

# 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

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Referred to: Reference Committee on Amendments to Constitution and Bylaws  
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*Error in judgment must occur in the practice of an art which consists largely of balancing probabilities*  
(William Osler)

## 1 INTRODUCTION

2  
3 The Institute of Medicine's report "To Err Is Human"<sup>1</sup> brought patient safety to the forefront of  
4 medical news. The report, published in 1999, makes clear that errors are often the consequences  
5 of multiple factors that are a byproduct of the increasing complexity of health care.  
6 Notwithstanding the complexity of medicine, physicians continue to play a central role in  
7 providing medical care to patients. Therefore, two separate but equally important challenges  
8 currently face the medical profession: renewing the commitment to improving the safety of  
9 patient care, and continuing to foster patient trust. To address these challenges, this report  
10 considers physicians' ethical responsibilities to identify, study, and prevent errors and their  
11 ethical responsibilities to patients who suffer harm as a result of an error. Both these sets of  
12 responsibilities flow from the AMA's *Principles of Medical Ethics*. Indeed, the *Principles* call  
13 upon physicians to "provide competent medical service with compassion and respect for human  
14 dignity and rights" and to "be honest in all their professional interactions."

## 15 16 DEFINITIONS

17  
18 Despite great advances, medicine remains an imperfect science, and some procedures carry  
19 considerable risks that patients are willing to assume in relation to the expected beneficial  
20 outcome. Although the possibility of an untoward outcome due to an error could be viewed as a  
21 form of risk, its potentially preventable nature makes it different.

22  
23 In 1994, one of the leading commentators on the topic of errors, Lucian Leape, defined errors as  
24 unintended acts or acts that did not achieve the intended outcome.<sup>2</sup> The Institute of Medicine  
25 offered a similar definition, stating that "An error is defined as the failure of a planned action to  
26 be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim  
27 (i.e. error of planning)."<sup>1</sup>

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

6  
7 Significantly, these definitions do not depend on the outcome, such that an error in the context of  
8 health care need not result in an injury. From the perspective of the Hippocratic tradition,  
9 whereby the first duty of physicians is to do no harm, errors that do not result in injury would not  
10 automatically imply an ethical lapse. Nevertheless, some errors are preventable. To enhance  
11 patient safety, they require careful attention.

12  
13 In this report, an “error” is defined as an unintended act or omission, or a flawed system or plan,  
14 that harms or has the potential to harm patients, whether the harm be direct (physical or  
15 psychological) or indirect (such as undermining patient trust). The term should be understood to  
16 refer to all errors occurring within a health care environment, and not just errors by physicians.

17  
18 It is clear that all instances of patient harm are not caused by errors.<sup>5</sup> Nevertheless, physicians’  
19 concern about the welfare of their patients should translate into a compassionate response  
20 whenever patients suffer harm. The medical profession’s stewardship of patient well-being is  
21 thus the ethical foundation of the profession’s commitment to the prevention of patient harm  
22 through error reduction. Additionally, the physician’s duty to deal honestly with patients extends  
23 the ethical responsibility beyond error reduction to a duty to relate with openness to patients who  
24 may have experienced harm.

## 25 26 HISTORY OF ERROR REDUCTION AND QUALITY IMPROVEMENT EFFORTS

27  
28 Historically, the medical profession gained much of its knowledge through open reporting of  
29 failed interventions, which was viewed as an important educational tool, particularly in the field  
30 of surgery. In the words of one commentator, “the open admission of mistakes and the truthful  
31 reporting of results among peers, therefore, was important for the development of the profession,”  
32 particularly until the introduction of science into medicine, which resulted in upgrading the  
33 standard of care,<sup>6</sup> and the institution of ethically based patient protections, such as informed  
34 consent.

35  
36 Various forms of peer review have long been utilized to discuss unsuccessful outcomes. These  
37 educational endeavors took the form of morbidity and mortality conferences, case review, and  
38 grand rounds.<sup>7</sup> The purpose of these discussions was to facilitate learning and to disseminate  
39 knowledge. In more recent times, peer review expanded with the relationship between physicians  
40 and hospitals. In this context, peer review has been used as a tool to evaluate the competence of  
41 individual doctors by examining the appropriateness of care. Sometimes seen as a disciplinary  
42 mechanism, rather than an educational tool, the misuse of peer review has been decried by many  
43 physicians. Therefore, there is great concern that peer review be conducted fairly and in good  
44 faith, and that appropriate safeguards be in place to protect all parties involved from punishment  
45 or unjustified recriminations.

46  
47 It also is argued that the threat of litigation has become a hindrance to open discussions of errors.  
48 Accordingly, many legal and medical commentators have stated that a fundamental reform of  
49 medical liability is required, since repetition of errors cannot be prevented if they are not reported  
50 and openly discussed.<sup>8,9</sup>

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

#### 4 5 ERRORS AT THE LEVEL OF THE HEALTH CARE SYSTEM

6  
7 Some investigators have described medicine as a culture of “perfection,” where committing an  
8 error is viewed as a flaw in character, which is then associated with incompetence, and which can  
9 lead to some sanction. Many have criticized this approach, noting that to threaten individuals  
10 with punishment or shame if they commit an error is a strategy that was abandoned long ago by  
11 industries that have achieved much greater levels of safety.<sup>8</sup> Fortunately, there now appears to be  
12 a shift away from framing errors as attributable to individual negligence or misconduct. In fact,  
13 recognition that many errors are “systems errors” related to the increasing complexity of health  
14 care delivery has shifted attention to the need for safer systems and processes. Therefore, the  
15 primary goal of a reporting system should be the prevention of future errors rather than the  
16 punishment of individual behavior and the system should be built as an educational tool.

17  
18 Physicians are uniquely positioned to have a thorough view of the medical care in a given setting.  
19 Working with all other relevant professionals, they should ensure that appropriate channels are  
20 established through which errors can be reported and reviewed, and operational improvements  
21 can be implemented as the result of such review. Mechanisms already should exist for early  
22 detection of impaired or incompetent colleagues, with the objective of providing rehabilitation,  
23 retraining, or restriction of practice *before* their behavior may result in patient injury.<sup>10</sup>

#### 24 25 DISCLOSURE OF ERRORS AT THE LEVEL OF THE PATIENT-PHYSICIAN 26 RELATIONSHIP

##### 27 28 *Tradition of honesty and compassion in medical ethics*

29  
30 In addition to error prevention, important ethical considerations arise when an error occurs that  
31 results in harm to a patient. Medical ethicists have long held that honesty is fundamental to the  
32 practice of medicine. This obligation stems from many important ethical traditions. Most  
33 recently, there has been a growing effort to include patients in the decision-making process as an  
34 expression of their autonomy. This has led to the expansion of the doctrine of informed consent,  
35 whereby physicians provide patients with information concerning treatment options. This  
36 approach allows the patient to make choices that are aligned with his or her values and  
37 preferences. Accordingly, when asked what should be done when a patient is injured, medical  
38 ethicists find the answer to be rather straightforward, regardless of whether the injury was  
39 inadvertent or preventable – information regarding the injury should be disclosed to the patient.

40  
41 The *Code of Medical Ethics* emphasizes this obligation in Opinion 8.12, “Patient Information,”  
42 stating that:

43  
44 Patients have a right to know their past and present medical status and to be free of any  
45 mistaken beliefs concerning their conditions. Situations occasionally occur in which a  
46 patient suffers significant medical complications that may have resulted from the  
47 physician's mistake or judgment. In these situations, the physician is ethically required to  
48 inform the patient of all the facts necessary to ensure understanding of what has occurred.  
49 [...] This obligation holds even though the patient's medical treatment or therapeutic  
50 options may not be altered by the new information.

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

14  
15 Any communication about harm resulting from an error should be made with tact, including an  
16 expression of regret. This expression of compassion, acknowledging that an untoward event has  
17 occurred, need not represent an admission of responsibility. In addition, to the extent it is  
18 possible, there should be an assurance that efforts will be made to prevent subsequent patients  
19 from experiencing harm resulting from similar circumstances. Physicians, and hospitals, may  
20 also consider whether there should be an offer of restitution for expenses resulting from an error.

21  
22 These strategies may help reduce the risk of liability in certain circumstances. For example,  
23 when the VA Hospital in Lexington, Kentucky, introduced a disclosure policy, which involved a  
24 discussion with the patient about the details of the incident, an expression of regret for the  
25 outcome, and an offer of restitution when indicated, it was found that the total liability payments  
26 at the facility were comparable to those at other facilities without similar disclosure policies.  
27 Furthermore, the hospital experienced lower legal costs per claim and lower settlement amounts  
28 per claim. These results have since motivated a system-wide disclosure policy for all VA  
29 hospitals.<sup>11</sup>

30  
31 *Patient advocacy: Promoting patient interests through the investigation of the causes of harm*

32  
33 Physicians’ unique role as patient advocates also requires them to participate in the investigation  
34 regarding the cause of the harm. A physician might feel such a heavy responsibility for a  
35 patient’s well-being that the physician might accept blame before careful investigation is  
36 undertaken. However, investigations often reveal multiple systemic causes that made the harm  
37 inevitable despite the physician’s intentions and performance. Examples include mislabeling of  
38 medications, or the failure to transmit important information. In these instances, the physician  
39 may have been the practitioner closest to the patient at the time the harm occurred, but might not  
40 have been the causal agent. Uncovering the exact causes of an error and correcting them when  
41 possible should be a high priority.

42  
43 Should the physician be responsible for serious harm to a patient, the physician must  
44 acknowledge responsibility to the patient. Many times, this will facilitate preserving trust, and  
45 will allow continuity of care with the same health care team, instead of a patient having to build  
46 new relationships with other caregivers. This will be most important when decisions need to be  
47 made promptly in response to the harm that has occurred. However, if the disclosure injures the  
48 patient’s trust in the physician or otherwise damages the patient’s relationship with the physician  
49 so severely that the patient prefers to obtain subsequent care from someone else, the physician has  
50 a responsibility to assist the patient in obtaining continuing care.<sup>12</sup> If a physician who is  
51 responsible for harm is unwilling or unable to acknowledge his or her responsibility to the patient,  
52 a neutral party should communicate the information to the patient.

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

7  
8 In the context of harm, a physician who has a long-standing relationship with a patient or has  
9 been involved in a recent course of treatment often will be in the best position to advocate on  
10 behalf of the patient with other health care practitioners, the hospital, or the insurance company,  
11 to resolve issues stemming from harm. Disclosure, ultimately, is an expression of fidelity to the  
12 patient’s interests.

### 13 *Errors committed by others*

14  
15  
16 A somewhat different challenge may present itself when health care professionals witness harm  
17 being committed or discover that a patient experienced harm in the past when someone else was  
18 caring for the patient. It may be argued that the absence of a relationship with the patient at the  
19 time an error occurred absolves the health care professional from ethical responsibilities to report  
20 it and to discuss it with the patient. Yet, it is clear that even if a physician is not responsible for  
21 the harm, that physician still has the ethical obligation to be honest and forthcoming with  
22 information pertaining to the patient. The physician also has an ethical obligation to protect  
23 patient welfare in general by reporting the occurrence and promoting operational improvements  
24 that enhance patient safety. This latter obligation is recognized under Principle II of the AMA’s  
25 *Principles of Medical Ethics*, which states in part that: “A physician shall uphold the standards of  
26 professionalism... and strive to report physicians deficient... in competence, or engaging in...  
27 deception, to appropriate entities.” Physicians are provided further guidance under Opinion  
28 | E-9.031, “Reporting Impaired, Incompetent, or Unethical Colleagues.”<sup>10</sup>

## 29 30 ERRORS AND PROFESSIONAL LIABILITY

31  
32 Physicians concerned with the rise in professional liability claims and awards may find ethical  
33 obligations regarding the reporting and disclosing of errors counter-intuitive. However, some data  
34 suggest that the major determinant of the initiation of professional liability claims may be faulty  
35 communication and patient dissatisfaction,<sup>13, 14</sup> rather than the quality of care.<sup>15</sup> On the basis that  
36 transparency – as opposed to secrecy – promotes trust, commentators have argued that open  
37 disclosure of errors may mitigate patient discontent and maintain patient confidence and,  
38 therefore, may be an important tool to reduce the risk of professional liability.<sup>16</sup> Such advice  
39 appears consistent with a recent study, which found that 98% of individuals who were presented  
40 with various scenarios expected or wished for the physician’s active acknowledgement of an  
41 error.<sup>17</sup> Indeed, it is considered that some patients may file a lawsuit specifically to uncover  
42 information they otherwise have not been able to obtain. Also, for many patients, an offer of  
43 money is less likely to make them terminate a legal action against a health care provider than an  
44 explanation and an apology, and an assurance that corrective measures would be undertaken to  
45 prevent future similar errors.<sup>18</sup> Changes in the current legal system that would facilitate reporting  
46 and investigating errors by ensuring confidentiality would enhance the prevention of patient  
47 harm.

## 48 49 CONCLUSION

50  
51 Most patients are confident that the medical care they receive is delivered competently and will  
52 produce beneficial outcomes. However, as medicine becomes more complex, and the provision of

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

5  
6 Physicians, because of the central role they play in the provision of medical care, and because of  
7 the unique ethical responsibilities that flow from caring for patients, must commit to the  
8 enhancement of patient safety through identification and correction of medical errors and the  
9 prevention of patient harm. This requires that physicians participate in the development of error  
10 reporting mechanisms that promote changes in systems rather than punishment. Furthermore, in  
11 instances when harm occurs, physicians must reinforce the trust that patients hold in the medical  
12 profession by offering an honest disclosure of events.

### 13 14 RECOMMENDATIONS

15  
16 The Council recommends that the following be adopted and the remainder of the report be filed:

17  
18 In the context of health care, an error is an unintended act or omission, or a flawed system or plan  
19 that harms or has the potential to harm a patient. Patient safety can be enhanced by studying the  
20 circumstances surrounding health care errors. This can best be achieved through a legally  
21 protected review process, which is essential for reducing health care errors and preventing patient  
22 harm.

- 23  
24 (1) Because they are uniquely positioned to have a comprehensive view of the care patients  
25 receive, physicians must strive to ensure patient safety and should play a central role in  
26 identifying, reducing and preventing health care errors. This responsibility exists even in  
27 the absence of a patient-physician relationship.  
28
- 29 (2) Physicians should participate in the development of reporting mechanisms that emphasize  
30 education and systems change, thereby providing a substantive opportunity for all  
31 members of the health care team to learn. Specifically, physicians should work with other  
32 relevant health care professionals to:  
33
- 34 (a) Establish and participate fully in an effective, confidential, and protected error-  
35 reporting mechanism;
  - 36 (b) Develop means to review and analyze objectively reports regarding errors, and to  
37 conduct appropriate investigations into the causes of harm to a patient;
  - 38 (c) Ensure that the investigation of causes of harm, and the review and study of error  
39 reports result in preventive measures that are conveyed to all relevant individuals;
  - 40 (d) Identify and promptly report impaired and/or incompetent colleagues so that  
41 rehabilitation, retraining or disciplinary action can occur in order to prevent harm to  
42 patients.
- 43  
44 (3) Physicians must offer professional and compassionate concern toward patients who have  
45 been harmed, regardless of whether the harm was caused by a health care error. An  
46 expression of concern need not be an admission of responsibility. When patient harm has  
47 been caused by an error, physicians should offer a general explanation regarding the  
48 nature of the error and the measures being taken to prevent similar occurrences in the  
49 future. Such communication is fundamental to the trust that underlies the patient-  
50 physician relationship, and may help reduce the risk of liability.

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

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

10  
11  
12 (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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