

Bioethics for clinicians:

23. Disclosure of medical error

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Abstract

ADVERSE EVENTS AND MEDICAL ERRORS ARE NOT UNCOMMON. In this article we review the literature on such events and discuss the ethical, legal and practical aspects of whether and how they should be disclosed to patients. Ethics, professional policy and the law, as well as the relevant empirical literature, suggest that timely and candid disclosure should be standard practice. Candour about error may lessen, rather than increase, the medicolegal liability of the health care professionals and may help to alleviate the patient's concerns. Guidelines for disclosure to patients, and their families if necessary, are proposed.

A 37-year-old woman with an unremarkable medical history visits her physician for a physical examination. As the physician is about to enter the examining room, she is taken aside by her nurse, who has just noticed for the first time that the patient's last Pap smear, done 3 years earlier, showed adenocarcinoma in situ. The report, although filed in the patient's chart, is a complete surprise to the physician as well. She cannot understand how it was missed because the patient had been seen several times in the clinic since the test was done. The physician considers what she should tell the patient.

A 12-year-old boy has cataract surgery at a large teaching hospital. At a critical moment the surgeon's hand slips, rupturing the lens capsule. The planned implantation of an intraocular lens has to be abandoned. Instead, the patient will have to use a contact lens. The physician wonders what he should tell the patient and his family about the surgery.

What is medical error?

Well-publicized cases of medical error in the United States,¹ Canada^{2,3} and the United Kingdom⁴ have raised public concerns about the safety of modern health care delivery. A new report from the US Institute of Medicine entitled "To Err Is Human" encourages efforts aimed at preventing patient harm.⁵ In this article we will focus on one aspect of the management of medical errors that can be difficult for practitioners: the issue of disclosure. What and how should patients be told when a medical mistake has been made or they have been harmed by medical care?

Medical errors are usually considered to be "preventable adverse medical events."⁶ Patients are harmed as a consequence of either what is done to them — errors of commission — or what is not done but should have been done to prevent an adverse outcome — errors of omission. Negligent actions should be distinguished from honest mistakes. The former are preventable, harmful errors that fall below the standard expected of a reasonably careful and knowledgeable practitioner acting in a similar situation.⁷⁻⁹ Negligence, strictly speaking, can be established only in a court of law.¹⁰ Whether *all* errors are truly preventable can be debated.¹¹

Why is the disclosure of medical error important?

Ethics

Failing to disclose errors to patients undermines public trust in medicine because it potentially involves deception¹² and suggests preservation of narrow profes-

Review

Synthèse

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sional interests over the well-being of patients. This failure can be seen as a breach of professional ethics — a lapse in the commitment to act solely for the patient's best interests. As well, patients may be caused avoidable harm if they are injured further by the failure to disclose. To consent properly to treatment for an injury caused by error, patients require relevant information about what transpired during and after the treatment that led to the injury.¹⁷

Disclosure of error, by contrast, is consistent with recent ethical advances in medicine toward more openness with patients and the involvement of patients in their care,¹⁴ advances explored in earlier articles on informed consent and truth telling.^{15,16}

Patients are also due information about errors out of respect for them as persons. Thus, they have a right to know about critical incidents even if they are not physically harmed by them. Furthermore, by the principle of justice or fairness, patients, when harmed, should be able to seek appropriate restitution or recompense. This ethical rationale for disclosure, based on a strong notion of autonomy, goes beyond what the law might require one to do. Non-disclosure may be rationalized by concerns about increasing patient anxiety or confusing the patient with complicated information.¹⁸ This position, now largely discredited, is one of “therapeutic privilege,” that is, protecting the “child-like” patient from “harmful” information.¹⁶

Finally, nondisclosure of error may also undermine efforts to improve the safety of medical practice¹³ if the error is not reported to the appropriate authorities.

Law

The law recognizes that physicians may make mistakes without negligence, but it frowns on dishonesty. In *Stamos v. Davies* a respirologist, in attempting a lung biopsy, mistakenly biopsied the patient's spleen.¹⁹ When the patient asked for the results, rather than honestly admitting the error, the doctor replied he had “got something else.” The judge found that the respirologist had breached a duty of disclosure owed to the patient “as a matter of professional relations.”

In another case, an orthopedic surgeon failed to tell a patient that he had operated on the wrong disc.²⁰ He then convinced the patient to undergo a second operation by him for the continued pain. This was considered fraudulent concealment of relevant information and nullified the validity of the patient's consent to the second operation. The Ontario Court of Appeal awarded the patient damages in excess of \$600 000, including punitive damages of \$40 000 for the surgeon's “highly unethical conduct.”

Punitive damages (of \$20 000) were also awarded in a recent British Columbia case in which a surgeon left an abdominal roll in the patient's upper abdomen during a laparotomy and presacral neurectomy.²¹ The surgeon waited over 2 months before telling the patient and, during that time, took active steps to try to cover up the mistake (e.g.,

by telling the nurses not to make any written record of it). The court described the surgeon's delay in informing his patient, and his deliberate attempts to cover it up, as demonstrating “bad faith and unprofessional behaviour deserving of punishment.” Also of interest was the court's conclusion that the nurses who were aware of the surgeon's error did not have any legal duty to tell the patient, because this role properly pertained to the surgeon. The nurses did have a duty to prepare an incident report for the hospital administration.

These decisions suggest that a doctor who makes an error in treating a patient has a positive legal duty to inform the patient.²²⁻²⁵ Unfortunately, the current adversarial legal climate is perceived as a disincentive for many physicians to be honest about error.

Policy

Disclosure of error is not explicitly addressed in the new CMA Code of Ethics.²⁶ Most professional bodies, such as the College of Physicians and Surgeons of Ontario, the province's regulatory body for physicians, have no policies requiring physicians to disclose error, except in some circumstances of professional incompetence or incapacity.²⁷ Insurers of medical professionals have been seen as wary of advising candour with patients when error occurs. This approach of professional prudence — and perhaps legal realism — is inconsistent with openly discussing error with patients. The Canadian Medical Protective Association (CMPA), however, advises honesty:

Physicians are advised to be accurate and factual in their disclosure to patients and avoid discussion of attribution of responsibility. The CMPA can provide assistance to physicians who contact the Association in advance of talking to patients and their families about serious error. [Dr. John E. Gray, Secretary-Treasurer, CMPA: personal communication, May 2000]

Most hospitals now have policies that encourage the reporting of “medical incidents” as part of quality-assurance programs,²⁸ but typically the policies do not address the question of whether or what to tell patients. This, too, may be changing. The Veteran's Administration Hospital System in New York State, for example, as part of a national Veteran's Administration effort to improve patient safety, has an elaborate policy on reporting adverse events that includes instructing practitioners to disclose errors to patients.²⁹ One hospital in Ontario is currently adopting a policy that encourages practitioners to disclose medical errors to patients;³⁰ the policy promises no retaliation against practitioners and staff who, in good faith, report and disclose errors, but obviously it cannot guarantee against legal or professional action taken by parties outside the hospital.

Efforts to reduce error and improve patient safety are the focus of the US Institute of Medicine report,³¹ which, among other things, encourages health care organizations to implement nonpunitive systems for reporting errors. Re-

vealing error to the public can be a positive experience for the medical community and can promote public confidence in medicine.³²

Empirical studies

Medical error is a significant quality-of-care problem.^{33,34} The Harvard Medical Practice Study from the mid-1980s showed that 3.7% of patients in hospital suffered an adverse event (an injury due to medical management that prolonged hospital stay or led to disability at discharge, or both) and that about half of these events were considered preventable.³⁵ The authors did not address whether patients or families knew about these events. The Quality in Australian Health Care Study, conducted in the mid-1990s, found that 16% of admissions were associated with an adverse event and 51% were preventable.³⁶ In Utah and Colorado 1992 data revealed a rate of injury from medical care of 2.9%.³⁷ There are, unfortunately, only partial statistics on the Canadian rate of error, but the magnitude of the problem here seems similar to that in the United States.³⁸

These data, although impressive, concern adverse events, not simply events involving error. Inconsistencies in definitions of error and in study methodology³⁹⁻⁴² should make us circumspect when considering claims that there is a hidden epidemic of physician error causing tens of thousands of avoidable patient deaths per year.⁴³ Assessors are more likely, for example, because of hindsight bias, to see error and negligence if they know the patient's outcome was bad.⁴⁴

Whatever the precise magnitude of the error problem, the issue of disclosure looms large for patients. When asked if they would like to know about physician error, the majority of patients prefer complete candour. In one study, in which patients of primary care physicians were given hypothetical situations, 98% wanted honest acknowledgement of errors, even if minor.⁴⁵ If not so informed, the surveyed patients indicated that they would be more likely to sue the physician. How patients who have experienced real adverse events from medical error feel about disclosure has not been studied.

Patients and physicians have different attitudes toward disclosure. In a recent study, ophthalmologists and eye patients were asked whether patients should always be told

about complications occurring during surgery (e.g. lens capsule rupture with a 10% risk of vision being affected).⁴⁶ Ninety-two percent of the patients favoured disclosure, as compared with 60% of the physicians.

In a study in which physicians were given a hypothetical case in which a patient dies because of a drug mistakenly administered by a physician, more than one third of those surveyed indicated that they would provide the family with incomplete or misleading information about what transpired.⁴⁷ Practitioners do not disclose or report error for various reasons, including ignorance about reporting requirements, uncertainty about how to report error, a wish not to upset patients and concerns for the consequences of disclosure.⁴⁸

The fear of retaliation, such as lawsuits and professional sanctions, is a significant impediment to disclosure,⁴⁹ but it seems exaggerated and misplaced.⁵⁰ The Harvard Medical Practice Study found that only 2% of negligent adverse events ever led to actual malpractice claims.⁵¹ Although some people do indeed sue for financial reasons, this does not explain all motivation for lawsuits against practitioners. In one study involving injured patients and the relatives who sued, plaintiffs were "disturbed by the absence of explanations, a lack of honesty, the reluctance to apologize, or being treated as a neurotic."⁵²

One large hospital in the United States that has a policy of active disclosure of adverse events to patients has actually experienced a decline in malpractice claims.⁵³ This suggests that candour may have a protective effect against malpractice claims. In one case of physician error, the presiding judge observed that the entire judicial action could have been avoided if the physician had simply "taken the patient into his confidence."⁵⁴

How should I approach medical error in practice?

Frankly disclosing error can be challenging for practitioners.^{54,55} Medical professionals have high expectations of themselves and, not surprisingly, find it difficult to acknowledge their errors openly before patients and colleagues.⁵⁶ Disclosing such events may be less traumatic if practitioners follow practical guidelines for breaking bad news.⁵⁷ If uncertain about how to talk to a patient concerning an error,

Disclosing error to patients

- Notify your professional insurer and seek assistance from those who might help you with disclosure (e.g., unit director, risk manager).
- Disclose promptly what you know about the event. Concentrate on what happened and the possible consequences.
- Take the lead in disclosure; don't wait for the patient to ask.
- Outline a plan of care to rectify the harm and prevent recurrence.
- Offer to get prompt second opinions where appropriate.
- Offer the option of a family meeting and the option of having lawyers present.
- Document important discussions.
- Offer the option of follow-up meetings.
- Be prepared for strong emotions.
- Accept responsibility for outcomes, but avoid attributions of blame.
- Apologies and expressions of sorrow are appropriate.

physicians would be wise to seek advice from the CMPA or skilled hospital representatives before doing so.

When harm to a patient occurs because of error, it is imperative to be sure about what happened. As for disclosing harm or the risk of harm in general,⁵⁸ the need to disclose an error to a patient is a proportionate one: it increases as the harm or risk of harm to the patient increases. The more challenging situation arises when an error is made but there is no current harm. Barring evidence to the contrary, it should be assumed that the patient would want full disclosure, particularly when harm may occur or when its potential occurrence requires departure from the usual care plan. Disclosure should, of course, take place at the right time, when the patient is medically stable enough to absorb the information, and in the right setting.

Physicians should take the lead in disclosing error to patients and their families.⁵⁹ They should try not to act defensively or evasively but, rather, to explain what happened in an objective and narrative way, trying to avoid reacting to the charged response that such disclosure can generate. A physician may say "I'm sorry." Patients often appreciate this form of acknowledgment and empathy. This may help to strengthen, rather than undermine, the physician-patient relationship.

If the adverse outcome requires medical attention, practitioners should disclose this and seek prompt help. Patients may be reassured by knowing that the physician is not only remorseful but also dedicated to rectifying the harm, and preventing further harm, by a clearly defined course of action. It may be wise to offer to get a second opinion or the option of transferring care to another physician if the physician-patient relationship no longer seems viable.

Meeting with patients, and their families if necessary, in a timely way after an error, especially if serious, can help avoid suspicions about a "cover-up." Although worrisome to clinicians, having lawyers present, if desired by the patient or the family, may help to ensure that all their concerns are expressed and addressed. A team meeting in advance of a conference with the patient and family should establish that all relevant information regarding the sequence of events leading to the adverse outcome is at hand, mutually understood and presented as clearly and openly as possible. It will also be important to say what, if anything, will be done to prevent the occurrence of such errors in the future. Patients and families may accept what has happened to them if they can be reassured that medical care will be improved in the future.

When practitioners witness errors made by other health care providers, they have an ethical, if not legal, obligation to act on that information. Depending on the circumstances and the magnitude of the error, options range from encouraging disclosure by the erring practitioner to discussing the situation with the hospital unit director, the department chief, risk management, a CMPA representative or a representative from a provincial professional association. Errors causing serious medical harm are ignored to the peril of the profession as well as the public.^{60,61}

The cases

Case 1

The physician should ensure that the report of the adenocarcinoma in situ is accurate and in the right chart. She should tell the patient, before the examination, about the report and admit that it seems the report was not acted upon. The patient may ask what the consequences now are for her health. The physician may be unable to answer the question at this time. False reassurances, blame placed on the patient for failed follow-up or blame placed on office staff will not be helpful. The patient should be offered an immediate and thorough examination with prompt retesting and, if needed, follow-up as soon as possible by an appropriate specialist. The physician should re-evaluate her office procedures and inform the patient of what will be done to prevent similar errors caused by ineffective data management.

Case 2

The surgeon should inform the patient and his family about the intraoperative event and the inability to achieve the intended outcome. Although the incident may not have a bad visual outcome for the patient, the surgeon must warn them of the possibility. He should arrange for appropriate follow-up surveillance and tell them what, if anything, can be done should the bad outcome occur. Since the possibility of the bad outcome was addressed in the initial informed consent, the surgeon is not responsible for contact lens expense; however, he may offer to provide help by making appropriate referrals (e.g., to social work) to address the issues of contact lens cost and management.

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Related Web sites

- US National Patient Safety Foundation: www.npsf.org
- Australian Patient Safety Foundation: www.apsf.net.au
- International forum for reporting critical incidents in anesthesia: www.medana.unibas.ch/eng/CIRS/CIRS.htm
- Canadian Institute for Safe Medication Practices: www.ismp-canada.org
- US Agency for Healthcare Research and Quality: <http://www.ahrq.gov/qual/errorsix.htm>
- US Institute of Medicine report "To Err Is Human: Building a Safer Healthcare System": www.nap.edu/books/0309068371/html

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