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Disclosure of Adverse Events in Healthcare

The disclosure of medical harm is now the standard of care. The ICU environment challenges clinicians to recognise and disclose adverse events affecting critically ill patients. This article reviews the literature on adverse events and offers suggestions for disclosing medical harm.

Introduction

It is now well established that patients commonly suffer injuries on account of medical treatment. Studies done in Canada, Spain, Australia, the UK, and the US reveal very similar rates of adverse events. About 10% of hospitalised patients experience an adverse event, 1 in 200 die in part due to these incidents, and 40% of all such incidents are considered preventable. As task complexity is one factor associated with adverse events, not surprisingly the incidence of adverse events is higher in the ICU than in general medical wards (Forster et al. 2008).

This does not mean ICUs are less safe units. The stakes are higher in the ICU with patients being so ill and undergoing so many interventions. Were it not for such dedicated units and staff, virtually every ICU patient would die. It is much more difficult in the ICU to distinguish an adverse event due to medical care from complications due to the patient's underlying disease / injury processes. This article pertains to those instances where it is clear that harm has occurred due to medical care or the failure to provide appropriate care, such as, for example, failing to ensure a patient's O2 is being delivered whereupon a respiratory arrest ensues.

A New Professionalism

One issue that arises is what to tell patients or their families about harmful incidents. If the harms to patients are serious and seemingly avoidable, the professional's reaction can be one of shame, guilt and embarrassment (Davidoff 2002). While in years past, clinicians might have been loath to reveal the true nature of medically related harm, there has been more recently a sea-change in attitudes towards disclosure (Witman 1996).

For example, the 'new professionalism' initiative launched in 2002 by the American Board of Internal Medicine (ABIM), American College of Physicians-American Society of Internal Medicine (ACPASIM), and the European Federation of Internal Medicine (EFIM) promulgated the 'Medical Professionalism in the New Millennium: A Physician Charter'. According to the charter, physician obligations include the commitment to:
- Professional competence;
- Honesty with patients;
- Improving quality of care, and
- Maintaining trust in healthcare.

Consistent with these commitments, current professional opinion calls for open and timely disclosure of harmful medical incidents to patients (and / or, where appropriate, to the patient's family or substitute decision-maker) (Robertson 2009). The question, then, is not whether but how and when to disclose information regarding such events. Despite this, evidence from the literature suggests such disclosure does not always take place and, when it does transpire, may not go well (Gallagher 2009). This may be for a variety of reasons including uncertainty as to who should do the disclosing, what should be disclosed, and to whom should the disclosure be made.

A New Regulatory Environment

The failure of healthcare professionals to meet expectations regarding the disclosure of adverse events has led to new Canadian regulations and laws compelling such disclosure. For example, several provinces have laws requiring disclosure of harmful incidents – albeit to health authorities and not to patients. Professional and regulatory medical authorities mandate openness with patients concerning adverse events (Forman 2008). Even professional insurers, typically resistant to openness for fear of self-incrimination, recognise that honesty about adverse events is the best medico-legal course. Hospital accreditation standards also will require that all hospitals have a system in place to ensure disclosure of 'critical incidents' to patients. New national guidelines encourage hospitals to devise disclosure policies. The focus is on the disclosure of harm, not of error or mistakes per se. The threshold for disclosure is any harm or significant threats to patient welfare. Where a harmful incident has occurred or has a significant likelihood of causing harm, this ought to be disclosed.

Help From Above

In my hospital, senior administrators act as the consultant-on-call for hospital staff and physicians who may wonder whether and how to disclose an incident. Any time a critical incident occurs, 24/7, physicians are directed to contact their Department Chief for guidance and support. If unavailable, physicians are directed to contact the Medical Director on call. Similarly, when it comes to harmful incidents, other staff may access the Risk Manager / Shift Manager for guidance and support. The role of such administrators is to facilitate the staff or physician's discussion about and investigations concerning the incident as well as to help plan the disclosure conversation with the patient and/or the authorised or substitute decision-maker.

As a general rule, acknowledgement and discussion of the unexpected event should be overseen or undertaken by the most responsible physician. Others who have a significant role in the patient's care, such as the primary nurse or resident, should also be involved. Disclosure of complex incidents ought to be inter-professional (Shannon et al. 2009). Educating clinicians in advance about the 'how-to's' of disclosure can make the real-world practice much easier (Gallagher et al. 2007).

The Disclosure Process

Establishing rapport with the patient is the first step in disclosure. Disclosure should take place as soon as possible after an incident has been identified and when the patient is stable and able to understand and appreciate the information. (In circumstances of severe patient injury or death, a meeting with the patient's substitute decision-maker ought not to be delayed.) At the outset, empathetic expressions, such as "I am sorry to see how things have turned out", can set an appropriate tone of acknowledgement of the harm. The focus of the disclosure should be on a narrative account of what transpired (a truthful account of what is known to have happened) rather than obfuscations or hasty conclusions as to 'who did it'. Uncertainty concerning the incident should not delay initial meetings but rather call for future meetings. Any questions the patient or family may have should be solicited and answers sought in an expeditious manner. It is important for patients also to be told what is being done to prevent the event's recurrence.

Apologies

No matter how innocuous or how serious the adverse event might be, the offer of genuine apologies by those caring for the patient is critical whether or not they were 'responsible' for the incident. Expressions of regret and acceptance of responsibility are morally proper, interpersonally appropriate, and should not be legally contentious. Studies do not bear out the worry that admitting to harm or error is likely to increase one's medico-legal liability, although, admittedly, the evidence is limited (Levinson and Gallagher 2007). In 2009, Ontario, like many other provinces, passed a 'uniform apology act' that immunises from liability clinicians who make apologies, whether they are expressions of empathy or acceptance of responsibility for adverse medical events (Getz 2007).

These new expectations accord with what we know concerning patient attitudes. A need for explanation and accountability and a concern for the standards of care underlie many medico-legal actions (Vincent et al. 1994). One study revealed that over 90% of patients want to be informed about even minor errors, (Witman et al. 1996) probably an impossible task. Another study in 2004 suggested 'full disclosure' of an adverse event reduces a clinician's malpractice relative risk by about 1/3rd (absolute risk reduction, 8%) (Mazor et al. 2004).

While disclosure does not confer immunity against lawsuits and complaints, such honesty has been shown to reduce the punitive 'sting' that sometimes accompanies proceedings against clinicians and hospitals (Kraman and Hamm 1999). In a recent US study, in adverse events with a severe outcome, an honest, empathic, and accountable approach to the error decreased by 59% the probability of participants' support for strong sanctions against the physician involved (Schwappach and Koeck 2004).

Conclusion

Medical-induced harms are common in healthcare. ICUs are a locus for such events given task complexity and the burden of illnesses in patients. The setting makes it challenging but perhaps not impossible, to offer patients and their families 'open disclosure' of adverse medical incidents.

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