to the HDC. Accordingly, injured patients seek various forms of accountability, many of which involve non-monetary goals. There is therefore a need to ensure that any system of redress accommodates all forms of accountability sought.

Liebman,C.B., & Stern Hyman, C., (2004), A mediation skills model to manage disclosure of errors and adverse events to patients, *Health Affairs* 23(4), 22-32.

U.S. literature such as Liebman and Hyman's article is instructive in that it enables examination of different types of accountability and both litigious and non-litigious methods of delivering them. Liebman and Hyman describe a mediation model for the process of open disclosure that they believe offers a template for accomplishing the goals of: litigation risk management (a major policy goal of open disclosure in the U.S.) and quality patient care (in the form of responsiveness to patients and families desires for information, an apology, assurance that steps have been taken to prevent others from being similarly harmed and fair compensation where appropriate). The researchers worked with four Pennsylvania hospitals which operate under Mandatory legislative open disclosure requirements.

They conducted a participant observation study in relation to open disclosure. As a result of the study the authors recommended, amongst other things, that mediation be used to settle potential claims early. The model works on the premise that parties are often concerned about more than money, such as knowing what exactly happened and what is being done to prevent a recurrence. The proposed model accordingly allows for both monetary and non-monetary remedies such as specific education for staff, and a new checklist for carrying out a procedure. Both lawyers and parties are encouraged to speak in joint and private sessions. The model also encourages an early apology of responsibility.

Duty to disclose

Faunce, T.A., & Bolsin, S.N., (2005) Fiduciary disclosure of medical mistakes: The duty to promptly notify patients of adverse health care events, 12, *Journal of Law and Medicine,* 478-482.

Faunce and Bolsin's article offers an example of the legal academic literature in Australia that discusses the issue of open disclosure in terms of whether or not a legal duty to disclose exists and what the potential sources of such a duty are. Whilst the main source of the legal duty to disclose adverse events in Australia is tort-based, the source of the duty in other jurisdictions such as Canada, is fiduciary-based. The authors state that fiduciary duties could be extended in Australia to encompass an obligation to disclose adverse events to patients.

Madden, B., & Cockburn, T., (2007). Bundaberg and beyond: Duty to disclose adverse events to patients., 14 *Journal of Law and Medicine*, 501-527.

Madden and Cockburn provide an overview of ethical and legal obligations to disclose adverse events to patients in Australia, as well as the Standards and guidelines in place, using the Bundaberg experience as a catalyst for the discussion. The article compares the Australian position with international jurisdictions including Canada, the U.S. and the U.K., and accordingly cites national and international codes, statutes, policies and case law. The article also raises, although it does not answer, the question of who should make the disclosure and who should be present when disclosure is made? Whilst the authors cite Liebman & Hyman's article on a mediation model of disclosure in this regard (see above), they do not endorse it or explore the issue of mediation any further.

Ranson, D., (2006) Ethical, professional and legal regulation of medical practice, 14 *Journal of Law and Medicine*, 20-23.

Ranson provides an overview of the linking of the ethical requirement for open disclosure set out in the New South Wales Medical Board's Code of Professional Conduct 2005 and the Medical Practice Act 1992 (NSW). The result of the link is that medical practitioners may potentially be held liable

for professional misconduct if they fail to openly disclose adverse events to patients. Some other Australian jurisdictions have adopted a similar link between their codes and legislation. The article is of interest in relation to the broader issue of regulation of open disclosure. The linking of codes and statutes is one method of regulation, however it must be considered within the broader regulatory context. Whilst Australia remains a fault-based legal system, the recent passing of civil liability legislation in all Australian jurisdictions, (for example, the Civil Liability Act 2002 (NSW)), imposes significant limits on the damages courts may award to people or relatives of people who are the victims of negligence. Since the passing of restrictive legislation in Australian jurisdictions, the number of claims brought against doctors and hospitals has reduced substantially. However, as was the case in New Zealand after the introduction of 'no-fault' legislation in the 1970's, in NSW the number of disciplinary complaints has increased: The major NSW medical insurer, United Medical Protection, issued figures early in 2006 showing that the rate of disciplinary complaints had risen from 7 per 1000 members in 2002 to 20 per 1000 members in 2005. In the same period, civil claims reduced from 21 to 14 per 1000 members. (For a list of the relevant provisions of the Australian Codes of Medical Practice and linking Legislation please see the Bibliography section of this Literature Review.)

Qualified Privilege

The Australian Council for Safety and Quality in Health Care, *The public interest in health care qualified privilege, Issues Paper,* August 2001.

Unfortunately, there has been little literature addressing the issue of legal privilege in relation to Open disclosure since the Council's 2001 Issues paper on the subject. The Issues Paper sets out the rationale for qualified privilege, the competing public interests associated with qualified privilege, judicial attitudes and international trends in relation to qualified privilege, in addition to the relevant Australian law at the time of publication and Freedom of Information issues. The Paper recommended that there be national action in relation to privilege including clear articulation of the specific scope of protection intended to be provided by each qualified privilege scheme.

The Australian Council for Safety and Quality in Health Care, National Report on Qualified Privilege, July 2002.

This Report addresses the context in which quality assurance and improvement activities are undertaken in the Australian health care system, and barriers to the participation of health care professionals in those activities. It also addresses the various public interest considerations that influence qualified privilege laws. The structure, scope and purpose of the various qualified privilege laws in the Commonwealth and all states and territories are discussed. Selected projects that have been undertaken utilising qualified privilege are also highlighted.

The report also provides a list of the committees/activities that have been declared under qualified privilege laws in each state and territory, together with details of relevant contact people in each state and territory, at the time of publication.

Apology and law

Vines, P. (2005). Apologising to avoid liability: Cynical civility or practical morality? *Sydney Law Review*, 27, 483-505.

Vines sets out and compares the legislation that is in place in Australian jurisdictions concerned with protecting apologies / expressions of regret from admissibility. Overall, Vines states that the evidence suggests that the issue is not whether the apology is admissible in evidence, but how the apology is articulated (as 'partial' or as 'full' apology). Vines states that it is more important that the apology incorporate taking responsibility for wrongdoing and less important that it is shielded from litigation. To date only NSW and ACT legislation allows for this possibility. The mere expression of regret allowable in other jurisdictions is most likely to lead to a situation where insincere and ineffective apologies are made. Vines acknowledges that, paradoxically, the apology which is most likely to be effective (an admission of wrongdoing) is also the riskiest. Further, Vines argues that the best way to think about apology in the civil liability arena is in the form of "corrective justice". There exist a plethora of apology legislation both nationally and internationally as well as some case law on how the courts deal with different forms of apology. Some examples are provided in the Legislation and Case lists in the bibliography of this Literature Review.

Kalra J, Massey KL, Mulla A. (2005) Disclosure of medical error: policies and practice. *J R Soc Med*;98(7):307-309.

The authors note the interest of governments in patient safety but that honest disclosure to patient or family is a neglected issue. The authors discuss the dilemmas of apology and suggest working towards a systematic and effective process although this is not outlined. The article is useful in setting out and comparing the open disclosure policies and components of the U.S., Australia, U.K. and Canada. The authors distinguish two sorts of apology (sympathy and responsibility) and outlines the barriers to open disclosure including legal liability and insincere apology. They comment that an appropriately worded apology by the doctor can reduce the likelihood of a lawsuit.

♦ Literature on the ethics of disclosure

Berlinger, N. (2003). Avoiding cheap grace. *Hastings Center Report,* 33(6), 28-36.

Berlinger's argument distinguishes inauthentic responses to medical harm from sincere apologies. Berlinger draws on theo-ethical writings by Bonhoeffer to alert those apologizing for medical errors to the problem of regarding saying sorry as a sufficient response to adverse events in itself, and the need to recognize that an authentic apology requires a dyadic or relational negotiation. To avoid 'cheap grace', this negotiation is in part driven by the receiver of the apology, who is (or should be) given the freedom to choose between rejection of the apology, deferral of a decision, and forgiveness for the harm. In Berlinger's view, apologies for medical harm are a complex practice of confession, repentance and forgiveness, requiring a stance that signals to those harmed that staff are prepared to take 'the view from below'.

Berlinger N. (2004) Ethical considerations in policy development. *Patient Safety and Quality Healthcare* 2004; Oct/Dec.

This paper is based on a presentation stemming from work the Hastings Centre has done on the ethical dimensions of quality improvement. The presentation focussed on how patient safety policies can encompass the safety of individuals affected by medical mistakes and other adverse events and how these policies can take into account the values and expectations about appropriate and inappropriate words and actions of all involved parties. Berlinger notes that people think it is natural to tell the truth, that not doing so is learned and that clinicians must relearn this skill and practise it. The ethical consideration of policy is that the obligation to disclose is met only when the patient and family understand what has happened. The best way to do so and to get clinicians to remember is via storytelling. Structured stories on patients and clinicians experiences are powerful resources that can be used in teaching.

Wojcieszak, D., Banja, J., & Houk, C. (2006). The sorry works! Coalition: making the case for full disclosure. *Journal on Quality and Patient Safety*, 32(6), 344-350.

Wojcieszak and colleagues promote the use of 'sorry' and of full honesty following incidents. Their arguments run parallel with those made by Nancy Berlinger and Michael Woods in that disclosure is framed within a morality of authenticity, and this morality is opposed to self-protective risk management and legal caution. Any attempt to constrain honesty on legal, insurance or reputational grounds is dismissed as privileging organisational or personal interests at the expense of patients' dignity. Disclosure, in this paradigm, does not conform to risk managerial prudence, but to interpersonal restitution. The intent of disclosure is to retrieve the trust – the fiduciary basis of the clinician-patient relationship – that is damaged as a result of the harm.

Woods, M.S. (2007). *Healing words: the power of apology in medicine.* Illinois: Joint Commission Resources

Michael Woods' book is a passionate plea for honesty between doctors and their patients. Woods' argument is based on his own experience of being sued, and on his realization and growing conviction that honesty is the best policy. Woods argues against mitigating or constraining the form of doctors' apologies on legal or risk managerial grounds. He regards legal and risk managerial considerations as being inimical to proper disclosure and detrimental to the doctor-patient relationship. He puts forward what he calls the five R's of apology: recognition (of the problem or incident), regret (for what happened), (acknowledging) responsibility (in so far as that is appropriate from the knowledge at hand), remedy (as a tangible solution to the patient's problem) and remain engaged (to ensure disclosure does not end with a single conference, but leads to a respectful and supportive relationship). In arguing for a 'culture of civility', Woods foregrounds two messages: one centres on the absolute importance of authenticity in our disclosure of incidents, the second centres on the need that we become attuned to our own bodily and verbal habits as communicators to obviate that patients (family members) are given sub-conscious messages that contravene our intent for honest disclosure.

Berlinger, N. (2005). *After harm: Medical error and the ethics of forgiveness*. Baltimore: Johns Hopkins Press.

Berlinger's book promotes a theo-ethical view of what medical-clinical staff need to do in response to having played a role in causing clinical harm. Drawing on discussion with both staff and consumers affected by incidents, Berlinger does not advocate retribution, but restoration. She is clear that clinicians, few of whom ever intend to harm their patients, are equally victims of medical harm, and she presents evidence of their suffering. The book delves deeply into the affective dimensions of harm, including the difference between clinicians' feeling like a failure and having made a mistake; the importance of their confronting their feelings of guilt, and the salutary effects of confession and disclosure. Berlinger is unforgiving however in her promotion of honesty and openness, framing disclosure exclusively in (theo)moral-ethical terms, and spending limited time discussing the organizational complexities, financial implications, legal complications and political depths of medical harm. A crucial resource for anyone interested in disclosure of incidents, the book is inspirational, confronting (in its focus on the affective dimensions of harm), and unwavering in its commitment to the patient as victim of harm.

The academic research literature

As noted, the academic research literature on open disclosure consists predominantly of scenario testing studies and hortatory (in-principle) arguments. No doubt because open disclosure deals with sensitive information, takes place in fraught circumstances and has not as yet settled as communication process (Iedema et al., in press), research into the enactment of disclosure may remain difficult for some time to come. There are some publications however that do now report on clinicians' and consumers' actual experiences of open disclosure (e.g. Duclos et al., 2005).

The literature regarding how to conduct and communicate open disclosure is more extensive. The majority of articles note that stakeholders are generally aligned in their view that errors should be disclosed, but note the disjunction between principles and practice. The main barrier is fear of litigation, although other barriers noted include a culture of secrecy, fragmentation of responsibility and action and protectionism. Several authors comment on the lack of evidence on which to base disclosure practice. They identify unanswered questions for research including: cultural variations, and the relationship between improving patient trust and decreasing lawsuits. Although the evidence that is available shows that implementation of disclosure policies and practices is patchy, there is also evidence of an increase in research interest in open disclosure based on current reports of implementation projects.

Patient perspectives

Duclos, C.W., Eichler, M., Taylor, L., Quintela, J., Main, D.S., Pace, W., & Staton, E.W. (2005). Patient perspectives of patient-provider communication after adverse events. *International Journal for Quality in Health Care*, 17(6), 479-486.

This study engages with 16 adults who have experienced adverse events (13 cases in total). By interviewing participants in focus groups, the study seeks to reveal what actual victims of harm experience and prefer. The study's conclusions do not diverge much from other scenario-based studies undertaken by Gallagher and colleagues: victims see timely discussions as important, and set great store by collaborative problem-solving and planning. While the study's method (focus groups) undoubtedly had effects on the ways in which participants responded to questions and other participants' comments, the study does not elaborate on whether or how these effects took place. The study promotes its focus on non-role-played and therefore non-hypothetical responses made by participants for enhancing our understanding of patients' and families' experiences and sensibilities following incidents. The study regards such actual responses as an important means for engaging with the lived dimension of harm.

Hobgood C, Peck CR, Gilbert B, Chappell K, Zou B. Medical errors--what and when: What do patients want to know? *Academic Emergency Medicine* 2002;9(11):1156-1162.

The authors note that little is known about how and when the public wish to learn of errors committed during their medical care, or whether patients endorse reporting of error to hospital committees or central reporting agencies. The authors undertook a pilot study in an Emergency Department (ED) on patients and families preferences about medical error disclosure, reporting to hospital patient safety committees, government reporting agencies, and state medical boards, and the role medical educators should play in error disclosure. A 12-item survey instrument was administered to 60,000 patients in a tertiary care hospital ED during the summer of 2000. The study found that an overwhelming majority of respondents wanted full disclosure of any medical mistakes, and that they wished to learn of it as soon as it is detected, even if the full extent of the error was not yet known. Patients also endorsed reporting of errors to hospital committees and regulatory agencies. Authors recommend further studies relating to specific examples of medical error explicit for error type and severity.

Communicating Open Disclosure

Fallowfield, L., & Fleissig, A. (2003). *Communication with patients in the context of medical error. Final Report*. London: Psychosocial Oncology Group Brighton & Sussex Medical School, University of Sussex; National Patient Safety Agency.

This 59 page report is intended to establish a set of principles to guide communication with patients and their families following medical error, and to prioritise an agenda for focussed research. The report contains an executive summary, section summaries, an introduction, definitions and taxonomy, sections on what is known about the practice of disclosure, reasons for and barriers to disclosure, practical issues to consider, suggestions for effective communication about adverse vents, training, support and further research. An appendix and references are included. Findings from a review of the literature is given including that: errors are common and multi-factorial; communication often has a central role in the origin, exacerbation and amelioration of the effects of medical error; there is little consensus about the process of communication including what should be communicated, when and who should do it; and communication is influenced by the nature of the error. Expected Improvements include learning from errors, asking for support, feeling relief from guilt and promoting trust, strengthening doctor-patient relationships and decreasing the likelihood of litigation. Barriers include litigation fears, disciplinary criticism and communication skill deficiency that may improve with increased organisational and professional support and training, commitment by top management and explicit staff and manager support. The authors note that little research evidence is available describing the practical problems of implementing and demonstrating measurable benefits. Research that has been done suffers from methodological

limitations and absence of data to inform recommendations. The report elaborates and discusses these issues, and in doing so, recognises that there is no universal formula that can be applied, although the detailed taxonomy provided is intended as a reference tool for use when considering the type of communication needed. Examples and descriptions of desirable communication strategies are provided under topic headings. An outline of ideas for further research is given, including the urgent need for a scoping exercise to identify examples of good practice and initiatives, among others.

Fallowfield, L., & Jenkins, V. (2004). Communicating sad, bad, and difficult news in medicine. *The Lancet, 363*(9405), 312-319.

Fallowfield and Jenkins are concerned about the stress that can result for patients, families and clinicians from insensitive approaches to breaking bad news. They discuss a range of interventions and note that despite communication training, guidelines and protocols, problems with communication remain. The authors review research on communicating difficult news and assess whether interventions help, focussing on three particular areas: an obstetric/paediatric setting, acute trauma situations and patients with cancer. Four tables are included that detail: research on doctors' views, research on patients' and families' views, examples of guidelines, and training courses. In obstetrics/paediatrics settings, patients were able to distinguish their personal reactions to the diagnosis itself and their reactions as to how doctors had informed them, most appreciating doctors who were confident, showed concern, and were caring, but who also allowed time to talk and ask questions. Details of an exemplary model of practice change and associated resources are given including a template for local policies, background reading, videos and a website. In the trauma setting, the important attributes for family members of clinicians was privacy when receiving the news, the attitude and knowledge of the news bearer and the clarity of the message. Cancer patients were able to classify six types of characteristics and qualities of clinicians that included: the inexperienced messenger, the emotionally burdened, the rough and ready, the benevolent but tactless, the distanced doctor, and the empathic professional. Discussion of Australian studies is prominent. Congruence is noted between guidelines and the views of patients and relatives, but the authors note that significant evidence of their implementation is lacking. Studies cited suggest that trainees could identify guidelines they not practice them and that clinicians experienced less stress in institutions with disclosure guidelines. The authors conclude that it would be a mistake to assume that only communication skills in breaking bad news needed improvement, suggesting that improving communication in general should be assessed. Based on a systematic review, successful methods appear to include a learner-centred approach, a cognitive component or evidence base for suggested skills, a behaviour component allowing participants to rehearse communication skills, and an affective component permitting participants to explore feelings evoked. Studies using these psychosocial methods reported improvement in skills still evident after 12 months.

Hoy, E. W. (2006). Disclosing medical errors to patients*. ENT: Ear, Nose & Throat Journal,* pp. 410-413.

A succinct outline of the history, issues and reasons for openly disclosing medical error is given, including the advantages to head and neck (otolaryngology) surgeons. The author cites a 2004 study by Shah et al that found 2,600 error-related major morbidity incidents and 165 error-related deaths in otolaryngology patients and raises the physicians' ethical and legal responsibilities, implications and improvement suggestions in this regard. Background is given on the Institute of Medicine report and findings, as well as focus group research that confirms physician's agreement that patients should be told of an error, and the uncertainty that clinicians express about disclosure including fear of litigation, being reported to a public registry and not knowing how to talk to patients about error. The author cites a literature review by Chan et al that outlines a five point framework for effective error disclosure, and notes surgeons' high score on describing medical facts but lower score on empathy and preventive steps. The article provides information on resources including a video with advice about communication and discusses the repercussions and risks that may result if communication is not entered into. The author refers to the importance of a structured and compassionate error-disclosure program in reducing the number of lawsuits and amount of compensation paid, citing the Lexington Veterans Administration Medical Centre policy of extreme honesty to manage high malpractice losses and the dramatic decline in number and size of liability settlements and of frivolous lawsuits following policy implementation. The author concludes that academic and private-sector institutions are implementing and monitoring full-disclosure policies that are critical to improving patient safety and redesigning safer systems.

Cantor, M.D., Barach, P., Derse, A., Maklan, C.W., Wlody, G.S., & Fox, E. (2005). Disclosing adverse events to patients. *Joint Commission Journal on Quality and Safety*, 31(1), 5-12.

The authors note that a variety of psychological and cultural factors inhibits clinicians and organisations from disclosing adverse events to patients. Organisations should develop clear policies supporting disclosure and should create supportive environments to enable clinicians to meet their ethical obligations in this regard. The Joint Commission recognises the experience and promotes the policy of the Veterans Health Administration (VHA) about routine disclosure of adverse events to patients. The policy includes practical recommendations for implementation. Disclosure is required when the adverse event has a perceptible effect on the patient that was not discussed in advance as a known risk, necessitates a change in the patient's care, potentially poses an important risk to the patient's future health, even if that risk is extremely small, and involves providing a treatment or procedure without the patient's consent. Disclosure of near misses is discretionary but advisable. Disclosure by a clinician involved in the patient's care is appropriate.

Fein S, Hilborne L, Kagawa-Singer M, Spiritus E, Keenan C, Seymann G, et al. A conceptual model for disclosure of medical errors. *Advances in patient safety* 2005;2:483-494.

This report of a research project is part of a compilation of research projects on patient safety supported by the Agency for Healthcare Research and Quality ('AHRQ'). Its aim was to construct a conceptual model of factors that facilitate or hinder disclosure of medical errors, so that health systems become aware of errors and so enhance the trustworthiness of the system for patients. A qualitative method was used involving 25 separate focus groups with attending physicians, nurses, residents, patients and hospital administrators at five academic medical centres in a U.S. university health care system. A hypothetical scenario was used to elicit responses about disclosure. All groups were aligned in their views that errors should be disclosed. Influences on whether disclosure should occur fell into four categories: provider factors (perceived professional responsibility, fears and training), patient factors (desire for information, level of healthcare sophistication, rapport with provider), error factors (level of harm and whether patients and others were aware of the error or harm) and institutional culture (perceived tolerance for error and a supportive infrastructure).

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.

Based on the current emphasis in patient safety on open communication and the promotion of the JCAHO standard, the authors seek to assess the strength of the evidence for disclosing errors to patients and to present practical suggestions for disclosing medical errors based on a review of the literature. No outline of the review process is given. They note that over the past twelve years only seven studies have assessed patients' attitudes to disclosure and over the past sixteen years only six studies have examined physicians' attitudes and practices. The studies reveal gaps between patients' preferences and current practice, as well as physician support for the principle of disclosure and hesitation to share information because of a fear of liability. Some institutions have adopted policies without adverse malpractice consequences. Practical suggestions are given for talking with patients about errors. The authors note that the literature contains important but unanswered questions such as cultural variations and whether disclosure does improve patient trust and decrease lawsuits. Research in this area is in its infancy. Future research should consider the broad range of outcomes before concluding whether disclosure has an overall positive or negative effect.

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.

The JCAHO standard to disclose and the Institute of Medicine ('IOM') report on error have prompted calls for greater transparency in health care. While there is an established ethical expectation for health care professionals to disclose errors, decisions about appropriateness, timing and content of disclosure remained a private matter. Using a survey instrument comprising three sections on institutional policies, disclosure practices and actual frequency of disclosure, the authors surveyed risk managers in a random sample of 493 hospitals stratified by size and region six months after the JHACO standard to ascertain how hospitals are dealing with it. Results showed that almost all (98%) of respondents reported disclosing harms at least some of the time, and 80% had disclosure policies in place or under development. Then, paradoxically, the authors provide a figure of 44% of surveyed hospitals as being in the process of developing disclosure policies at the time of the survey. The authors took this high rate as a sign that the IOM message was being listened to. However, calculation of the rates of adverse events from the IOM estimates and comparison of this figure with actual disclosures reported by the respondents reveals the number of disclosures to be low. The authors questioned whether harms were being recognised by hospitals staff and whether known harms were being disclosed. Fear of litigation was most strongly associated with reluctance to disclose. The authors conclude that without malpractice reform and a cultural change to overcome the secrecy encouraged by the legal system, major safety improvements will be slow to occur.

Liang BA. A system of medical error disclosure. *Qual Saf Health Care* 2002;11(1):64-68.

The author notes that external mandates such as cost savings, individual moral obligations and patients' rights and internal mandates such as patient safety have driven medical disclosure. The 'name and shame' approach has not worked. The author advocates a system of disclosure including education about the systems nature of error, a philosophy of mutual respect and integrating the patient/family as a partner in error reduction so as to improve the system, the patient/provider relationship and the overall quality of care. The article outlines the process for disclosure and provides rationales for the main steps. The article differs from others by setting out a process through which the patient/family is asked to assist in the error investigation. The author notes the legal barriers to efforts to discuss medical errors, and recommends the use of a system of alternative dispute resolution, such as mediation. The author concludes that the approach advocated can only work if all members of the healthcare enterprise truly accept the beliefs and philosophies regarding systems improvement and mutual respect.

Mazor, K.M., Simon, S.R., & Gurwitz, J.H. (2004). Communicating with patients about medical errors. *Archives of Internal Medicine*, 164(Aug 9/23), 1690-1697.

The authors note that even though many organisations advocate disclosure, there is little empirical evidence to guide practitioners. The authors undertook a literature search of four electronic databases with empirical data relating to disclosure of medical errors. Of the 825 articles identified only 17 were reviewed, the majority of which were descriptive. The authors comment on the wide variety of definitions of medical error across the studies. The study reports on three particular areas: deciding to disclose, the disclosure process and the consequences of disclosure. It found that there is empirical support for concluding that disclosure often does not occur, that patients and the public favour disclosure, and that physicians also support disclosure. However, no empirical details emerged to guide practitioners with respect to practical questions of who, what, when, and to whom to disclose. Future work would encompass evaluation of the relative importance of factors raised in the study, the extent to which fear of litigation, reputation and loss of privileges were barriers and methods for minimising the likelihood of anticipated negative consequences. A coherent framework for investigating the influence of a range of organisational variables on disclosure is also needed, to facilitate systematic examination of the relationships between variables that could be used in the development of guidelines of practitioners.

Vincent, C. (2003). Understanding and responding to adverse events. *New England Journal of Medicine*, 348(11), 1051-1056.

Vincent believes that the learning and organisational change following investigation of an incident and the patient's perspective have not been given sufficient attention in health, but are essential components of quality and safety strategies. He has developed a framework of contributing factors to adverse events, provides an explanation of the reactions of clinicians and patients to medical error, and provides a rationale for why and how medical error should be addressed. A targeted literature review was undertaken. The review includes: establishing when a care management problem has occurred, identifying contributory factors to the problem, initiating the investigation process, gauging the effect of adverse incidents on patients and families, planning how to care for patients harmed by treatment, gauging the effect of adverse incidents on staff, and establishing how to support staff after an adverse incident. The author recommends that an institutional policy on open disclosure should be available, supported by guidelines for discussing errors with patients, that training in communicating with patients and families should also be available, and that basic education in the law and legal processes surrounding medical incidents should be offered to reduce anxiety about legal action.

Walshe K, Shortell S. (2004) When Things Go Wrong: How Health Care Organizations Deal With Major Failures. *Health Affairs,* 23(3):109-118.

High-profile major failures around the world are causing concern about patient safety. The authors sought to investigate the ways these failures were dealt with in several countries, namely the U.S., U.K., Australia, New Zealand and Canada. In the absence of a central register or database of major failures, a literature review and telephone interviews with several key informants in each country were undertaken. The article reports on the nature of major failures, barriers to disclosure and investigation, policy implications and recommendations and why other industries appear to take safety more seriously than health. Common themes in the major failures include: longstanding problems, problems that are well-known but not resolved, potential causes for immense harm, and the lack of management systems to identify repeat incidents. Barriers include an endemic culture of secrecy and protectionism, fragmented knowledge and responsibility about how to handle problems, individual and organisational self-deception and post hoc rationalisation, use of informal mechanisms to deal with the problems of poor performance, binding nondisclosure agreements on civil actions for medical negligence, and confusion of multiple investigative agencies. Policy recommendations include making systems more effective and translating lessons into explicit and agreed recommendations. Reasons why the public health system appears complacent in rectifying errors compared to industry are given. The authors conclude that non-action is an issue of great international concern and that major failures in health care are a product of the distinctive culture of the organisations, the health care professionals and the health system. Reforms will include changes in medical and health professional education, greater public demand for accountability, advances in measurement and reporting of health care quality and patient outcomes data and more principled clinical and managerial leadership in health care organisations.

♦ Debate - Potential increased litigation

Studdert, D. M., Mello, M. M., Gawande, A. A., Brennan, T. A., & Wang, Y. C. (2007). Disclosure of medial injury to patients: an improbable risk management strategy. *Health Affairs, 26*(1), 215-226.

Studdert and colleagues' paper alerts us to the possibility that Open Disclosure may prompt more claims and complaints than avert them. The article's findings are derived from survey responses mailed in by medico-legal experts (not consumers) in response to hypothetical incident scenarios. These subjects' responses suggest that 32% of victims of severe harm might be deterred by Open Disclosure and that 31%, upon being told about the adverse event, might be prompted to lodge claims, indicating "a 60 percent chance that comprehensive disclosure of sever injuries would at least double the annual number of claims nationwide and a 33 percent chance that volume would increase by threefold or more" (p. 219). In elaborating their argument, the authors adopt a rather ambivalent stance, however. Its title classifies Open Disclosure as 'an improbable risk management strategy'; at the same time, the authors acknowledge that disclosure is the ethical thing to do. The reader is left with the dilemma of reconciling the threat of rising levels of litigation in response to disclosure, and the moral imperative that non-disclosure is no longer an acceptable option.

Kraman, S., & Hamm, G. (2007). Bad modelling? Health Affairs, 26(3), 903.

Kraman and Hamm's response to the 2007 Studdert et al paper in the same journal questions Studdert's et al's methodology and reasoning. The methodology is seen as problematic because it relies on 'anonymous experts' whose expertise and bases for making claims are not clarified. The reasoning is seen as problematic because it ignores the findings reported in Kraman and Hamm's (1999) paper, where they report on "seven years' experience using a full disclosure and voluntary compensation system (which is now in its twentieth year)". Their study "supported a conclusion of more claims but no more direct cost" (p. 903). Kraman and Hamm go so far as to dismiss Studdert et al's paper as "a flawed study that is apt to encourage risk managers to stay the deny-and-defend course because of the (unfounded) fear of doubling or tripling their liability exposure". The authors judge the paper to be "both irresponsible and bad science".

Wakefield, J., Jorm, C., & Ryan, C. (2007). Open Disclosure: Details matter - A Response to Studdert et al 2007. *Health Affairs, 26*(3), 903-904.

Wakefield and colleagues' response challenges Studdert et al's paper just cited on grounds similar to those mentioned by Kraman and Hamm, noting that a "study using a convenience sample of experts giving opinions on cases lacking detail is of doubtful value". They note that the study "ignores the substantial evidence that communication and relationships between staff, patients, and family are critical".

Studdert, D., Mello, M. M., Gawande, A., & Brennan, T. A. (2007). Disclosure: The authors repond. *Health Affairs, 26*(3), 904-905.

Studdert et al respond to the Kraman & Hamm and the Wakefield et al critiques by legitimating their reasoning, if not their methodology. Thus, they note that it would be unwise to discount disclosure's likely dual impact: "While deterring some patients from suing, or encouraging them to settle more quickly and for less, disclosure will also prompt some proportion of patients who would not otherwise have sued to do so". Rather than defending their choice of survey respondents and reliance on their opinions, Studdert et al point to the plausibility of their findings: "Are these numbers implausible? Can disclosure really be expected to change the litigation decisions of more than one-quarter of patients who have sustained negligent injury and would, in the normal course, have sought recovery for it? Is it unreasonable to expect that it would prompt one in four negligently injured patients to seek compensation?" Overall, it is clear that Studdert et al have articulated a concern that is prominent for those who consider disclosure still to be an option and whose economics might motivate some to delay if not indefinitely defer it. Recent studies are suggesting that open disclosure is no longer an option, but an obligation whose inescapability is anchored in emergent social norms and values rather than linear calculations. As an emergent social ethos that affects public institutions well beyond health (Moore, 1995), the ultimate effect of open disclosure cannot be deduced from past behaviours and current non-deliberative approaches to running and designing health care services (Iedema, Jorm, Wakefield, & Ryan, under review).

♦ Overview articles

Kaldjian, L., Jones, E., Rosenthal, G., Tripp-Reimer, T., & Hillis, S. (2006). An empirically derived taxonomy of factors affecting physicians' willingness to disclose medical errors. *Journal Of General Internal Medicine, 21* (9), 942-948

The authors note the importance of physician disclosure of medical errors to patient safety, patient care and professional education but also that the variables that facilitate or impede disclosure are diverse and lack conceptual organisation. Based on a mixed-method study of literature search, analysis, focus groups and expert review, the authors developed a comprehensive taxonomy of factors affecting voluntary disclosure. The taxonomy includes four facilitating factors, namely responsibility to patient, responsibility to profession, responsibility to self and responsibility to community, and four impeding factors, namely attitudinal barriers, helplessness, uncertainties and fears and anxieties. Sub-factors are identified in each major factor grouping. The authors conclude that the taxonomy suggests directions for educational and institutional change, including acknowledging the diversity of factors, viewing disclosure holistically, complementing the individual's role with a systems orientation, teaching medical ethics and professionalism and addressing both the facilitating and impeding sides of the equation.

Levinson, W. & Gallagher, T. H. (2007) Disclosing medical error to patients: a status report in 2007. *Canadian Medical Association Journal,* 177.

This article gives a brief overview of open disclosure in Canada, stemming from research findings concerning the extent of adverse events in Canada, studies that suggest that medical error is infrequently disclosed and the observation that even though the malpractice environment is less onerous in Canada than in many other countries, Canadian patients are no more likely to be informed about harmful errors than patients elsewhere. The rationale for disclosing medical errors is given, including informed-consent provisions, physicians' ethical duty, room in the medical profession to initiate improvement, patients' desire for full disclosure and the opportunity that near misses presents for quality improvement. The authors note the 'disclosure gap' between what patients want and professionals provide. They outline what is happening in Canada and other countries. In Canada, guidelines and legislative requirements are being developed, including legislation that patients must be informed of errors and in British Columbia that an apology for an adverse event is inadmissible in court for the purposes of providing liability. The situation in the U.S. relating to malpractice insurance is outlined, as are moves by some U.S. health systems to disclose error and to provide appropriate financial compensation. They note emerging evidence that the number of malpractice claims may either stay the same or decrease. Finally, they outline what is required for high-quality disclosure including education, training, a genuine apology and that professionals and systems learn. They also note the importance of institutional support including senior management reviewing medical errors and creating policies, developing training courses and round-the-clock staff coaching services. Finally, they note the little research that is being done on the relationships between professionals' education programs, patient satisfaction and other outcomes.

♦ Conclusion

In undertaking this review, we had the opportunity to study what is presently available in the field and to present our impressions of the major issues emerging and hence the present state of knowledge. What we found is that open disclosure is multidimensional, emergent, and complex. We know that facing up to a mistake, admitting it to peers, talking openly to patients and apologising to those who have been harmed is difficult. Conflicting values and norms play a role. Open disclosure harbours strong passions about what is right alongside risk managerial prudence to preserve the economic viability and reputation of services and specialties.

Most prominent is that the current legal environment fuels fear of litigation, of making an error, and of owing up to it. Such fear is contrary to clinicians' and patients' perceptions of what is right. The legal regulatory limitations impinge on individual aspects of the open disclosure process, such as the effect of different types of apology and access to documents created as part of open disclosure. Moreover, the debate around the type of apology that is appropriate has become polemical. Some believe that apologies must be sincere; others regard a formulaic response to be sufficient.

While much of the work around open disclosure acknowledges the impact on patients, the emotional responses of clinicians is also being acknowledged as an important factor. Some fear the shame induced by admitting an error, while others appear to exhibit a misguided optimism that open disclosure can solve all of the ills of the system. What is becoming particularly evident are the additional 'incidents' that a poorly developed understanding of open disclosure principles and poorly developed execution of the open disclosure process might cause. It is now imperative that the implementation phase of open disclosure does not produce cumulative problems. That is, extra training, research and support are needed to ensure that openly disclosing a clinical error will not produce a backlash as a result of errors of process, inconsistencies in disclosure, or inappropriate communication in the context of changing criteria of legal liability.

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Appendix: The policy literature

The policy literature around open disclosure revolves around general principles and broad-based guidelines whose relation to incident management and practice improvement is gradually being developed (e.g. Queensland Health, 2006). Policy is mostly articulated at the jurisdictional and service delivery level, both in Australia and internationally, showing particularly rapid progress in the U.S. Equally, open disclosure policy development remains an iterative process as clinicians implement the principles and guidelines in a changing legal and insurance / indemnity environment. The policy literature reviewed below is drawn from information available on governmental websites relating to the policy and practice of open disclosure.

All States in Australia have open disclosure policies with the exception of Tasmania and the Northern Territory. The policies differ markedly. Some explicitly address open disclosure, developing policy overviews and specific procedural processes to guide staff in implementing open disclosure processes. Others approach managing adverse events via a risk management perspective that focuses on mandatory reporting from an organisational perspective. In the latter instance, the place of the patient as the primary focus of rectifying an adverse event is minimised. In most instances the information references the National Standard developed by the Australian Council for Safety and Quality in Health Care and associated resources, and provides guidance to clinicians undertaking the open disclosure process.

Internationally, initiatives on open disclosure are occurring in Canada, the U.K. and the U.S., with policies and guidelines available on the relevant government websites. In the US, health services are actively implementing open disclosure practices following JHACO mandating that patients are entitled to be informed of unanticipated outcomes of care. The American Society for Healthcare risk Management's monographs are particularly instructive in assisting hospitals in the U.S. to develop consistent and defensible policies and practices. Several jurisdictions remain at the incident reporting stage and have not yet posted information on open disclosure, notably New Zealand and the World Health Organization. Few peer reviewed publications exist on open disclosure policy. Those that are available reference the ethical criteria of disclosing errors to patients. Others advocate for a more integrated systems and systematic approach to open disclosure.

♦ Australian policy

Australian Council for Safety and Quality in Health Care (2003). Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care. Sydney: Australian Council for Safety and Quality in Health Care.

http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/former-pubs-archive-disclosure

There is often a great deal of uncertainty and confusion currently on the part of health care professionals and health care providers about disclosing information following an adverse event. The Australian Council for [now 'Commission on'] Safety and Quality in Health Care developed a national standard to promote a clear and consistent approach by hospitals, and other organisations where appropriate, to open communication with patients and their nominated support person following an adverse event (Australian Council for Safety and Quality in Health Care, 2003). The approach includes a discussion about what has happened, why it happened and what is being done to prevent it happening again. It also aims to provide guidance on minimising the risk of recurrence of an adverse event through the use of information to generate systems improvement and promotion of a culture that focuses on health care safety. The standard has no legal standing; it is a resource for organisations seeking to implement open disclosure. It provides a framework to be used initially in hospitals in the development or upgrading of an organisation's internal policies, processes and practices regarding adverse events and open communication. The standard is divided into two sections: Section A provides an overview of the Standard; Section B describes the open disclosure process. A comprehensive education and support package has been developed to assist with implementation.

NSW Health (2007). Open Disclosure. Sydney: NSW Health.

http://www.health.nsw.gov.au/quality/opendisc/policies.html

The NSW Government aims to ensure that if an incident occurs a formal process of open disclosure ensues that it is routinely practised by all staff. It has developed and revised an open disclosure policy that is accompanied by open disclosure guidelines. The policy is in the form of a directive to staff which sets out the objectives of the policy, the principles of open disclosure, the roles and responsibility of staff if an incident occurs and other associated organisational issues, such as record keeping, performance measures and definitions of incidents and their response levels. The open disclosure guidelines provide a framework for implementing the open disclosure policy in NSW health facilities. It includes an outline of the process, steps to be taken in the event of a high or low level incident and a flow diagram of the process. In addition to the issues covered in the policy, the guidelines also cover issues such as offering an apology, supporting the clinician and feedback to the patient and compensation.

Victorian Department of Human Services (2007). Clinical risk management. Melbourne: Victorian Department of Human Services.

http://www.health.vic.gov.au/clinrisk/downloads/open_disc_pilot_project.pdf

This information document describes the implementation of a project to develop and test open disclosure processes in pilot sites in six metropolitan and six rural and regional sites, as part of a national project. The document outlines the background to the project, governance arrangements, the education process for staff involved in the project and guidelines to sites about policy development and funding and refers the reader to the resources accompanying the national standard. A state and national evaluation of the project is intended to be the basis for future direction of open disclosure policy implementation in Victoria. Seven recommendations emanate from the evaluation including state wide rollout of standardised education and training, a toolkit to assist organisations implement open disclosure, incorporation of open disclosure in the state clinical governance framework, integration of open disclosure into organisational clinical risk management frameworks and policies, legislation to protect internal deliberative discussions as part of root cause analysis investigations, including of open disclosure in patient charter and a change to a more meaningful name.

Queensland Health (2007). Incident management. Incident management policy & clinical incident management implementation standard. Brisbane: Queensland Government.

http://www.health.qld.gov.au/patientsafety/im/webpages/IncidentMan.asp

This standard is intended to provide staff with a comprehensive “how to?” guide in relation to managing clinical incidents. It outlines responsibilities for all levels of staff and provides the necessary tools and processes to do so. It is accompanied by an incident management policy and a clinical incident management implementation standard, and directs readers to related information and tools, including forms to brief senior managers on incidents.

South Australian Department of Health (2006). National open disclosure standard pilot project. Adelaide: Government of South Australia, Department of Health.

http://www.safetyandquality.sa.gov.au/Default.aspx?tabid=103

This document provides a brief outline of the pilot project that the South Australian Department of Health is implementing. The overview references the National Open Disclosure Standard and is accompanied by a range of resources including a brochure for clinicians giving information on open disclosure, a pocket card and project governance arrangements. The overview document describes the implementation of the project in three sites.

Western Australia Department of Health (2007). Open disclosure. Perth: Office of Safety and Quality in Health Care.

http://www.safetyandquality.health.wa.gov.au/involving_patient/open_disclosure.cfm

This is a brief introduction to open disclosure. The document directs the reader to the initiative of the Australian Council for Safety and Quality in Health Care Open Disclosure Standard and to a range of associated resources.

ACT Health (2006). Significant incident response policy. Canberra: ACT Health.

http://www.health.act.gov.au/c/health?a=dlpol&policy=1156898859&did=10107160&sid=

The policy briefly describes the process of providing prompt, effective and consistent feedback to patients following a significant incident. It is accompanied by a policy on mandatory reporting of significant incidents that includes information on reporting to senior organisations staff as well as to the patient, client, consumer or family following rollout of the open disclosure standards in the Territory. The policy contains mandatory reporting flow charts and report forms.

♦ International policy

National Patient Safety Agency (2005). Being open. Communicating patient safety incidents with patients and their carers: NHS.

http://www.npsa.nhs.uk/patientsafety/improvingpatientsafety/beingopen/

The agency aims to promote a culture of reporting and learning from patient safety incidents to reduce the levels of harm. The strategy outlined in the policy document *Being open* is central to the government's initiative to establish a safer and better healthcare service and the NPSA's commitment to improving communication between healthcare organisations and patients and/or their carers when a patient is harmed or has died as a result of a patient safety incident. The policy was developed from feedback from pilot sites. It follows the *Seven steps to patient safety*; it enunciates key elements of being open, and is set out in nine sections, including principles, patient issues, staff issues, organisational issues, incident detection, initiating the process, documentation, follow-up and completing the process. It is accompanied by a program of resources including an e-learning toolkit, a video based training program and a review of bereavement and counselling services in NHS-funded care in England and Wales and is integrated with other risk management procedures.

Canadian Patient Safety Institute (2007). Draft national guidelines for disclosure of adverse events. Edmonton, Alberta: Canadian Patient Safety Institute.

http://www.patientsafetyinstitute.ca/uploadedFiles/Events_And_Publications/Draft%20National%20Disclosure%20guidelines%20May%202%202007.pdf

This policy was developed following findings of the overall incident rate of adverse events in Canadian hospitals and aims to support and encourage appropriate bodies in the health system to develop and enhance disclosure policies and practices. The guidelines are based on a national and international environmental scan and literature review. The comprehensive library of resource material on the ethical, professional and legal aspects of disclosure of adverse events developed through the project is accessible through the CPSI website. The guidelines are intended to assist and support healthcare providers, interdisciplinary teams, organisations and regulators in developing and implementing adverse event disclosure policies, practices and training methods. The guidelines contain guiding principles, advice on building the foundation for disclosure, description of the disclosure process, reference to particular circumstances, e.g. paediatric care. Five appendices include a recommended reading list, recommended elements of a disclosure policy and a checklist for the disclosure process.

New Zealand Ministry of Health (2001). Reportable events: Guidelines. Wellington: New Zealand Ministry of Health.

http://www.moh.govt.nz/moh.nsf/f872666357c511eb4c25666d000c8888/ddfcefcd693aebc4cc256ad0007f41bb/$FILE/ReportableEvents.pdf

The report notes that the health care sector has failed to learn from lessons from reportable events and that it has an outmoded approach compared to other industries. The authors assert that there needs to be a fundamental rethinking of the way the health care sector approaches the challenge of learning from when things go wrong. This document is an attempt to systematically design safety into the process of care. The implementation of the guidelines is intended to create an environment that supports self-learning, promotes systems redesign, supports a culture of personal responsibility of health care workers for consumer safety and rewards the discovering and reporting of problems.

World Health Organization (2005). WHO draft guidelines for adverse event reporting and learning systems: From information to action. Geneva: World Health Organization.

http://www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf

The authors (Lucian Leape and Susan Abookire, both from Harvard) note that a frustrating aspect of health care for patients and professionals is the apparent failure of health care systems to learn from their mistakes. Hence reducing medical errors has become an international concern, and a global

effort by the World Alliance for Patient Safety has developed these guidelines for all Member States to make health care safer. One solution is reporting mistakes, hazards, risks and where the system is breaking down. The objectives of the guidelines are to allow countries to select, adapt or modify the recommendations in their specific environments or for their specific purposes. The guidelines draw on a review of the literature about reporting systems, a survey of countries about existing national reporting systems, and the experience of the authors.

♦ Policy relevant publications

ASHRM (2001). Perspective on disclosure of unanticipated outcome information. Chicago: American Society for Healthcare Risk Management of the American Hospital Association.

American Society for Healthcare Risk Management of the American Hospital Association or 'ASHRM' (2003). Disclosure of unanticipated events: the next step in better communication with patients. Chicago: American Society for Healthcare Risk Management of the American Hospital Association.

ASHRM (2003). Disclosure of unanticipated events: Creating an effective communication policy. Chicago: American Society for Healthcare Risk management of the American Hospital Association.

ASHRM (2004). Disclosure: What works now and what can work even better. Chicago: American Society for Healthcare Risk Management of the American Hospital Association.

In July 2001 the Joint Commission on Accreditation of Health Care Organizations (JCAHO) released its Patient Safety Standards mandating that patients are entitled to be informed of unanticipated outcomes of care. Following release, a great deal of activity occurred around interpreting the standards to comply with them, as organisations feared that a lack of policies and procedures would create liability exposure. This series of four monographs provide a 'state of play' of the role of disclosure in health care. The first monograph presents an overview. The second sets out the barriers to disclosure, models for managing the process and experiences with disclosure. An historical perspective is provided envisioning the evolution of disclosure and concluding that interpersonal communication skills are now essential for partnering with patients and that the new wave of activity will revolve around integrating the concept of open communication into all aspects of the health care environment. The third monograph includes discussion around building an effective policy that includes special consideration for specific patient populations and care settings and special considerations for the risk manager. The fourth monograph is intended as a communications guide for those involved in the disclosure process. It looks at components of effective communication of an anticipated outcome, considerations about how these components can be taken into account in various settings, and provides a basic review of the skills required to communicate effectively with patients and families after an unexpected event.

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Sparkman, C. (2005) Health Policy Issues: Legislating Apology In The Context Of Medical Mistakes. AORN, 82, 263-4.