Virtual Mentor
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THE CODE SAYS
The AMA *Code of Medical Ethics*' Opinions on Patient Safety

Opinion 8.12 - Patient Information
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.

Report issued March 1981; updated June 1994.

Opinion 8.121 - Ethical Responsibility to Study and Prevent Error and Harm
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 for objective review and analysis of 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 for continuity of care to patients who may have been harmed during the course of their health care. If, because of 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.

Report issued December 2003, based on Ethical Responsibility to Study and Prevent Error and Harm in the Provision of Health Care, adopted June 2003.

Opinion 9.032 - Reporting Adverse Drug or Device Events

A physician who suspects the occurrence of an adverse reaction to a drug or medical device has an obligation to communicate that information to the broader medical community, (e.g., through submitting a report or letter to a medical journal or informing the manufacturer of the suspect drug or device). In the case of a serious adverse event, the event should be reported to the Food and Drug Administration (FDA). Spontaneous reports of adverse events are irreplaceable as a source of valuable information about drugs and medical devices, particularly their rare or delayed effects, as well as their safety in vulnerable patient populations. Although premarketing and mandated postmarketing studies provide basic safeguards for the public health, they suffer from inherent deficiencies that limit their ability to detect rare or unexpected consequences of drug or medical device use. Physicians who prescribe and monitor the use of drugs and medical devices constitute the group best able to observe and communicate information about resulting adverse events.

Serious adverse events, such as those resulting in death, hospitalization, or medical or surgical intervention, are the most important to report and are the only adverse events for which the FDA desires a report. Certainty, or even reasonable likelihood, of a causal relationship between the drug or medical device and the serious adverse event will rarely exist and is not required before reporting the event to the FDA. Suspicion of such a relationship is sufficient to give rise to an obligation to participate in the reporting system.

Report issued June 1993, based on Reporting Adverse Drug and Medical Device Events, adopted June 1993; updated June 1994.

Opinion 9.14 - Quality
As professionals dedicated to promoting the well-being of patients, physicians individually and collectively share the obligation to ensure that the care patients receive is safe, effective, patient centered, timely, efficient, and equitable.

While responsibility for quality of care does not rest solely with physicians, their role is essential. Individually and collectively, physicians should actively engage in efforts to improve the quality of health care by:

1. Keeping current with best care practices and maintaining professional competence.
2. Holding themselves accountable to patients, families, and fellow health care professionals for communicating effectively and coordinating care appropriately.
3. Monitoring the quality of care they deliver as individual practitioners—e.g., through personal case review and critical self-reflection, peer review, and use of other quality improvement tools.
4. Demonstrating a commitment to develop, implement, and disseminate appropriate, well-defined quality and performance improvement measures in their daily practice.
5. Participating in educational, certification, and quality improvement activities that are well designed and consistent with the core values of the medical profession.

Issued November 2009, based on Quality, adopted June 2009.

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