Imagine this scenario: a patient visits the hospital and undergoes a cardiac procedure. He is discharged a few days later. He continues to have some difficulties, and his cardiologist does an outpatient echo-cardiogram, which reveals a collection of blood adjacent to the heart. The patient is brought back to the operating room, where a small incision is made below the xiphoid process and a catheter advanced in an attempt to “suction” out this blood. Massive bleeding is encountered and the patient expires on the operating room table. What should the physician tell the patient’s wife and daughter who are in the waiting room?

**Patient Safety Act**

The Patient Safety Act (PSA), landmark legislation passed in 2004, changed the paradigm for dealing with medical errors and serious adverse events in New Jersey. Previously limited to an ethical responsibility, the legislation created a legal duty to disclose medical errors to patients or their surviving families in the event of death. At least four other states have mandated disclosure of medical errors to patients. Of the fifty states and the District of Columbia, thirty-six have enacted “apology laws” protecting voluntary disclosures of medical errors.

The PSA defines an “adverse event” as an event that is “a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.” A “serious, preventable adverse event” is defined in the PSA as “an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility.” The legislature stated that its intent in mandating disclosure of serious, preventable adverse events was to “increase the amount of information on systems failures, analyze the sources of these failures and disseminate information on effective practices for reducing systems failures and improving the safety of patients.”

Thus, the patient must be informed of any serious preventable adverse events before the end of the episode of care, or in a timely manner if the error is
discovered after the episode of care has ended. In addition, the Department of Health and Senior Services (DHSS) must be notified of the occurrence of the error. In August 2006, the legislature clarified some of the ambiguous provisions of the PSA and the penalties resulting from non-compliance. Physicians or medical providers are required to notify a patient of a medical error within twenty-four hours of its discovery. The patient must be notified by telephone or certified mail or in person if he is still at the facility. The disclosure must be documented in the patient's chart along with details of date, time, the persons informed, and the names of all individuals present at the time the disclosure was made. A report to DHSS must be made within five days of the occurrence or discovery of the adverse event.

Specific details that must be included in the report to DHSS include (a) the date and time the event occurred, (b) a brief description of the event, (c) a statement about the impact of the event on the health of the patient, (d) the date and time the facility became aware of the event, (e) how the event was discovered, (f) the immediate corrective actions the facility took to eliminate or reduce the adverse impact of the event on the patient, and (g) what steps were taken to prevent the occurrence of future similar events.

The Act penalizes non-compliance by healthcare facilities at a rate of $1000 per day. Medical providers are fined $1000 for failing to disclose to neither the patient nor the DHSS. However, if there is no disclosure to the patient, but a disclosure was made to the Department, the fine increases to $5000.

An Ethical Responsibility

The American Medical Association Code of Ethics describe the doctor-patient relationship as one that is “based on trust and gives rise to physicians’ ethical obligations to place patients’ welfare above their own self-interest and above obligations to other groups and to advocate for their patients’ welfare.” The clinical encounter between a patient and a doctor is described as “fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering.”

Based on the principles that trust and patient-welfare are central to the physician-patient relationship, the American Medical Association Code of Ethics states that physicians have an ethical obligation to advice patients of the occurrence of a significant medical error when “a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment.” The American College of Surgeons endorses in its Code of Professional Conduct that surgeons “fully disclose adverse events and medical errors.” The American College of Physicians’ Ethics Manual also directs physicians
to disclose errors if disclosure of this information is “material to the patient's well-being.”

Similarly, many organizations that oversee healthcare entities support disclosure of errors and adverse events. In 2001, the Joint Commission issued the first nationwide disclosure standard, which required that patients be informed about all outcomes of care, including “unanticipated outcomes.” The standard did not specify the content of disclosure, nor did it mandate that patients be told when unanticipated outcomes were due to error.

In 2006, the National Quality Forum endorsed full disclosure of “serious unanticipated outcomes” as one of its thirty “safe practices” for healthcare. In legally mandating these standards in the form of the PSA, the legislature stated that “[h]ealth care facilities and professionals must be held accountable for serious preventable adverse events.” The necessity of a law to supplement an ethical obligation implies that the ethical imperative alone has been inadequate in creating this accountability.

**The Gap between Ideals and Reality**

Most patients harmed by medical errors are never told that these errors have occurred. Interviews and surveys regarding error disclosure have shown that patients want to be informed of errors in their medical care, to receive an explanation of the occurrence of the errors, and to learn how recurrences will be prevented. Physicians agreed with disclosure, but indicated that they “choose their words carefully” when telling patients about errors.

Full disclosure of an error includes a description of the error, an acknowledgement of responsibility, and an apology. But a careful choice of words may be used to subvert this disclosure by not informing the patient of the actual error that occurred and the full extent of the effect on his or her health. Another study estimated that nationwide, physicians are only disclosing errors to patients about one-third of the time. These studies demonstrate the great disconnect between the ideals that support error disclosure and its actual performance.
Reasons for Non-Disclosure of Errors

The psychological underpinnings that cause physicians to resist disclosing medical errors to patients are complex and can be traced to the basic structure of medical training; admission of errors is difficult for physicians. Historically physicians in residency training have trained in a culture where disclosure to peers is considered a sign of weakness. Instead skill in “roundsmanship” is valued, that is, creative and contemporaneous responses to cover deficiencies or errors when reporting to more senior physicians.37 “Medical narcissism” is defined as the need of health professionals to preserve their self esteem leading to the compromise of error disclosure to patients.38 Additionally, there is “an atmosphere in health care that can breed narcissistic inclinations and attitudes that make it very difficult to disclose medical errors truthfully and ethically.”39

Consequently, this “narcissism” creates a significant psychological barrier in allowing physicians to acknowledge that they could have committed an error, which in turn leads to the “phenomenon of medical error concealment” and other efforts to obscure the occurrence and facts related to the error.40 The “rationalizing” of errors by medical professionals is another mechanism whereby the significance of the error is minimized by terming it as an “incident,” by stating that it did not conclusively result in harm to the patient, and, if harm did occur, that it was minimal and not “anybody’s fault.”41

The primary factor that is widely understood to limit full error disclosure is a fear of resultant medical malpractice lawsuits.42 A landmark study suggested, however, that non-disclosure of errors is more likely to lead patients to change physicians and seek legal advice regarding the errors.43 In contrast to patients reporting that error disclosure would be unlikely to lead them to sue for medical malpractice are the results of recent financial risk analyses using mathematical modeling to evaluate the financial risks associated with error disclosure. While conceding that disclosure of medical errors is “the ethically right thing to do,” the authors of the study concluded that disclosing errors would likely prompt patients to sue, resulting in increases in medical malpractice costs.44 Nonetheless, it is questionable whether a desire to avoid financial responsibility for mistakes is a valid basis for abandoning an ethical obligation. Other significant factors contributing to non-disclosure include concerns about loss of reputation and referrals, the desire of physicians to remain self-regulated, and the fear of retribution for reporting.45 While there are many reasons for non-disclosure of errors, none of these negate the basic ethical imperative for disclosure.

Possible Effects of the PSA

In 1999, an Institute of Medicine publication reported that as many as ninety-eight thousand Americans die in hospitals each year as a result of medical error.46 Viewed in the context of the significant biases that afflict voluntary reporting of
adverse events, these statistics may have represented an underreporting. Since the publication of this report, issues of patient safety and medical error reporting have received a great deal of attention from the medical community.

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The effects of legal mandates on medical error disclosure and eventually patient safety are yet to be fully understood. In theory, the PSA should result in an increase in the number of error disclosures to patients and to the DHHS. There may be no effective way, however, of validating that this is indeed occurring.

Certain occurrences fall within well-defined classifications of “serious preventable adverse events,” such as burns sustained by a patient while undergoing surgery or errors in blood transfusions. “no one's fault.” Truly egregious errors are likely to go unreported due to concerns of liability and fears of negative publicity following reporting to the DHSS.

Other “incidents,” such as the one described above where a patient dies following attempts to suction blood from around the heart, may be “rationalized” as Hence, in the absence of independent monitoring, the mandated disclosure of errors will not necessarily ensure the compliance of healthcare providers and hospitals.

Conclusions

The creation of a law requiring disclosure of medical errors in New Jersey indicates that the legislature does not consider valid any reasons put forward for non-disclosure. Data collected through the mandatory reporting system can identify the factors that lead to medical errors, and in turn eliminate or minimize these factors as far as feasible. Additionally, patients are provided information to make informed choices about future medical care.

The effect that this law will have on the frequency of medical malpractice suits remains debatable. The enactment of PSA is a significant step towards mandating transparency in healthcare. Whether a law can truly bring about the desired transparency and result in improved patient safety remains to be seen.
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