Open disclosure is the “open discussion of incidents that result in harm to a patient while receiving health care”. While honest communication between clinicians and patients is by no means a novel concept, the formalisation of “open discussions” with patients and their families about unexpected clinical outcomes is a recent practice.

In Australia, open disclosure entered the national policy agenda as one dimension of improved clinical incident management, in a climate of new awareness of the frequency of adverse events and a national litigation crisis. The Australian Open Disclosure Standard was published in 2003, following endorsement by the Australian Health Ministers’ Conference. The intention of the Standard is to facilitate more consistent and effective communication after adverse events. It describes the elements of open disclosure as: an expression of regret, a factual explanation of what happened, consequences of the event, and the steps being taken to manage the event and prevent recurrence. Open disclosure thus also provides a crucial role in eliciting the information flow that is needed to reduce error.

Since publication of the national Open Disclosure Standard, states have begun to create supportive policy, however, there remains considerable variation in legislative protection and, despite wide agreement with the moral imperative for open disclosure, anxiety about its potential impact also remains. An anecdotal report of six sets of distraught parents resulting from a disclosure being shared by the parents of the single affected infant in a neonatal intensive care unit is one example. Insurers abhor uncertainty, and a recently published article highlighting the possibility of open disclosure prompting litigation has caused some alarm in local indemnity circles. Apart from theoretical argument and anecdote, however, there has been very little research on the actual effects of open disclosure practice on health care staff or patients.

A planned national pilot of the Open Disclosure Standard’s implementation was delayed due to concerns by state government insurers about the legal implications of offering expressions of regret to those harmed, and also by the transition from the Australian Council for Safety and Quality in Health Care to the Australian Commission on Safety and Quality in Health Care. However, the National Open Disclosure Steering Committee recommenced activity in April 2006, and 42 sites (two of which were private sector institutions) volunteered to participate in a 12-month funded pilot (two public sites subsequently withdrew). Start dates varied, but the pilot officially concluded in December 2007. Sites were given full discretion as to the manner and scale of implementation. Some involved only selected wards or units, although most sites were whole hospitals; New South Wales conducted a statewide implementation.

Here, we report findings from interviews with health care staff and consumers, which formed the basis of an external evaluation of the National Open Disclosure Pilot. The investigating group addressed the central question of realistic evaluation by aiming to determine what it is about this kind of intervention that works, for whom, in what circumstances, in what respects, and why. This was the most appropriate approach for evaluating implementation of a complex policy intervention, where there were no baseline data, or control or comparison groups.

METHODS

Data collection

The evaluation of the National Open Disclosure Pilot assessed 21 of the 40 pilot sites: six in Victoria, three in South Australia, seven in Queensland, and five in NSW. This low number was due to several factors: non-approval by ethics committees (five sites); legislative provisions designed to privilege quality assurance activities, thus precluding discussion with interviewees about specific open disclosure matters (four sites); ethics approval being ruled out by a lack of local organisational support for the evaluation or by statements that open disclosure had not taken place (five sites); and ethics approval being granted, but hospital organisations declining to participate (five sites).

The primary method of data collection was the interview (survey data were also collected but are not included here). Pilot site project officers identified health care staff and consumers who had been involved in open disclosure, and requested permis-
sion for the research team to contact them. No information was requested from pilot sites on the total number of patients and staff who had been involved in open disclosure, nor if staff or patients were asked but declined to be interviewed.

In total, 154 interviews were conducted between March and October 2007. Of these, 131 were with health professionals: 19 in NSW, 26 in SA, 27 in Victoria, and 59 in Queensland. Health professionals interviewed comprised 49 doctors, 20 nurses, and 62 managerial and support staff. There were 23 consumer interviews: 15 in Queensland, five in Victoria, two in SA, and one in NSW. Fifteen interviews were with patients and eight with family members (only one of whom was related to a patient who was also interviewed). Many hospitals responded with considerable hesitation to the request to interview consumers, resulting in the low number of consumers we were ultimately able to contact.

The interview schedules will be included in the Appendices to the Final report: a national evaluation of the open disclosure pilot (to be published later in 2008).

Interview data analysis

The interviews were semi-structured and in-depth, ranging from 45 minutes to 2 hours in duration. Interviews were transcribed from sound files by project team members. Interview transcripts were then coded by three (in some instances four) team members independently, supplemented by post-interview summary reports prepared by interviewers. The transcript codings were tabulated and collated for verification, comparison and further refinement.

The transcripts were analysed using semantic discourse analysis.16 This analytical method was able to capture not just the detail of health care professionals’ and consumers’ experiences, but also the emotional and interpersonal subtleties embedded in their responses. The analysis created an in-depth map of current open disclosure practices and perceptions in Australia, complemented with individuals’ stories enriching these descriptions with contextual and personal detail.

RESULTS

Interviewees (both clinicians and consumers) expressed overwhelming support for open disclosure and even a sense of relief. The following quotation is one of many supporting comments made by staff.

The clinician had made an error in judgement and had not picked up on something. Now he wasn’t the only one that didn’t pick up on it, there were other people involved, and there was a series of things that had taken place that allowed that to happen. And, it was an amazingly big group in this room, I’ll never forget it, it must’ve been about 15 people and a couple of relatives because the patient was unconscious at that time. And it was just the most powerful thing I’ve ever seen, this [clinician] saying “I really don’t know what happened. I really can’t explain what happened, but it shouldn’t have happened, and I have to take the responsibility for that. I was the one that had the responsibility for it.” You could see he was gutted and the family responded to that. This was a human, and their loved one was in there not well and really nobody knew how things were going to progress. [But the patient] did wake up, and the relationship that was formed between the patient and her partner and the clinician was really quite phenomenal and they both learnt such a lot from that whole episode … (Support personnel 14, 33)

For staff, open disclosure practice was seen to harbour uncertainties, including what should trigger a formal response, the unknown impact on individuals’ and the organisation’s reputation, unclear legal and insurance implications, and unreliable support by colleagues for those carrying out open disclosure. These uncertainties were said to be fuelled by the complexity of adverse events and consumers’ different responses and needs after such events. Staff commented that these factors make it hard to apply a simple metric to structure their open disclosure response. Box 1 shows a number of practical measures that staff regard as crucial for successful open disclosure.

Consumers commented on the importance of staff structuring their open disclosure response with an awareness of patients’ (or family members’) perception of the severity of the adverse event. This includes conducting appropriately formal open disclosure for serious events, and involving trained staff who are able to “hear” the consumers’ expressions of their needs, wants and cultural preferences.

I was visited once by the obstetrician when I was in hospital … but it wasn’t a planned [meeting] … she just popped up to see me … so I didn’t have any questions planned or anything. (Consumer 9, 88)

And one said “It’s not life threatening”, like, you know, “You can cope”, and “It’s not as if he’s got leukaemia”, but it is bad to me. I would rather him be born with nine fingers or nine toes! There’s nothing more important than your sight and your hearing! (Consumer 3, 26)

Also considered important by consumers is having staff inform patients and family comprehensively and continuously about the unfolding of the adverse event, about the management plan, and about the investigation.

I probably would like to have known a bit more of the process that went on after that interview. We were just left. (Consumer 13, 106)

Consumers further expected to be able to ask questions about the event, and inform

1 Findings of the National Open Disclosure Pilot evaluation: what works for health care staff

Open disclosure works for health care staff when:

• it is planned, conducted and/or closely supported and monitored by staff who have been trained and have gained experience in carrying out open disclosure
• it is coordinated and supported by staff with specialised administrative-managerial appointments (eg, the Patient Safety Officer or the Director of Clinical Governance)
• senior clinical (particularly senior medical) staff participate
• it is conducted by staff who have excellent communication and listening skills
• it is conducted in circumstances where clinicians involved in the adverse event have already established a good relationship and understanding with the patient (and family)
• it is a sub-component of an established clinical governance system
• it encompasses careful pre-planning, responsive disclosure, adequate follow-up and internal as well as independent counselling support
• it is structured to include consideration of paying for patients’ and/or family members’ out-of-pocket expenses
Open disclosure works for patients and family members when:

- it shows respect to the patient (and/or family members) by offering an immediate and sincere apology
- it is conducted as much as possible by those originally involved in the patient’s care
- consumers can appoint a support person
- consumers are engaged by:
  - staff eliciting from them the matters they want to see clarified and action taken on
  - staff sharing carefully structured feedback as matters come to light rather than delaying feedback until the end of a closed-door investigation
- it counterbalances the fragmentation of health care by:
  - housing for staff who move to other institutions
  - preventing different staff expressing conflicting perspectives on the causes of the unexpected outcome
  - preventing revelations of adverse events being made by staff at alternative institutions without pre-emptive communication with the facility where the original care was provided
- it is deployed as a formal process for all high-severity adverse events
- it is carried out in a way that is sensitive to consumers’ culturally and linguistically diverse backgrounds

... when we did go to the meeting, [the patient liaison officer] said he’d like to shut up and let me talk … he asked me … “What do you want to get out of it?” And basically my answers were I wanted to make sure that it never happened again … and it was really good because [the liaison officer] allowed me to say that … I liked that I could talk and I could ask questions … Like I said to [the doctor], “Look, I’m sorry for saying this but this is how I felt at the time when you said this…”, and I felt … I was attacking exactly what she said … but she didn’t retaliate … She tried to explain why she said it. (Consumer 1, 13)

An important theme that emerged in consumers’ comments is their desire for open disclosure to minimise the effects of intra- and inter-organisational fragmentation. Consumer findings are summarised in Box 2.

**DISCUSSION**

A limitation of our study was that our sample of health care staff interviewees comprised a self-selected group of volunteers who had decided to become involved and champion open disclosure in their organisations. Their enthusiasm remained strong despite the challenges of limited resources, suspicious peers, the threat of litigation, and persisting uncertainty about the position taken by insurance and indemnity organisations. Indeed, their experience with open disclosure made them insist “there is no going back”. Although interviewees recounted having participated in difficult and challenging open disclosure meetings, they also reported feeling that they had benefited from conducting these meetings. Similarly, consumers were not unanimously satisfied with the outcomes of open disclosure, but none regretted having participated.

It was clear that staff felt they were occupying a “grey zone” where adoption of open disclosure was being advised, but without staff having all the necessary resources to decide on the type of response needed, the appropriate degree of staff training, required levels of resources, and the structure of well planned follow-up, reliable administrative back-up processes, and the support of peers and managers.

Interviewees’ enthusiasm and support suggest that open disclosure could become the central component of negotiating bad news in clinical practice. However, our findings cannot be held to be representative of the views of Australian health care staff generally, nor of the Australian public. A larger study should be initiated to link open disclosure to complaints trends, litigation levels and, most importantly, staff-consumer relational dynamics.

This study paves the way for an exploration of consumer involvement in clinical incident management, given consumers’ interest not merely in the medical consequences of the harm for them, but also in what staff would change in response to the adverse event. Already, overseas initiatives are involving consumers in formal processes to inject new insights into clinical service redesign and clinical practice improvement.

Finally, the impact of open disclosure may exceed its immediate purview. As a practice that emphasises openness and “no blame”, open disclosure affects how clinical staff relate to each other and to consumers generally, and how consumers realise their rights, obligations and expectations in the context of health care provision. Open disclosure is also beginning to galvanise alternative ways of negotiating health care-related knowledge with consumers, affecting the dialogues that precede treatment and negotiations during treatment.

**COMPETING INTERESTS**

Rick Iedema and Suyin Hor received payment from the project funds for the transcriptions and analyses carried out for the project. Nadine Mallock was the project manager on the evaluation that this article reports on and drew a salary from the project. Anthony Tuckett and Allison Williams received payment and expenses for conducting a number of interviews in Queensland and Victoria, respectively. Suzanne Brownhill received a salary for transcribing part of the interview sound files gathered for the project and for contributing to the transcript analysis.

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**2 Findings of the National Open Disclosure Pilot evaluation: what works for consumers**

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