Ethics and the Law: Is There Common Ground on Informed Consent for Disparities in Hospital Outcomes?

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The association between procedure volume at institutions and outcomes of cancer surgeries has been widely published in the medical literature; discussed in the lay press; and, during the past 15 years, incorporated into quality improvement endeavors. In certain cases, institutional volume has become a proxy for quality. Despite the vast amount of retrospective data on this topic, physicians generally have been unsure how to approach the information and interpret it for their patients. Even more challenging to some physicians has been deciding whether the data oblige them to either direct patients with cancer to high-volume centers for care or discuss the

data with these patients as part of informed consent. An additional challenge is that physicians must understand laws related to these issues and that these laws are unclear. This article reviews the ethical arguments for including disparities in hospital outcomes as part of informed consent and examines whether legal precedent can shed light on this debate.

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For more than 3 decades, retrospective analyses of large data sets have established a relationship between the number of cancer surgeries performed at hospitals and improved disease outcomes (1–14). For certain types of cancer, such as pancreatic and esophageal cancer, this volume–outcome relationship has been substantial and consistent and has led governmental and private organizations to use institutional volume as a quality indicator (15–18). This body of research has sparked policy initiatives and dialogue among legal and ethical scholars about the role of volume–outcome data in informed consent (19–21). However, there is no clear ethical or legal consensus on this matter.

We review the ethical and legal understandings of informed consent and the concept of volume–outcome data in the setting of informed consent. Our goal is to provide a cohesive model for the discussion of the volume–outcome relationship during the informed consent process and to empower physicians to use these data in a manner that protects their patients' ability to make autonomous decisions.

THE RELATIONSHIP BETWEEN MEDICAL ETHICS AND THE LAW IN INFORMED CONSENT

It is difficult to find any description of informed consent in the medical ethics literature without an accompanying legal decision or precedent. The roots of patient autonomy lie in English common law (22), and most texts cite the legal opinion of Judge Cardozo in 1914 as the first modern affirmation of the requirement to obtain consent for a procedure (22–24). In addition, the term *informed consent* was coined in the 1954 case *Salgo v Leland Stanford Jr. University Board of Trustees* (25) and was popularized in the latter half of the 20th century with the *Canterbury v Spence* case (26).

The 2 prevailing standards of disclosure in informed consent, the reasonable-person standard and the professional-practice standard, are often used to guide legal decisions and vary in use among each state (27). The professional-practice standard states that the customary practices of the

professional community determine adequate disclosure, whereas the reasonable-person standard states that the relevance of information is based on the significance that a reasonable person would attach to it in making a decision. These 2 standards uphold the ethical principles of respect for autonomy, nonmaleficence, beneficence, and justice. The subjective standard, which is based on the specific informational needs of the individual patient, is not often cited by legal or ethical authorities because of the difficulty for both the physician and the patient in determining the patient's specific needs (28).

It is unfortunate that bad outcomes prompting litigation have brought informed consent into modern bioethics discourse. However, this situation provides a thoughtful prism through which to view the role that disparities in hospital outcomes play in the informed-consent process.

THE ETHICAL DEBATE

The professional-practice standard of disclosure has been cited as the basis for the argument that physicians should tell their patients when there is a substantial and consistent difference in outcomes of cancer surgeries between low- and high-volume institutions (20). This is based largely on recommendations of the National Cancer Policy Board of the Institute of Medicine and, subsequently, the Agency for Healthcare Research and Quality of the U.S. Department of Health and Human Services, which state that hospital volume should be used as a quality indicator for surgeries with outcomes that are driven by institutional volume.

The only 2 cancer surgeries that the National Cancer Policy Board and Agency for Healthcare Research and Quality cited as having the strongest and most consistent volume–outcome relationship are those for esophageal and pancreatic cancer. Some researchers are tentative about accepting the statistical validity of the volume–outcome relationship (29). However, the recognition by governmental and nongovernmental agencies of the importance of this

relationship in the outcomes of these 2 cancer surgeries must be confronted and somehow interpreted for patients. The ethical issues arise from questions of disclosure—namely, what should be disclosed and by whom.

Numerous opinions have been proposed about what should be disclosed. One belief is that mortality and survival differences among institutions should absolutely be discussed during the informed consent process of patients with esophageal and pancreatic cancer. The discussion of disparities in outcomes of other cancer surgeries for which only a few publications have found substantial absolute differences should be included in the shared decision-making process but not mandated (20).

A complementary opinion is that informed consent should include a discussion of some of the limitations of the volume–outcome literature. These limitations include the retrospective nature of the data; the lack of a direct causal relationship; the absence of risk adjustment in earlier studies; and the population-based nature of the data, which may not always apply to an individual patient (21). Experts agree that the data should not be overextrapolated to include major surgeries, such as pneumonectomy, gastrectomy, and ovarian cancer resection, for which no discrepancy seems to exist between high- and low-volume centers, (5, 30). Finally, it has been proposed that statistical models should be used to predict outcomes, with centers where treatment is to be pursued serving as variables in prediction models (31). Although a single quantitative model does not exist, this type of tailored informed consent could be useful to patients and would certainly fulfill the subjective standard of disclosure.

In addition to the “what” of volume–outcome disparities, the “why” should be elucidated for patients in a way that facilitates their decision making. Numerous investigations have demonstrated that processes of care, such as preoperative testing, specialist consultation, interventional services, and the use of adjuvant therapies, differ between high- and low-volume institutions. Studies have suggested that these differences contribute to differences in outcome (10, 13, 32, 33). Certain policy initiatives that direct patients to high-volume centers would probably facilitate disclosure of this information, not only because physicians would be more willing to disclose the information as a reason for outside referral but also because patients would be more willing to ask why they must go to another hospital for their care.

The other crucial issue has been the question of who is responsible for this disclosure. The results of outcome studies have permeated U.S. newspapers and magazines (34–40), and consumer groups and private organizations provide information on hospital volume on their Web sites (18). However, it is questionable whether media and consumer groups suffice in providing the results of outcomes research and whether these outlets should supplant an earnest conversation between patient and surgeon. Market researchers and surveys have reported that only 1% to 2% of

patients have used publicly reported quality ratings to choose hospitals and surgeons (41, 42). This finding suggests that public reporting seems to have little practical impact on patients’ decisions on where to seek care.

Because the data on institutional volume reflect more on hospitals than on individual physicians, some have argued that the hospital is responsible for conveying this information (19). Indeed, some high-volume hospitals do publish their outcome data online (43–45). Although hospitals are responsible for ensuring that consent is obtained for a surgical procedure, the courts have been averse to the idea that a hospital is responsible for ensuring the content of the consent and that the consent is, in fact, informed (23).

This leaves the physician, who, despite the prevalence of information from the media and the Internet, still serves as the predominant source of facts for patients with cancer (46). It is reasonable to expect that physicians who treat esophageal and pancreatic cancer know when discrepancies in cancer outcomes demonstrate a volume-driven relationship. In addition, it has been argued that, just as physicians are accountable for guiding patients to treatment options based on the best medical evidence, they also should bear the responsibility of directing patients where to go when the evidence shows that treating facilities can have statistically significantly different outcomes (20). However, this option may place a burden on physicians to discuss the outcomes of other hospitals as opposed to their own outcomes.

Finally, some (20) have argued that disclosure of volume–outcome disparities may have unanticipated consequences—namely, that surgeons and hospitals may hesitate to operate on patients with cancer who are considered high-risk, or shy away from more radical procedures to avoid increasing complication rates. Another potential consequence of disclosure of volume–outcome disparities could be the regionalization of volume-driven operations to high-volume centers, thus driving medium- and low-volume centers into becoming very low-volume centers and decreasing the quality of care delivered there. However, supporting a “therapeutic privilege” to withhold information for possible but unproven inadvertent results may be difficult.

THE COURTS AND THEIR DECISIONS

Some but not all ethical obligations also translate into legal obligations. The courts are responsible for upholding justice, one of the fundamental ethical principles of medicine. If there is a legal obligation to disclose volume–outcome information relating to the institution where a procedure will be performed, this would stem from an extension of the core obligation to inform patients of the benefits, risks, and alternatives of the procedure to obtain legally adequate informed consent (47). Without informed consent, the provider is at legal risk if an undisclosed outcome occurs and the former patient, now plaintiff, can show that he or she

would have declined to have the procedure if he or she had known of the risk.

Twerski and Cohen (48) noted almost 20 years ago that, in one way, a claim about comparative outcome and volume data would be easier to prove than a traditional informed consent claim. Although most patients would probably agree to undergo a procedure that is within the standard of care to recommend, they probably would prefer to have this procedure performed by a provider with a history of good outcomes and in a facility where the expected outcome was better than at other institutions. The law should clearly protect against substandard medical care, but the consequences of legal protection against suboptimal care would be undoubtedly problematic (49).

Nonetheless, there are surprisingly few reported cases based on failure to disclose this information (47). The most widely known such case is *Johnson v Kokemoor* (50), in which the court affirmed a judgment for the plaintiff when the physician had misled her about the availability of other centers and physicians better able to perform a particular procedure. The decision in that case also approved the admission of testimony and articles from the medical literature that demonstrated the importance of experienced surgeons and tertiary care centers with the proper intensive care unit and microsurgical facilities for a particularly difficult surgery.

A case in Delaware (51) found that the patient should have been able to introduce testimony about the physician's failure to disclose his previous experience with a particular procedure or that other nearby hospitals specialized in that type of surgery. However, both a Pennsylvania and a Michigan court held that informed consent only required the disclosure of information about the surgery itself, not about the physician's experience or success rate (52, 53). In *Wlosinski v Cohn* (52), the Michigan court stated that success rates do not constitute risk information and do not need to be disclosed to obtain informed consent. Even the court in *Johnson v Kokemoor* warned that comparative risk statistics do not always need to be provided as part of informed consent, because they will not always be "sufficiently reliable to be non-prejudicial." In a similar case, the New Jersey Supreme Court did not absolutely rule out the possibility of a claim based on this sort of information but warned that "misrepresented or exaggerated physician experience would have to significantly increase a risk of a procedure in order for it to affect the judgment of a reasonably prudent person" and, thus, to demonstrate lack of informed consent (54).

The question of whether and when physicians are legally required to inform patients about facts other than those related to the procedure itself has vexed the courts, and there is no clear pattern among the cases (55, 56). The secondary literature—written primarily by lawyers, legal scholars, and ethicists—has tended to call for a strong, legally enforceable obligation to disclose such information (57–63). However, some courts and scholars have ex-

pressed various concerns about permitting plaintiffs to raise these issues (always after a bad outcome) because they believe that evidence from statistical data about past treatment is often insufficient to show that the outcome of a particular patient's surgery would have been different if the patient had received treatment elsewhere.

The difficulties of precisely controlling for the many confounding variables can make available data unreliable. This problem is exacerbated in the context of litigation, where facts are presented by each side in an attempt to persuade the fact-finder rather than to search for truth. Problems of sufficiently reliable and comprehensible data are especially compelling regarding the experience and success rates of individual providers (64, 65).

Even if the data are sufficiently accurate and reliable, they may not provide a strong enough case for the patient-plaintiff to prevail. If the differences between the defendant and the average physician are modest, it is unlikely that the patient-plaintiff can show that the outcome would have been different if the surgery were done by a different provider or in a different facility. It may not necessarily be reasonable to compare an institution's outcomes with a higher-volume center if a patient would not have had access to a high-volume center anyway because of limitations of geography or insurance coverage. Some experts have suggested that courts should look to "marginal substitutes that are readily available under similar economic conditions in the same market" (48). Of note, 1 reason that patients rarely use the Pennsylvania *Consumer Guide to Coronary Artery Bypass Graft Surgery* is that patient choice is often limited by a lack of alternative hospitals within what patients may perceive as a reasonable distance (42).

It is difficult to predict how the law across the 50 states will develop in regard to requiring such disclosures. In this case, the slow development of the law is probably beneficial because the law should follow, not lead, the development of sufficiently accurate and reliable data.

CONCLUSION

Common to both the ethical and legal debates on informed consent is the desire to protect the autonomous choice of patients without placing an unrealistic burden on physicians. Although legal precedent sets a framework for the disclosure of data on institutional volume and outcomes, this information is not always entirely helpful in guiding the informed consent process for an individual physician and patient. Informed consent should always be done while keeping in mind the underlying principles of respect for autonomy, nonmaleficence, beneficence, and justice. What this means, in practicality, is that a physician will be within legal and ethical standards if he or she provides a patient with the best information to make a decision; is honest in explaining the possible reasons for outcome disparities between institutions; does not overstate the experience of an institution; and does not overwhelm patients with more

information than they can understand or process, which would render the information useless to them. This level of respect and honesty is crucial to ensure the best care, regardless of where a patient pursues treatment.

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