Open disclosure

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The first part of this article appeared in the 4/2009 issue of the Bulletin. The issues addressed previously included harm data, definitions of open disclosure, the legal and ethics aspects and the consequences of adverse events.

Elements of Open disclosure

There are slight variations in the elements of open disclosure. These are stated succinctly in the Australian Open Disclosure Standard 2003 which includes:

- Acknowledge that an adverse event has occurred;
- Acknowledge that the patient is unhappy with the outcome;
- Express regret for what has occurred;
- Provide known clinical facts and discuss ongoing care, including any side effects to look out for;
- Indicate that an investigation is being, or will be undertaken to determine what happened and prevent such an adverse event happening again;
- Agree to provide feedback information from the investigation when available; and
- Provide contact details of a person or persons within the health care organisation whom the patient can contact to discuss on-going care.

The Australian Standards are similar to those found in the policies in other health care systems i.e. the Chief Medical Officer, United Kingdom 2003 Disclosure Working Group, the Canadian Patient Safety Institute 2008 and the Joint Commission on Accreditation of Health Care Organizations, 2001.

There are additional elements of Open Disclosure found in the standards of other health care systems. The Chief Medical Officer, United Kingdom 2003 Disclosure Working Group included the following additional standards:

- Exemption from disciplinary action for those professionals reporting adverse events or medical errors, except where there is a criminal offence; and
- Legal privilege is provided for reports and information identifying adverse events except for information that is not recorded by the health care centre

The United States Department of Veteran Affairs Manual 2008 include the following:

- Patient or family are informed of the event as soon as possible, and of further medical assistance that will be provided to the patient;
- Counsel will advise the patient regarding their legal rights; and

- Patients are advised about the available remedies for the unanticipated outcome, and in circumstances involving malpractice or injury the Department of Veteran Affairs may advise patients to make a claim against the government.

Objectives of open disclosure

There are several objectives of open disclosure. They include lessening the likelihood of litigation, facilitating a feeling of relief from guilt; promotion of trust; strengthening of doctor-patient relationships; promotion of learning from errors by professionals and provision of support to professionals. *(Fallowfield and Jenkins. Communicating sad, bad, and difficult news in Medicine. The Lancet, 2004; 363(9405): 312-319)*

In addition, open disclosure provides an environment where patients and their support person receive the information they need to understand what happened; creates an environment where patients, their support persons, health care professionals and managers all feel supported when things go wrong; builds investigative processes to identify why adverse events occur; brings about any necessary changes in systems of clinical care, based on the lessons learned; *(Australian Council for Safety & Quality in Health Care. Open disclosure standard: A national standard for open communication in public and private hospitals, following an adverse event in health care, 2003; Iedema et al. The national open disclosure pilot: Evaluation of a policy implementation initiative. Medical Journal of Australia, 2008; 188: 397-400)* and provides patients with information regarding errors, so that they can make informed decisions regarding their subsequent treatment. (*Levinson and Gallagher. Disclosing medical errors to patients: A status report in 2007. Canadian Medical Association Journal, 2007; 177(3): 265-267)*

When to disclose

Open disclosure should occur in a timely manner following the adverse event but will depend upon a number of factors including clinical condition of the patient, including their emotional & psychological state; availability of key staff and of the patient's relatives/support person; patient preference & privacy (*Australian Council for Safety and Quality in Health Care, 2003)*

What to disclose

This is a particularly pertinent issue for doctors and other health care professionals. The Australian Council for Safety and Quality in Health Care (2003) provide useful guidance. They advise that in discussions with the patient or support person the doctor may acknowledge that an adverse event has occurred; acknowledge that the patient is unhappy with the outcome; express regret for what has occurred; provide known clinical facts and discuss ongoing care, including any side effects to look out for; indicate that an investigation is being, or will be undertaken to determine what happened and prevent such an adverse event happening again; agree to provide feedback from the investigation when completed and provide the contact details of a designated person within the hospital who the patient will be able to contact to discuss ongoing concerns and care.

What not to disclose

This is equally pertinent. The Australian Council for Safety and Quality in Health Care (2003) also provide useful guidance. They advise that one should be aware of the risk of making an admission of liability during the open disclosure process; state only the facts as they know them and when they know them; and must not state or agree that they are liable for the harm caused to the patient or that they were negligent and/or that another health care professional and/or the health care organisation is liable for the harm caused to the patient or was negligent.

Apology

An apology is an essential component of the open disclosure process. It is an expression of sympathy or regret, or of a general sense of benevolence or compassion, in connection with any matter whether or not the apology admits or implies an admission of fault in connection with the matter. It does not constitute an admission of fault or liability and neither is it relevant to the determination of fault or liability in connection with a matter. *(New South Wales Health Open Disclosure Guidelines 2007)*

An apology has the potential for therapeutic effects on both patient and doctor. It can facilitate the patient's exoneration of and reconciliation with the doctor and/or other health care professional. The feelings of guilt, and even shame, of the doctor and/or other health care professional can also be mitigated by the apology.

Communication

Open disclosure is neither simple nor comfortable. Doctors and other health care professionals require training to do this effectively. They need to be cognizant of their legal, ethical and professional obligations in this regard. The response to medical errors has to simultaneously address the needs of the patient, the doctors and other health care professionals as well as the facility.

Communication skills play a crucial role in ensuring effective open disclosure.

The Canadian Medical Protective Association's succinct recommendations in its document, *Disclosure Road Map*, are worthy of consideration for adoption. They are:

- First things first - Attending to clinical care**;** Addressing clinical needs; Dealing with emergencies; Considering the next steps in clinical care; Providing emotional support; and Documenting the care provided.
- Planning the initial disclosure - What are the facts? Thinking about what you will say. Who will be present? Who will lead? When will the initial meeting occur? Deciding where to meet.

- Initial disclosure meeting - Providing facts as known; Expressing regret as appropriate; Avoidance of blame and speculation; Confirmation of plan for further clinical care; Outlining of expectations for further information; Arranging follow-up and identification of contact processs; and Documentation of the disclosure discussions in the medical record
- Analysis
- Post-analysis disclosure – Provision of further facts and information on any actions taken; Expression of regret again; Consider apology only if appropriate; and Documentation of the discussions.

The American Society for Healthcare Risk Management, in its document *Disclosure: What Works Now & What Can Work Even Better. Chicago, 2004,* recommends skills based communication. Its features include:

- Preparation - Review the facts Identified and involve the appropriate participants; and Usage of an appropriate setting.
- Verbal initiation of the conversation – Determination of the patient and family's readiness to participate; Assessment of the patient and family's medical literacy and ability to understand; and Determination of the patient and family's level of medical understanding in general.
- Presenting the facts - Simple description of what happened; What is known of the outcome at that point in time; Describe the next steps; and Sincere acknowledgement of the patient and family's suffering.
- Concluding the conversation - Summarize the discussion; Repeat the key questions raised; and Establishment of the follow-up.
- Documentation of the event and the discussion.

Other communication considerations include non usage of medical jargon, cultural and language barriers; need to speak slowly, awareness of body language; avoidance of overwhelming the patient with information; avoidance of oversimplification; allow ample time for questions i.e. avoidance of monopolizing the conversation; and avoidance of words like wrong, error, mishap, incorrect, mistake.

Inform Medical Defence Organisation

Prior to open disclosure, it would be prudent to seek advice from one's medical defence organization (MDO).

A written incident report should be submitted to the MDO. The report should include matters like inappropriate of incorrect medication or dosage, failure to diagnose, major surgical complication, clear error, unanticipated death or injury, foreign bodies left behind, and patient dissatisfaction with outcome or adverse event, patient conflict with staff.

The guiding principle should always be "If in doubt, notify"

Documentation

Documentation is of the essence in medical practice, particularly when an adverse event occurs. It is a fact that one cannot mount a credible defence, even if the adverse event was unavoidable, if the medical records are of poor quality or absent.

It is essential to document the known facts of the adverse event in the medical records without consideration of cause or assignment of blame. It is worthwhile remembering that communications and documents (including e-mail) produced in response to an adverse event may have to be disclosed later in any legal proceedings and that all communications and documents, state as fact, only what is known to be correct and not opinion or interpretation.

Barriers to Open Disclosure

There are several barriers to open disclosure. They may be at an individual, organizational and/or professional level. The reports from several papers are summarized below.

Fallowfield and Jenkins, in their paper, *Communicating sad, bad, and difficult news in medicine. (The Lancet 2004; 363(9405): 312-319)* included litigation fears, disciplinary criticism and/or action as a result of disclosure, lack of commitment by top management, and lack of explicit staff and manager support.

Wei, in the paper, *Doctors, apologies, and the law: An analysis and critique of apology laws. (Journal of Health Law, 2007; 40(1): 107-159)* discussed litigation fears, disciplinary criticism and/or action as a result of disclosure, fear of risk to reputation, loss of respect from peers and colleagues, morbidity and mortality conferences being a chance to present interesting cases rather than reporting errors, anxiety of exposing individual fault, fear of loss of referrals and social norms such as the prohibition of criticism amongst professionals i.e. patient is the responsibility of the attending doctor, thus other doctors privy to information feel they are not in a position to comment.

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Lamb, in the paper, *Open disclosure: The only approach to medical error. (Quality and Safety in Health Care, 2004; 1: 3-5)* report litigation fears, lack of institutional support and fear of risk to reputation. Hoy, in the paper, *Disclosing medical errors to patients. (Ear, Nose & Throat Journal, 2006; 85(7): 410-413)* report litigation fears – malpractice liability, anxiety about being reported to an external organisation or public registry and not knowing how to talk to patients regarding error.

Walshe and Shortell, in their paper, *When things go wrong: How health care organizations deal with major failures (Health Affairs, 2004; 23(3): 103-111)*, stated that "…so called whistle blowing can leave the individual exposed to victimisation, disciplinary action, or even dismissal…". They also mentioned a "Club Culture" where physicians may encompass a culture of secrecy and protectionism.

Levinson and Gallagher, in their paper, *Disclosing medical errors to patients: A status report in 2007 (Canadian Medical Association Journal, 2007; 177(3): 265-267),* report a disclosure "gap" between the information that patients desire and what health professionals provide after an error has occurred.

Effectiveness

There are some outcome studies that have evaluated the effectiveness of open disclosure.

The study reported by the Department of Veterans Affairs, Lexington, Kentucky, United States (*Kraman & Hamm. Risk management: Extreme honesty may be the best policy. Annals of Internal Medicine, 1999; 131(12): 963-967)* is informative. In the year prior to the introduction of open disclosure, two claims cost the centre US$1.5 million. In the 7-year period after the implementation of open disclosure, the facility had 88 malpractice claims, averaging US$190,000 per year i.e. total of US $1.33 million for 7 years

The University of Michigan Health System has a similar program to fully disclose medical errors and to provide appropriate financial compensation without patients having to resort to litigation. They report that the program has resulted in:

- ***"The number of claims and lawsuits has dropped dramatically.*** In July 2001 we had more than 260 pre-suit claims and lawsuits pending, already an enviable number in our region. We currently have just over 100.
- ***Our legal costs appear to be down dramatically, with the average legal expense per case down by more than 50 percent since 1997.*** We went to court over seven cases between August 2001 and September 2002, using the principle of court as the last resort. If we had lost all of them, we estimate the verdicts would have cost us more than $8 million. If we had settled all seven at the lowest pre-trial settlement demands, it would have cost about $2.5 million. We won six, and in the seventh the verdict called for a penalty of $150,000, far less than the $550,000 settlement demanded before trial. Trying all seven cost us $320,000 in legal fees. So, if you combine the settlement and the legal fees we paid, and compare it with the cost of settling all seven, we saved $2 million just in the first year of using this approach. We are still tallying results from later years.
- ***The severity of our claims is rising far less rapidly than the national average.*** Nationally, the predicted severity of malpractice suits is rising by more than 10 percent each year. We're also seeing an increase, but it's about 2.6 percent each year. The slope of our claim severity graph began to change for claims arising from care in 2000, coinciding with our claims management changes in 2001 and 2002.
- ***Opening-to-closing times for claims are dramatically shorter***, down to about 10 months from more than 20 months in 2001.
- ***Our malpractice premiums are practically level, despite increases in our clinical business.*** Both in terms of total expense and premium paid per adjusted hospital discharge, this goes completely against state and national trends. Because we're self-insured, this is a true savings that helps us spend our Health System's resources where they are needed.

- ***We have instituted many changes to our clinical care based on lessons learned from patient complaints."*** **(**www.med.umich.edu/news/newsroom/mm.htm#summary accessed 1 April 2010)

Need for empirical evidence

There are still many gaps in the knowledge base of open disclosure. Among them are the factors required for successful open disclosure; the question of whether open disclosure brings about substantial and measurable advantages; barriers to the use of open disclosure and the needs of patients, families, professionals and institutions when involved in open disclosure. Needless to say, these gaps will be filled in the course of time.

Conclusions

When an adverse event occurs in medical practice, there are two victims i.e. the patient and the doctor. The latter has an ethical and legal duty to disclose the adverse event and the measures taken to remedy it. Concomitantly, the doctor has to be mindful of exposure to potential medico-legal problems.

In addressing this potential conflict situation, it would be prudent to be mindful of one's legal and ethical responsibilities, the elements of open disclosure and the barriers of open disclosure. When, what and how are pertinent considerations. There are reports of the effectiveness of open disclosure. In the final analysis, there is a need to improve the health care delivery system to minimize the incidence of preventable adverse events.

The views expressed in this article are personal and do not represent that of any organization the writer is associated with.