8.6 Promoting Patient Safety

In the context of health care, an error is an unintended act or omission or a flawed system or plan that harms or has the potential to harm a patient. Patients have a right to know their past and present medical status, including conditions that may have resulted from medical error. Open communication is fundamental to the trust that underlies the patient-physician relationship, and physicians have an obligation to deal honestly with patients at all times, in addition to their obligation to promote patient welfare and safety. Concern regarding legal liability should not affect the physician's honesty with the patient.

Even when new information regarding the medical error will not alter the patient's medical treatment or therapeutic options, individual physicians who have been involved in a (possible) medical error should:

(a) Disclose the occurrence of the error, explain the nature of the (potential) harm, and provide the information needed to enable the patient to make informed decisions about future medical care.

(b) Acknowledge the error and express professional and compassionate concern toward patients who have been harmed in the context of health care.

(c) Explain efforts that are being taken to prevent similar occurrences in the future.

(d) Provide for continuity of care to patients who have been harmed during the course of care, including facilitating transfer of care when a patient has lost trust in the physician.

Physicians who have discerned that another health care professional (may have) erred in caring for a patient should:

(e) Encourage the individual to disclose.

(f) Report impaired or incompetent colleagues in keeping with ethics guidance.

As professionals uniquely positioned to have a comprehensive view of the care patients receive, physicians must strive to ensure patient safety and should play a central role in identifying, reducing, and preventing medical errors. Both as individuals and collectively as a profession, physicians should:

(g) Support a positive culture of patient safety, including compassion for peers who have been involved in a medical error.

(h) Enhance patient safety by studying the circumstances surrounding medical error. A legally protected review process is essential for reducing health care errors and preventing patient harm.

(i) Establish and participate fully in effective, confidential, protected mechanisms for reporting medical errors.

(j) Participate in developing means for objective review and analysis of medical errors.

(k) Ensure that investigation of root causes and analysis of error leads to measures to prevent future occurrences and that these measures are conveyed to relevant stakeholders.

AMA Principles of Medical Ethics: I,II,III,IV,VIII

Background report(s):

CEJA Report 3-A-16 Modernized *Code of Medical Ethics*

CEJA Report 2-A-03 Ethical responsibility to study and prevent error and harm in the provision of health care

CEJA Report 9-A-94 Patient information

CEJA Report 3-A-16

8.6 Promoting Patient Safety

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As professionals uniquely positioned to have a comprehensive view of the care patients receive, physicians must strive to ensure patient safety and should play a central role in identifying, reducing, and preventing medical errors. Both as individuals and collectively as a profession, physicians should:

(g) *Support a positive culture of patient safety, including compassion for peers who have been involved in a medical error. [new content addresses gap in current guidance]*

(h) Enhance patient safety by studying the circumstances surrounding medical error. A legally protected review process is essential for reducing health care errors and preventing patient harm.

(i) Establish and participate fully in effective, confidential, protected mechanisms for reporting medical errors.

(j) Participate in developing means for objective review and analysis of medical errors.

(k) Ensure that investigation of root causes and analysis of error leads to measures to prevent future occurrences and that these measures are conveyed to relevant stakeholders.

AMA Principles of Medical Ethics: I,II,III,IV,VIII

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 2 - A-03

Subject: Ethical Responsibility to Study and Prevent Error and Harm in the Provision of Health Care

Presented by: Leonard J. Morse, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Donna A. Woodson, MD, Chair)

Error in judgment must occur in the practice of an art which consists largely of balancing probabilities
(William Osler)

INTRODUCTION

The Institute of Medicine's report "To Err Is Human"[1] brought patient safety to the forefront of medical news. The report, published in 1999, makes clear that errors are often the consequences of multiple factors that are a byproduct of the increasing complexity of health care. Notwithstanding the complexity of medicine, physicians continue to play a central role in providing medical care to patients. Therefore, two separate but equally important challenges currently face the medical profession: renewing the commitment to improving the safety of patient care, and continuing to foster patient trust. To address these challenges, this report considers physicians' ethical responsibilities to identify, study, and prevent errors and their ethical responsibilities to patients who suffer harm as a result of an error. Both these sets of responsibilities flow from the AMA's *Principles of Medical Ethics*. Indeed, the *Principles* call upon physicians to "provide competent medical service with compassion and respect for human dignity and rights" and to "be honest in all their professional interactions."

DEFINITIONS

Despite great advances, medicine remains an imperfect science, and some procedures carry considerable risks that patients are willing to assume in relation to the expected beneficial outcome. Although the possibility of an untoward outcome due to an error could be viewed as a form of risk, its potentially preventable nature makes it different.

In 1994, one of the leading commentators on the topic of errors, Lucian Leape, defined errors as unintended acts or acts that did not achieve the intended outcome.[2] The Institute of Medicine offered a similar definition, stating that "An error is defined as the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning)."[1]

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* Reports of the Council on Ethical and Judicial Affairs are assigned to the reference committee on Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

Independently of whether there are any negative consequences, it is possible to speak of "mistakes," where decisions or actions with potentially negative consequences would be judged by peers to have deviated from standards.[3] Other investigators have focused on adverse events as "situations in which an inappropriate decision was made when, at the time [when] an appropriate alternative could have been chosen."[4]

Significantly, these definitions do not depend on the outcome, such that an error in the context of health care need not result in an injury. From the perspective of the Hippocratic tradition, whereby the first duty of physicians is to do no harm, errors that do not result in injury would not automatically imply an ethical lapse. Nevertheless, some errors are preventable. To enhance patient safety, they require careful attention.

In this report, an "error" is defined as an unintended act or omission, or a flawed system or plan, that harms or has the potential to harm patients, whether the harm be direct (physical or psychological) or indirect (such as undermining patient trust). The term should be understood to refer to all errors occurring within a health care environment, and not just errors by physicians.

It is clear that all instances of patient harm are not caused by errors.[5] Nevertheless, physicians' concern about the welfare of their patients should translate into a compassionate response whenever patients suffer harm. The medical profession's stewardship of patient well-being is thus the ethical foundation of the profession's commitment to the prevention of patient harm through error reduction. Additionally, the physician's duty to deal honestly with patients extends the ethical responsibility beyond error reduction to a duty to relate with openness to patients who may have experienced harm.

HISTORY OF ERROR REDUCTION AND QUALITY IMPROVEMENT EFFORTS

Historically, the medical profession gained much of its knowledge through open reporting of failed interventions, which was viewed as an important educational tool, particularly in the field of surgery. In the words of one commentator, "the open admission of mistakes and the truthful reporting of results among peers, therefore, was important for the development of the profession," particularly until the introduction of science into medicine, which resulted in upgrading the standard of care,[6] and the institution of ethically based patient protections, such as informed consent.

Various forms of peer review have long been utilized to discuss unsuccessful outcomes. These educational endeavors took the form of morbidity and mortality conferences, case review, and grand rounds.[7] The purpose of these discussions was to facilitate learning and to disseminate knowledge. In more recent times, peer review expanded with the relationship between physicians and hospitals. In this context, peer review has been used as a tool to evaluate the competence of individual doctors by examining the appropriateness of care. Sometimes seen as a disciplinary mechanism, rather than an educational tool, the misuse of peer review has been decried by many physicians. Therefore, there is great concern that peer review be conducted fairly and in good faith, and that appropriate safeguards be in place to protect all parties involved from punishment or unjustified recriminations.

It also is argued that the threat of litigation has become a hindrance to open discussions of errors. Accordingly, many legal and medical commentators have stated that a fundamental reform of medical liability is required, since repetition of errors cannot be prevented if they are not reported and openly discussed.[8, 9]

Overall, the prevention of patient harm through error reduction should be seen as part of a long tradition of mutually beneficial peer review and shared knowledge, and professional dedication to improving the continually expanding provision of medical care.

ERRORS AT THE LEVEL OF THE HEATH CARE SYSTEM

Some investigators have described medicine as a culture of "perfection," where committing an error is viewed as a flaw in character, which is then associated with incompetence, and which can lead to some sanction. Many have criticized this approach, noting that to threaten individuals with punishment or shame if they commit an error is a strategy that was abandoned long ago by industries that have achieved much greater levels of safety.[8] Fortunately, there now appears to be a shift away from framing errors as attributable to individual negligence or misconduct. In fact, recognition that many errors are "systems errors" related to the increasing complexity of health care delivery has shifted attention to the need for safer systems and processes. Therefore, the primary goal of a reporting system should be the prevention of future errors rather than the punishment of individual behavior and the system should be built as an educational tool.

Physicians are uniquely positioned to have a thorough view of the medical care in a given setting. Working with all other relevant professionals, they should ensure that appropriate channels are established through which errors can be reported and reviewed, and operational improvements can be implemented as the result of such review. Mechanisms already should exist for early detection of impaired or incompetent colleagues, with the objective of providing rehabilitation, retraining, or restriction of practice *before* their behavior may result in patient injury.[10]

DISCLOSURE OF ERRORS AT THE LEVEL OF THE PATIENT-PHYSICIAN RELATIONSHIP

Tradition of honesty and compassion in medical ethics

In addition to error prevention, important ethical considerations arise when an error occurs that results in harm to a patient. Medical ethicists have long held that honesty is fundamental to the practice of medicine. This obligation stems from many important ethical traditions. Most recently, there has been a growing effort to include patients in the decision-making process as an expression of their autonomy. This has led to the expansion of the doctrine of informed consent, whereby physicians provide patients with information concerning treatment options. This approach allows the patient to make choices that are aligned with his or her values and preferences. Accordingly, when asked what should be done when a patient is injured, medical ethicists find the answer to be rather straightforward, regardless of whether the injury was inadvertent or preventable – information regarding the injury should be disclosed to the patient.

The *Code of Medical Ethics* emphasizes this obligation in Opinion 8.12, "Patient Information," stating that:

> Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. […] This obligation holds even though the patient's medical treatment or therapeutic options may not be altered by the new information.

Some contend that the doctrine of "therapeutic privilege" permits a physician to withhold information that, if disclosed, could cause psychological distress or could undermine trust and lead the patient to rash decisions that result in even greater negative effects. In the rare instances where this may be a concern, the physician should involve appropriate members of the patient's family, or other advocates, and consult a disinterested party, such as a trusted colleague. More often, candid disclosure of an error that caused harm may help the patient deal better with the situation and enhance the patient's trust of the physician and the hospital. Physicians, however, should be cautious that premature conclusions may be misleading and inappropriate. If there is uncertainty as to the cause of harm, a physician should explain what is known and what remains to be investigated, and should assure the patient that appropriate information will be shared honestly and openly. If harm is ignored or glossed over, however, patients may feel angry and abandoned; therefore, it is important that their perceptions be validated to the extent that is possible.

Any communication about harm resulting from an error should be made with tact, including an expression of regret. This expression of compassion, acknowledging that an untoward event has occurred, need not represent an admission of responsibility. In addition, to the extent it is possible, there should be an assurance that efforts will be made to prevent subsequent patients from experiencing harm resulting from similar circumstances. Physicians, and hospitals, may also consider whether there should be an offer of restitution for expenses resulting from an error.

These strategies may help reduce the risk of liability in certain circumstances. For example, when the VA Hospital in Lexington, Kentucky, introduced a disclosure policy, which involved a discussion with the patient about the details of the incident, an expression of regret for the outcome, and an offer of restitution when indicated, it was found that the total liability payments at the facility were comparable to those at other facilities without similar disclosure policies. Furthermore, the hospital experienced lower legal costs per claim and lower settlement amounts per claim. These results have since motivated a system-wide disclosure policy for all VA hospitals.[11]

Patient advocacy: Promoting patient interests through the investigation of the causes of harm

Physicians' unique role as patient advocates also requires them to participate in the investigation regarding the cause of the harm. A physician might feel such a heavy responsibility for a patient's well-being that the physician might accept blame before careful investigation is undertaken. However, investigations often reveal multiple systemic causes that made the harm inevitable despite the physician's intentions and performance. Examples include mislabeling of medications, or the failure to transmit important information. In these instances, the physician may have been the practitioner closest to the patient at the time the harm occurred, but might not have been the causal agent. Uncovering the exact causes of an error and correcting them when possible should be a high priority.

Should the physician be responsible for serious harm to a patient, the physician must acknowledge responsibility to the patient. Many times, this will facilitate preserving trust, and will allow continuity of care with the same health care team, instead of a patient having to build new relationships with other caregivers. This will be most important when decisions need to be made promptly in response to the harm that has occurred. However, if the disclosure injures the patient's trust in the physician or otherwise damages the patient's relationship with the physician so severely that the patient prefers to obtain subsequent care from someone else, the physician has a responsibility to assist the patient in obtaining continuing care.[12] If a physician who is responsible for harm is unwilling or unable to acknowledge his or her responsibility to the patient, a neutral party should communicate the information to the patient.

The obligation to uncover and disclose information regarding an error is related to physicians' responsibility to act as patient advocates and to promote the patient's best interests, irrespective of other interests. This standard has recently been expressed in CEJA Report 1-A-01, "The Patient-Physician Relationship." The report reminded physicians that high ethical responsibilities flow from caring for patients as a consequence of their illness and their dependence on the medical expertise of physicians.

In the context of harm, a physician who has a long-standing relationship with a patient or has been involved in a recent course of treatment often will be in the best position to advocate on behalf of the patient with other health care practitioners, the hospital, or the insurance company, to resolve issues stemming from harm. Disclosure, ultimately, is an expression of fidelity to the patient's interests.

Errors committed by others

A somewhat different challenge may present itself when health care professionals witness harm being committed or discover that a patient experienced harm in the past when someone else was caring for the patient. It may be argued that the absence of a relationship with the patient at the time an error occurred absolves the health care professional from ethical responsibilities to report it and to discuss it with the patient. Yet, it is clear that even if a physician is not responsible for the harm, that physician still has the ethical obligation to be honest and forthcoming with information pertaining to the patient. The physician also has an ethical obligation to protect patient welfare in general by reporting the occurrence and promoting operational improvements that enhance patient safety. This latter obligation is recognized under Principle II of the AMA's *Principles of Medical Ethics*, which states in part that: "A physician shall uphold the standards of professionalism… and strive to report physicians deficient… in competence, or engaging in… deception, to appropriate entities." Physicians are provided further guidance under Opinion E-9.031, "Reporting Impaired, Incompetent, or Unethical Colleagues."[10]

ERRORS AND PROFESSIONAL LIABILITY

Physicians concerned with the rise in professional liability claims and awards may find ethical obligations regarding the reporting and disclosing of errors counter-intuitive. However, some data suggest that the major determinant of the initiation of professional liability claims may be faulty communication and patient dissatisfaction,[13, 14] rather than the quality of care.[15] On the basis that transparency – as opposed to secrecy – promotes trust, commentators have argued that open disclosure of errors may mitigate patient discontent and maintain patient confidence and, therefore, may be an important tool to reduce the risk of professional liability.[16] Such advice appears consistent with a recent study, which found that 98% of individuals who were presented with various scenarios expected or wished for the physician's active acknowledgement of an error.[17] Indeed, it is considered that some patients may file a lawsuit specifically to uncover information they otherwise have not been able to obtain. Also, for many patients, an offer of money is less likely to make them terminate a legal action against a health care provider than an explanation and an apology, and an assurance that corrective measures would be undertaken to prevent future similar errors.[18] Changes in the current legal system that would facilitate reporting and investigating errors by ensuring confidentiality would enhance the prevention of patient harm.

CONCLUSION

Most patients are confident that the medical care they receive is delivered competently and will produce beneficial outcomes. However, as medicine becomes more complex, and the provision of

health care becomes a sophisticated set of interwoven processes, it is inevitable that there will be occurrences that have the potential to cause harm to a patient and may be repeated if they are undetected or uncorrected. These occurrences may arise from unintended actions or omissions or from flawed systems or plans.

Physicians, because of the central role they play in the provision of medical care, and because of the unique ethical responsibilities that flow from caring for patients, must commit to the enhancement of patient safety through identification and correction of medical errors and the prevention of patient harm. This requires that physicians participate in the development of error reporting mechanisms that promote changes in systems rather than punishment. Furthermore, in instances when harm occurs, physicians must reinforce the trust that patients hold in the medical profession by offering an honest disclosure of events.

RECOMMENDATIONS

The Council recommends that the following be adopted and the remainder of the report be filed:

In the context of health care, an error is an unintended act or omission, or a flawed system or plan that harms or has the potential to harm a patient. Patient safety can be enhanced by studying the circumstances surrounding health care errors. This can best be achieved through a legally protected review process, which is essential for reducing health care errors and preventing patient harm.

(1) Because they are uniquely positioned to have a comprehensive view of the care patients receive, physicians must strive to ensure patient safety and should play a central role in identifying, reducing and preventing health care errors. This responsibility exists even in the absence of a patient-physician relationship.

(2) Physicians should participate in the development of reporting mechanisms that emphasize education and systems change, thereby providing a substantive opportunity for all members of the health care team to learn. Specifically, physicians should work with other relevant health care professionals to:

    (a) Establish and participate fully in an effective, confidential, and protected error-reporting mechanism;
    (b) Develop means to review and analyze objectively reports regarding errors, and to conduct appropriate investigations into the causes of harm to a patient;
    (c) Ensure that the investigation of causes of harm, and the review and study of error reports result in preventive measures that are conveyed to all relevant individuals;
    (d) Identify and promptly report impaired and/or incompetent colleagues so that rehabilitation, retraining or disciplinary action can occur in order to prevent harm to patients.

(3) Physicians must offer professional and compassionate concern toward patients who have been harmed, regardless of whether the harm was caused by a health care error. An expression of concern need not be an admission of responsibility. When patient harm has been caused by an error, physicians should offer a general explanation regarding the nature of the error and the measures being taken to prevent similar occurrences in the future. Such communication is fundamental to the trust that underlies the patient-physician relationship, and may help reduce the risk of liability.

(4) Physicians have a responsibility to provide continuity of care to patients who may have been harmed during the course of their health care. If, due to the harm suffered under the care of a physician, a patient loses trust in that physician, the obligation may best be fulfilled by facilitating the transfer of the patient to the care of another physician.

(5) Physicians should seek changes to the current legal system to ensure that all errors in health care can be safely and securely reported and studied as a learning experience for all participants in the health care system, without threat of discoverability, legal liability or punitive action.

(New House/CEJA Policy)

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The Council wishes to acknowledge the valuable contributions of Lucian L. Leape, MD and Paul Barach, MD, MPH in reviewing this Report.

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4. Whatever the statute of limitations, a physician should measure time from the last professional contact with the patient.

5. If a patient is a minor, the statute of limitations for medical malpractice claims may not apply until the patient reaches the age of majority.

6. Immunization records always must be kept.

7. The records of any patient covered by Medicare or Medicaid must be kept at least five years.

8. In order to preserve confidentiality when discarding old records, all documents should be destroyed.

9. Before discarding old records, patients should be given an opportunity to claim the records or have them sent to another physician, if it is feasible to give them the opportunity.

(The Retention of Medical Records Opinion will appear in the next edition of Current Opinions with Annotations as Opinion 7.05 and is derived from Principles IV and V of the Principles of Medical Ethics.)

9. PATIENT INFORMATION*

HOUSE ACTION: FILED

It is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients. Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. Only through full disclosure is a patient able to make informed decisions regarding future medical care.

Ethical responsibility includes informing patients of changes in their diagnoses resulting from retrospective review of test results or any other information. This obligation holds even though the patient's medical treatment or therapeutic options may not be altered by the new information.

Concern regarding legal liability which might result following truthful disclosure should not affect the physician's honesty with a patient.

(The Patient Information Opinion will appear in the next edition of Current Opinions with Annotations as Opinion 8.12 and is derived from Principles I, II, III and IV of the Principles of Medical Ethics.)

10. ANENCEPHALIC INFANTS AS ORGAN DONORS

HOUSE ACTION: FILED

Anencephaly is a congenital absence of a major portion of the brain, skull and scalp. Infants born with this condition are born without a forebrain and without a cerebrum. While anencephalics are born with a rudimentary functional brain stem, their lack of functioning cerebrum permanently forecloses the possibility of consciousness.

It is ethically permissible to consider the anencephalic as a potential organ donor, although still alive under the current definition of death only if (1) the diagnosis of anencephaly is certain and is confirmed by two physicians