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Disclosure of Adverse Events and Errors in Healthcare

An Ethical Perspective

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Abstract

Adverse events and medical errors affecting patient care are recognised internationally as major problems in medicine. The failure of health care professionals and health institutes to address this problem has threatened to undermine public confidence in the health care system as a whole. Less focus has been directed at the ethical issues raised by negative outcomes of care, specifically the issue of disclosure. Efforts to prevent negative outcomes of care must be supplemented by policies of increased honesty and openness with patients and their families about adverse incidents. Disclosure should be made easier, not riskier, for healthcare practitioners so clinicians can learn from mistakes and improve patient care. Ethical guidelines for error disclosure must distinguish between disciplinary action and reporting of adverse incidents. Disclosure of negative outcomes requires tact and good communication skills. Healthcare institutions should provide training for the clinicians in this area, if necessary. As a general rule, patients should be informed of unexpected adverse incidents as soon as possible. Medical staff should be rewarded for adverse event reporting and protected from institutional retaliation on account of errors made in health care.

1. Why is this Issue Important Now?

In the delivery of healthcare, errors and adverse events are increasingly recognised as an international problem for medicine.[1-4] The failure of healthcare professionals and their institutions to properly address issues of error and adverse events, as they affect patients, has threatened to undermine public confidence in the healthcare system as a whole.[5] The longer that healthcare professionals and institutions delay open and honest ways of handling negative outcomes of patient care, the more likely it is that the patients and public will respond in a vindictive way by instituting legal and regulatory proceedings against them.[6] Such a situation will lead to public and professional dismay and dissatisfaction, exacerbating professional fears about malpractice and making it harder to improve patient safety.

The purpose of this article is to review the ethical responsibility of healthcare professionals to disclose negative outcomes of care to patients. This ethical obligation extends to all healthcare professionals, although the primary responsibility most often rests with a patient's attending physician. Whether there is a corresponding legal duty to disclose such outcomes will vary from country to country. The legal obligation regarding disclosure of adverse events and errors in health care is nar-

rower than that related to ethical obligation and cannot provide a reliable guide for professionals.

2. The Scope of Problem

A number of studies published in the last decade reveal just how big the problem of negative unanticipated outcomes in healthcare is. A 1998 meta-analysis of 30 years of studies of unintended drug effects, in hospitalised patients, estimated that 6.7% of hospitalised patients experienced a serious adverse drug reaction.[7] The authors suggested that this would have resulted in 106 000 fatal cases of adverse drug reactions in the US in 1994, making adverse drug reactions the fourth to sixth leading cause of mortality in the US. Surprisingly, the authors also found that the incidence of serious adverse drug reactions had not changed in the 30-year period studied.

More recent studies on medication errors have found comparable rates of medical errors and adverse drug events in adult and paediatric medical wards, occurring in approximately 5 to 6% of admissions.[8,9] Many of these adverse events were preventable and many more could have been prevented with modifications to the design of drug ordering and by having ward-based pharmacists.

The Harvard Medical Practice Study, a retrospective chart review of over 30 000 patients in approximately 50 hospitals in New York State during the mid-1980s,[10] found that adverse events occurred in 3.7% of hospitalised patients. An adverse event was defined as death or disability prolonging hospital stay as a result of mismanagement of the patient's medical condition as opposed to death or disability due to the patient's illness. An error, considered to be a preventable adverse event, characterised more than half of the adverse events. 25% of the adverse incidents were considered to be due to negligence and 14% resulted in the death of the patient. Medication errors were responsible for 19% of the adverse events reported, the largest single contributor to the adverse event rate.[11]

One of the lead authors of the Harvard Medical Practice Study, Lucien Leape, reported later that, 'if these rates are typical of the US, then 180 000 people die each year partly as result of iatrogenic injury, the equivalent of three jumbo jet crashes every two days.'[12] This would make adverse medical events the third leading cause of death in the US, after deaths from heart disease and cancer. If roughly half of these adverse events were preventable, then 90 000 people die each year in the US as a result of preventable incidents in healthcare.

Similar studies, carried out in Australia,[13] the UK,[14] and in the US,[15] have revealed comparable adverse event and error rates in healthcare. Negative outcomes of care are, thus, not uncommon in medicine. These studies led the US Institute of Medicine (IOM) to release a report on building a safer health system.[16] The latter report galvanised the issue of medication errors and adverse drug events for the American public and the various legislative bodies. New state laws and regulations aimed at increasing public disclosure and reporting medical error are seen as ways to improve patient safety in the US.[17]

The figures used in the IOM report have not gone unchallenged.[18,19] Indeed, it cannot be said that all patients who died would have lived had it not been for the 'errors' related to their care.[20] Instead it might be more accurately said that medication errors were partly responsible for deaths in these patients. Many patients in the studies were no doubt seriously ill and would have succumbed to their illnesses in any case; indeed, they may have succumbed to their illness because of their underling fragility and not primarily because of the drug-related adverse event. However, the overall conclusion of the Harvard study, that healthcare is needlessly dangerous for patients, remains unchallenged.

3. Ethical Issues

Unintended and harmful outcomes related to patient care are associated with practical ethical issues for healthcare professionals. What should patients or their families be told about such adverse events? Should such events be reported to authorities in the healthcare institution or outside it? Who is responsible for such disclosure? How far does the duty to disclose extend? What are the events

that should be disclosed or reported? What responsibility do healthcare institutions have to ensure that such disclosure and reporting takes place? What are the pros and cons of error disclosure? What guidelines can help direct clinicians when it comes to error disclosure? These questions deserve attention and thoughtful consideration by both institutions and professionals concerned with the quality of care and patient safety.[21,22]

4. Why is Disclosure Important?

The requirement for openness and honesty about adverse outcomes related to patient care is so obvious and compelling that it is hard to see why it troubles many clinicians. Truthfulness about such adverse incidents is what patients and their families want and expect. Secondly, although difficult at times for clinicians, disclosure about error can be therapeutic for clinicians and prevent later distress. It preserves trust in medicine and allows improvements in the quality of care for patients. Thirdly, disclosure of error is the professional thing to do and, increasingly, expected by regulatory and legal authorities in many countries (table I).

Table I. Why is disclosure important?

It is respectful of patients and their families
It allows learning from mistakes made
It can prevent harm to the patient or to future patients
It is the professional thing to do
It can be therapeutic for practitioners involved

4.1 Patient Factors

Modern bioethics takes the default stance that telling the truth as regards bad news is preferable to nondisclosure no matter how distressing such disclosure might be to the patients or clinicians.[23] Obviously, the disclosure of unanticipated negative outcomes of care is a type of 'bad news' disclosure. Such disclosure is, no doubt, difficult to carry out and distressing for patients and their families. Clinicians have been provided with learning materials that can help soften the blow of even the most devastating sort of bad news.[24]

Despite the clinician's concern that disclosure of bad news will cause harm to patients, most patients prefer such disclosure. Most patients generally have high expectations of disclosure of information from physicians. For example, in a survey of medical outpatients, 98% of patiens wanted acknowledgement by clinicians of even minor errors.[25] A recent study in British ophthalmologists and their patients probed attitudes to adverse event disclosure.[26] In the latter study, situations used to explore attitudes involved an adverse outcome during eye surgery and intraoperative eye capsule rupture with a 10% risk of future vision being affected. Although 92% of the patients wanted to be informed of such events, only 60% of ophthalmologists would report these adverse events to patients. Another study related to medication errors, over a period of 5 years, in a paediatric teaching hospital in the UK revealed that 48% of the parents of these children were not told an error had occurred.[27] This was partly because, despite mistakes being commonplace, serious consequences to patients were rare. Nonetheless, families of these children overwhelmingly favoured knowing about the medical error.

Informing patients and/or their families about error is considered to be an ethical duty on account of patient autonomy, that is, the respect due to patients and their right to know important information clinicians may have concerning them. If further treatment is needed due to a medical error, disclosure of unanticipated results is an extension of the clinician's duty to inform. Patients must be fully informed about untoward events in order to be able to provide proper informed consent for any proposed future treatment.[28]

At times, patients and/or their families cannot do much with the information about adverse outcome such as when no treatment is required or is possible for an unanticipated result because the error-induced injury is too trivial to treat or is irreversible. Nevertheless, patients and their families often want to know about such events out of a desire to be informed about the quality of medical care they receive. Being honest with them, about the limitations in care, is simply an issue of trust. Thus, it

can be helpful to provide patients and/or their families with a full explanation of unexpected events, even if such events are 'minor'.[29]

Informing families and patients in a straightforward manner what is known about harmful incidents, fosters a healthier and more realistic understanding of medical care and may prevent anger at a later stage. Cases that frequently prompt public anger are those serious adverse events where no one has taken the responsibility for the mishap and there is perception of a 'cover-up' by the professionals and health institutions involved. The failure of professionals to be thoroughly honest about mistakes causing death or serious harm is a sad story that is being told again and again in the media.[30,31]

4.2 What Clinicians Do

Unfortunately, medicine and the medical profession has exhibited the all too human characteristic of denying and hiding their mistakes. The few empirical studies in this area suggest that, although such a practice is accepted as the criterion for legally acceptable care in some jurisdictions, it is not a reliable guide to ethically appropriate practice. A US study on physicians' attitudes revealed that a serious medical error resulting in a patient's death would frequently be hidden by physicians.[32] In another study dealing with medical house officers, only 24% informed patients about serious errors and only 54% discussed such events with the attending physicians.[33]

This discrepancy between what patients expect and what physicians do is not surprising. Clinicians take a typically utilitarian approach to adverse event disclosure. If the burden of disclosure (such as time required to disclose, anxiety caused to patient and family, etc.) outweighs the benefits, then clinicians are unlikely to feel any obligation to disclose an event to a patient. If little harm was done to the patient or if the adverse event inflicted was irreversible, disclosure is considered unnecessary. As one physician in training was told: 'no one needs to know'.[34] Physicians also take into account legal and professional hazards associated with disclosure. Irreversible harm and threats of professional sanctions constitute compelling barriers to veracity and openness about unexpected outcomes. Thus, healthcare professionals worry about the consequences of reporting and disclosure of mishaps.[35] Fears of punishment and retribution typically drive adverse event reporting and disclosure underground and prevent learning and improvements in patient safety. In a recent study, Vincent et al.[36] explored the reasons why over 75% of reportable adverse events were not being reported in an obstetrics ward. Reasons included clinician judgement that the error in care had been corrected, that they were too busy to report the event, and worries that junior staff would be unfairly blamed or that there might be negative legal consequences for them.

Some patients and/or their families pursue legal action against clinicians as a matter of natural justice or fairness or for financial recompense on account of harms and setbacks experienced by poor outcomes of care. Studies of patients and families who sue doctors reveal not just desire for financial recompense, but rather a need for explanation, accountability, and a concern for the standards of care.[37] It is the failure to have these informational needs and concerns met that lead to legal action against clinicians and their institutions.

Studies relating to physicians who have been sued because of nondisclosure, compared with those not sued, reveal interesting findings. What distinguishes nonsued from sued physicians is the process, not the outcomes, of care.[38] Nonsued physicians were more likely to listen to their patients and provide them information and opportunities for discussion of their medical condition. Such factors have led to more patient satisfaction and have protected the doctors against lawsuits when outcomes of care were unanticipated, poor or adverse. As one Canadian judge remarked concerning a case involving medical error that came before him: it could have been avoided had the clinician, 'taken the patient into his confidence'.[39]

Despite legal concerns, most clinicians will readily admit, in a general way, to making mistakes. They need to discuss and review such events which is often not possible because of secrecy surround-

ing the issue.[40] Such secrecy impedes learning from the mistakes and can leave the clinician who participated in the poor outcome with a negative emotional burden of guilt and shame. Certain medical errors have been self reported by clinicians and remind us of the tremendous psychological strain doctors undergo when they inadvertently harm the patients they serve.[41,42] Clinicians need to be supported as they, too, suffer when patients are harmed.[43] Disclosure of the untoward event can be therapeutic for clinicians and prevent the corrosive effects of duplicity on one's self esteem as a healthcare professional.

4.3 Professional Regulation

Professional regulation is meant to ensure that professionals act within the laws of that country and in ways conducive to patient welfare. The legal standing as regards disclosure of adverse events varies from country to country. Many countries see such disclosure as a matter of professional judgement. In Canada, there is a legal obligation to disclose harmful outcomes of patient care based on the premise that a reasonable person would want to be informed of such errors.[44] Nevertheless, court proceedings are uncommon.

The law sets a moral minimum for healthcare professionals while ethics aim for something more, such as a code of collective conduct that directs physicians what to do under special circumstances. A basic test of moral correctness is to ask oneself the question: 'how would you like it if someone did that to you?'[45] It is unlikely any clinician would condone duplicity about error affecting his or her own well being.

Regardless of the law of the land, an ethical professional should take responsibility for his or her actions related to medical errors and put the patients' interests ahead of his or her own. This selfless ethos, the ethics of altruism, characterises the fiduciary nature of medicine[46] and transcends national boundaries. Care that harms a patient is more likely to be seen as 'an unacceptable lapse' if accompanied by a failure of moral character on the part of the clinician. What is unacceptable is not to take responsibility for his or her participation in such events and to attempt to cover it up.[47] Such unprofessional behaviour is considered a wilful violation of rules deserving punishment.

Until recently, there was little positive direction regards error disclosure from professional insurers, peer organisations, and regulatory bodies for medicine. In fact, professional insurers are typically understood by clinicians everywhere to recommend silence following significant errors and have advised against open discussion of them with affected patients. This attitude and belief is prevalent even today despite evidence that honesty about error may lessen the risk of vindictive lawsuits.[48] Professional codes of ethics are often not helpful to clinicians because they do not address the problem of medical error and what to tell patients. An exception to this is the Ethics Manual of the American College of Physicians which states that disclosure of error to patients is necessary if such information significantly affects the care of the patient.[49] Some regulatory bodies for medicine, such as the Ontario College of Physicians and Surgeons, which conducted disciplinary hearings, have turned away from punitive action and towards educational interventions to improve physician practice.[50]

The IOM Executive Report on medical error, published in 2000, has heralded significant changes in how regulators and enterprises of medicine deal with error. Most importantly, error is finally being taken seriously in many jurisdictions. Educational, research and regulatory efforts have dramatically increased over the past few years. There is also a new acceptance that unexpected outcomes of care are a 'systems issues'.[51] This new understanding of poor outcomes of care, including error, requires collective corrective action, something that will not be achieved by punishing erring professionals.[52] Getting professionals to feel less threatened about errors and seeing them as opportunities for practice improvement will help restore public confidence in medicine as an enterprise dedicated to protecting patients first and foremost. This, however, demands new standards of openness by healthcare institutions about error.

Some healthcare institutions practice frankness and honesty as the best way to deal with adverse events. Kraman and Hamm,[53] reported on the experience in an American Veteran's Administration hospital that routinely informed patients/families of medical error and offered them help in filing legal claims for recompense. Even in the litigious world of American medicine, this pro-active policy of error disclosure resulted in more local, out-of-court settlements and this particular hospital had claims that were the eighth lowest out of 36 comparable Veteran's Administration hospitals in the US. While error disclosure is no guarantee against suits and complaints, such honesty can take away the punitive sting that sometimes accompanies judgements going against clinicians, especially if a lack of veracity is involved. The Joint Commission on the Accreditation of Healthcare Institutions will require all US hospitals, as of July 1, 2001, to have policies and procedures in place to disclose unanticipated negative outcomes of care to patients.[54]

It would obviously be easier for clinicians to comply with these fiduciary responsibilities if disclosure and reporting of adverse events and errors were made less risky for them. One way would be to explore new no-fault compensation schemes for medical injury. Healthcare institutional liability, rather than individual liability, might provide some reassurance to clinicians and also spark the much needed institutional impetus to improve patient safety.[55] The challenge for medical enterprises is to encourage disclosure of unanticipated outcomes of care without increasing professional fears over reprisals and recriminations.[56]

5. Ethical Management of Error

What is a realistic ethical response to error and adverse medical events? The most ethically defensible stance is one of openness and transparency with patients and/or their families concerning such events. It is unrealistic, however, to expect institutions and professionals accustomed to secrecy to change overnight. Healthcare institutions can support new directions in openness by developing policies and procedures concerning reporting and disclosure that encourage and support honesty by staff. To take error seriously is to address the cultural barriers that exist in medicine towards honesty and to weave patient safety into the fabric of clinical life.[57] A realistic approach is to start with policies and procedures that the healthcare institution already has and to improve them.

Most hospitals now have systems and policies in place to report adverse incidents. These reporting procedures vary in their effectiveness.[58] Reports are often collected but not always analysed and acted upon. This failure breeds cynicism about reporting and must be addressed in an urgent manner by healthcare institutions.

As a first step, adverse incident reporting policies must be taken seriously by healthcare institutions and such policies must be utilised to help clinicians improve their practice. Using adverse event reports as a clinical improvement tool helps gain clinician support for new directions in error appreciation.[59]

Polices related to adverse incident reporting are usually not directed toward the issue of disclosure to patients and, so, are not conducive to transforming the culture of silence related to unexpected outcomes of care. These policies, therefore, have to be supplemented by policies that encourage disclosure of error to patients and families in order to reassure the public that healthcare institutions take this issue seriously. Many authorities suggest that if such policies also provide guidance and support to clinicians and if they emphasise learning and prevention rather than blame and punishment, they could make disclosure and adverse incident reporting safer and less risky for clinicians.[60]

Policies regarding disclosure of adverse medical events also could help do so by separating reporting and disclosure of adverse outcomes from discipline.[61] They need to provide guidelines as to what distinguishes reportable events requiring disclosure and those that do not require disclosure. Clinicians need to know the threshold of harm that requires disclosure. Not every unanticipated event merits disclosure; 'near misses', for example, outweigh actual harmful events and to require disclo-

sure of all such events would overwhelm and trivialise the duty to disclose.

Overall, the greater the impact an adverse event has or may have upon a patient, the greater is the obligation to disclose that event to the patient and/or the family. By corollary, nonsignificant events such as 'near misses' that do not imperil patients, do not require disclosure. However, just what 'significant' means may depend on individual or subjective factors that need to be taken into account by clinicians when deciding whether they ought to disclose an unanticipated outcome to the patient. In general, when in doubt, it is better for clinicians and institutions to err on the side of disclosure than nondisclosure. Helpful policies regarding disclosure should provide routes for reporting such events and resources for discussion, for those clinicians who might be uncertain about when and what to disclose.

Disclosure of unanticipated negative outcomes requires tact and strong communication skills. If deficient in these, the involved clinician should have resources provided by the healthcare enterprise upon which he/she could call. Sensitivity to the patient's situation requires recognition as to when and how disclosure should take place. Once again, the institution can provide resources, such as training programmes in disclosure, to improve clinician comfort in this area.

As a general rule, disclosure of the unexpected event should take place as soon as possible after it has been identified and when the patient is stable and able to understand and appreciate the information. Patients, or their families, should receive as much information as is known at the time. Serious events require prompt attention to collecting all relevant information. The physician in charge of the patient's care, whether or not he or she caused the adverse event, should meet with the patient or family in order to present the information. Such disclosure should focus on a narrative account of the events surrounding the adverse event and avoid inappropriate allegations of responsibility. It is very helpful for patient/family to know that someone has taken responsibility for the event. This person should be able to express regret and apologise for the mishap. Such expressions, if done carefully, ought not to amount to a confession of incompetence or liability but rather emphasise compassion and concern.[62]

Unanticipated outcomes should trigger appropriate internal reporting and corrective measures.[63] Disclosure concerning adverse outcomes and error is thus important because only by being open about such events can healthcare practitioners learn from them and improve the future care of patients.[64]

Staff ought to be rewarded for adverse event reporting and not be subjected to institutional retaliation on account of errors made in healthcare.[65] As one report from the UK recommended: 'the hospital . . . needs to empower all staff to report incidents without the fear of disciplinary action'.[66] This can be a very hard lesson for institutions and the public to heed as it requires suppressing the urge to find simple solutions for complex problems by blaming individuals. Instead, healthcare institutions must back up such policies by providing tangible rewards to those whose reports do the most to improve patient safety.

New policies promoting openness about error are not without their problems. They must establish the threshold prompting to disclose. There may be an element of subjectivity here. The best response to this is to require independent review of reported incidents to see whether they ought to be disclosed to the patient. Even so, clinicians, used to the old system of cover-up, will require time to discover that the healthcare enterprise is not out to retaliate when they honestly report their mistakes or the mistakes of others. Unfortunately, inconsistencies in institutional practice in this area may undermine reporting improvement efforts.[67]

The problem of negligent or reckless practitioners cannot be dismissed and may indeed make it hard for the honest practitioner to trust the change in culture. Most practitioners make mistakes unintentionally through an error of judgement or lapse in concentration that will not recur. Despite this, medical institutions must make patient safety their priority and must not allow a disclosure policy to provide sanctuary for the incompetent or danger-

ous practitioner. To be trusted, institutions also need to find ways of providing support to, rather than abandoning, the well-meaning clinician involved in an adverse outcome.

In addition, errors in care made by others that are witnessed or revealed by internal audit cannot be ignored. A commitment to patient safety may make an institution aware that a colleague has problems; the auditor could find a physician or surgeon is at risk to disclose certain circumstances to the relevant intra-institutional authorities.[68] This is especially necessary where the unanticipated outcomes of care are serious and recurrent and the involved clinician fails to exercise due diligence about the events. Healthcare institutions must have effective and safe reporting systems capable of responding to untoward events and erratic practitioners in a speedy, comprehensive, and decisive way.

Such ethical duties of reporting pertain not just to physicians but to other healthcare professionals, such as pharmacists and nurses who may witness unreported errors made by physicians. These healthcare professionals must be encouraged and supported to go against the authority and power gradient and report on clinicians who may be a danger to others. Transforming institutional culture as regards error and adverse events requires more than well-written policies. Commitment and support for error initiatives must come from the top management of the enterprise. One-off efforts will fail dismally. Audits before and after the introduction of new policies can help determine whether such policies are found helpful and effective.

Finally, hospital policies cannot address the problem of error and adverse events in the community and in ambulatory care. Clinicians in institutions practice in a goldfish bowl, as it were, and are by that very fact held to higher standards of conduct, it seems. The solution to this is to study outpatient care more and to ensure professional regulators take the lead by promoting understanding and honesty, rather than punishment, concerning negative outcomes of outpatient care.

6. Conclusion

Medical error and adverse events together constitute a major problem for modern medicine; it is a problem for professionals and institutions alike. In order to comprehensively deal with the problem and to assure the public that medicine takes such events seriously, efforts to address unanticipated negative outcomes of care from a total quality improvement perspective must be supplemented by increased honesty and openness about adverse incidents. One way to demonstrate this is to ensure transparency of disclosure of significant adverse events and errors to patients and their families. The extent of the problem and the long history of professional secrecy means that changes will not come about overnight. Ethically sound institutional policies of practice regarding disclosure of negative outcomes must go forward despite the absence of evidence of the best way to do so. It is simply the right thing to do.

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