SELECTED SUMMARY

When a doctor makes a mistake

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Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *N Engl J Med* 2007; 356: 2713-9.

Patients expect to be informed promptly when they are harmed by medical care. However, when such injury is a result of an error, patients are rarely informed. Hospital regulators, accrediting agencies and governments in the US, England and Australia are developing standards, training programmes and regulations to encourage transparent communication between providers and patients. While many doctors want to be open about their errors, fear of litigation, embarrassment and uncertainty regarding the best way to disclose such information lead to a professional ethos of discretion or even cover-up after harmful errors. Yet, despite such fears, studies have shown that aggressive disclosure policies may actually reduce malpractice claims.

Disclosure standards

In 2001 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued the first disclosure standard requiring patients to be informed about all outcomes. The JCAHO rules did not specify the content of disclosure, or that the unanticipated outcome was due to an error. By 2005, 69 per cent of US hospitals had developed some sort of a disclosure policy.

In 2003 Australia and England promulgated disclosure requirements encouraging "transparent communication with patients after unanticipated outcomes". Like the JCAHO, neither addresses disclosure of error. Compliance with these standards is not mandatory.

In November 2006 the US National Quality Foundation (NQF), a consortium of hospitals and clinics, convinced that disclosure of unanticipated outcomes is a core component of safe clinical practices, issued guidelines on disclosure of serious unanticipated outcomes to patients. These guidelines recognise that disclosures require appropriate staff training and coaching just before a disclosure. They also provide the basic content of the discussion (an expression of regret and an apology).

The JCAHO and NQF have enforcement mechanisms. The Leapfrog Group, which includes more than half the hospital beds in the US, uses the NQF standards in their pay-for-performance programmes and publishes the information on the Internet. The authors write: "This combination of direct financial incentives and visibility to consumers... may encourage

... development of ... sophisticated disclosure programs." While compliance is voluntary, and the data are not externally validated, the link to "pay-for-performance" may prove to be important.

Legal developments

In the US a Federal Bill mandating disclosure of errors introduced in 2005 by Hillary Clinton and Barack Obama did not pass. Seven state governments have enacted Bills requiring disclosure of serious unanticipated events. The Pennsylvania 2002 law requires hospitals to notify patients in writing within seven days. The law also bars the use of disclosure statements in any subsequent litigation. Thirty-four states have similar laws precluding the use of apology statements in malpractice litigation. However, it is extremely difficult to enforce such laws as it would require heavy staff time to review charts and talk to patients to verify if the laws were followed. With the exception of Pennsylvania, none carry specific penalties and are probably mostly ignored.

Disclosure discussions must be "tailored to the nature of the event, the clinical context, and the patient-provider relationship". Thus, it is very difficult to write cookbook laws covering disclosure. Also, many of the state laws only protect the expression of regret and not the additional information provided to the patient. Even though not admissible in a court, to a plaintiff's attorney, any information provided during a disclosure is still helpful in building their cases.

Do disclosure policies have an impact on litigation? The debate continues. Proponents argue that poor communication is a known factor in patient's decision to sue. While disclosure may reduce some patients' anger and interest to sue, there will be patients who would never have known about the error had they not been informed through a disclosure.

How effective are disclosure programmes?

The evidence is mixed. While a report from one Veterans Administration Hospital in Kentucky reported no significant difference in the number of lawsuits filed and the amount of the payouts, the University of Michigan Hospital system reported a 60 per cent reduction in cost of litigation over five years after implementing an open discussion programme. The "3Rs" programme at COPIC, a physician-directed liability insurer in Colorado insuring 6,000 doctors, was adopted in 2000. In over 3,000 cases since, 25 per cent of the patients received

compensation averaging US\$ 5,400 each. Only seven went on to litigation, with just two of the seven receiving additional compensation. The low average payment per incident shows that compensation may not be the main objective for patients.

Future developments

It is very likely that experimentation will continue and disclosure programmes will proliferate. "The momentum for change is now too great for any stakeholder group to brush aside demands for transparency," note the authors. Eventually, most organisations will provide disclosure training for their clinical staff. The risks of a poorly conducted disclosure interview may prompt some organisations to train special dedicated teams to handle disclosures. The transformation has begun and is likely to become the norm rather than the exception within the decade.

Discussion

At first glance, one would wonder what compelling doctors to say sorry to patients they have hurt has to do with India. The patients' rights movement is very much in its infancy and more compelling issues have to be addressed to reduce the paternalistic attitudes prevalent in society. However, most improvements in healthcare delivery that evolve in the West sooner or later find their way to India. With the increasing importance of medical tourism in India, such reforms will have to be adopted earlier than later.

How do patients deal with medical errors? While interviewing patients who had been injured as a result of an error during treatment for a documentary, Delbanco and Bell (1) found that family members, even though they know that they could not have prevented the error, still feel guilty about it. Patients and their families fear further harm from retribution from clinicians if they express their concerns about errors being made while delivering care. Moreover, patients who have suffered from an error feel isolated as the clinical staff, consciously or not, starts to avoid them.

Clinicians who may be responsible for an error apart from feeling guilty for committing the error are also fearful for their reputation, their job, their licence and their own future. As hospitals, insurers and attorneys advise healthcare workers against using words like "error", "harm", "negligence", "fault" or "mistake", it leads patients to view physicians as uncaring.

The fear that doctors may not treat them properly in the future was the most common reason for patients and their families refusing to be interviewed. This was particularly true for members of minorities.

Most of all, patients and their families complained about feeling isolated. While providers back away from injured patients and their families, it may be because of their own feelings of guilt, fear and isolation, compounded by legal or institutional advice. A physician-patient with third-degree burns from a heating blanket applied to his anaesthetised skin said, "The most important point would be to go see the patient more, not less." His wife added, "I would have still felt great pain, but I wouldn't have felt as alone."

Delbanco and Bell advise that honest and direct communication with the patient and their families would allow all to move on and find closure. A simple "sorry" would go much further than any amount of spin. Patients and their families "want to understand their situation fully and to know what the event has taught caregivers ... [S]ilence and evasion just breeds mistrust." However essential apology and disclosure may be, forgiveness requires that there be a "shared understanding, rekindled trust, acceptance, and closure".

Delbanco and Bell stress the need for an established formal structure to restore communication and provide appropriate emotional support. Doctors and nurses must be trained in both error prevention and how to respond when an error has occurred. Hospitals have to develop transparent reporting systems that do not stigmatise individuals (we all make mistakes). Each institution must develop a system of first response to guide patients and staff when an error has harmed a patient. The system should facilitate communication and involve patients in developing solutions to prevent similar errors in the future. As summed up by Delbanco and Bell: "Patients and families will bring ideas to the table that expand the horizons of health care professionals. The yield from working in partnership could be enormous, both improving people's experience with medical error and preventing harm from occurring in the future."

Reference

1. Delbanco T and Bell SK. Guilty, afraid, and alone: struggling with medical error. N Engl J Med 2007; 357:1682-3.