EDITORIAL

John Banja, PhD[1]
Jason S. Schneider, MD[2]

[1] John and Susan Wieland Center for Ethics, Emory University, Atlanta, Georgia

[2] Division of General Medicine, Emory University School of Medicine, Atlanta, Georgia

Ethical Challenges in Disclosing Risk

Autonomy is one of the most familiar principles in Western bioethics, whereas informed consent is probably its most practical expression.[1] Autonomy's modern formulation was particularly shaped by political philosophers like John Locke (1632-1704), who worried about the coercive powers of the state.[2] As Lockean-inspired governments evolved over the last 3 centuries, their legislatures became increasingly disposed to granting citizens an ever-increasing number of individual rights and freedoms. In American medicine, that sensibility began to take a determinate shape early in the 20th century, such as in Judge Benjamin Cardozo's famous declaration in 1914 that:

> Every human being of adult years and sound mind has a right to determine what shall be done with his body, and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages.[3]

Another half century would be required, however, to agree on the informational content, or "scope of disclosure," that would reasonably educate patients on what they would be consenting to. Precedent-setting decisions in the 1960s and 1970s, such as in *Natanson* v. *Kline*[4] and *Canterbury* v. *Spence*,[5] ultimately held that informing a patient about a proposed clinical intervention must include an explanation as to why the intervention is recommended and what particular benefits might accrue from it. Most important, however, is informing the patient about any significant risks the intervention poses. Not associated with or pertaining to error or negligence, but rather understood as foreseeable complications or adverse events that could occur even if the standard of care was scrupulously followed, risk information must be imparted to decisionally able patients or their surrogates to honor their autonomy, or right of bodily ownership.[6]

The problem with determining whether a risk should be disclosed is that it is often reduced to a judgment call about a risk's severity and frequency. The common understanding is that risks whose severity and frequency are both extremely low need not be discussed. Risk disclosure becomes complex when either of these variables begins to increase, but even then, a significant likelihood of temporary headache or gastrointestinal upset associated with some treatment might not be mentioned. On the other hand, courts have awarded damages to plaintiffs who experienced the materialization of a 1 in 2500 chance of a serious but undisclosed risk.[7] The ethical challenge in judging whether a particular risk needs to be disclosed involves the difficulty inherent in determining at what point in the comingling of risk severity and likelihood of materialization does disclosure become required.[8]

The article by Upadhyay et al. investigates a related facet

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about risk disclosure.[9] For a long time, hospitals have exhibited inconsistent policies for securing informed consent for certain common but nevertheless risky procedures or treatments, especially those involving medications. Many hospitals, for example, would have staff members simply tell patients that they needed diuretics or thrombolytics, even though in certain instances, and especially with thrombolytic agents, the risk of a significant adverse event could well exceed some reasonable disclosure threshold (which is often set at 1%).[8]

The article by Upadhyay et al. suggests at least 3 issues meriting serious ethical consideration. The first is that the risk scenario primarily discussed in the article—a serious cerebral bleed from thrombolysis with a frequency of from 1% to 20%—would most certainly require formal informed consent from patients. To the extent that hospitals recognize such risk scenarios but fail to secure informed consent, they are violating their patients' autonomous rights. The article by Upadhyay et al. is therefore a clarion call to these institutions to become more aggressive and conscientious in honoring their informed consent duties to patients.

A second issue is that the patients surveyed in the study overwhelmingly desired risk disclosure. Notice that if a treatment's risk magnitude is such that it would normally obligate disclosure, the only factors that would preclude disclosure in nonemergent cases would be (1) if the patient was deemed judgmentally or psychologically impaired (and even then, next of kin or the patient's proxy would need to be contacted and informed) or (2) if the patient refused to hear a recitation of the risks (perhaps because it would cause him or her excessive anxiety).[10] Otherwise, and as implied by the empirical findings reported in the article, disclosure in an instance like thrombolysis would not only be consistent with (and therefore obligated by) more familiar instances of disclosure such as occur in surgical interventions, it would also be consistent with "patient centeredness," as indicated by the responses of the research participants themselves.

But a third issue raises a serious ethical complication. Many patients interviewed in this study also wanted informed consent (or at least wanted to provide permission) for seemingly banal medical interventions. Although respecting patient autonomy is an enduring tenet of medical ethics, it can be argued that it could be limited by other ethical constraints. If respecting a patient's autonomy becomes synonymous with an ethical obligation to disclose *all* potential risks of *every* possible treatment regardless of their likelihood or severity, the physician's time might be unreasonably compromised.[11] For example, it seems fair to say that many physicians would think it ethically excessive or unreasonable to demand that busy hospitalists discuss the risks, benefits, alternatives, and likelihood of success before ordering intravenous furosemide, potassium supplementation, or routine phlebotomy.

In the general care of hospitalized patients, virtually all physicians will obtain specific, written informed consent prior to invasive procedures, but many might assume that consent for "routine" medical care has been secured during the consent documentation process of the patient's admission to hospital. Upadhyay et al.'s findings, however, make us question the extent to which "consent on admission" is ethically sufficient. If it is not, then we must ask what other opportunities exist for effecting patient-centered explanations of proposed interventions without unduly compromising a health professional's duties and commitments during the workday.

A solution may consist in the way that artful communication skills are key to the physician–patient relationship. The Accreditation Council on Graduate Medical Education outlines 6 core competencies that all resident physicians should attain during training. One core measure is communication skills: "Residents must be able to demonstrate interpersonal and communication skills that result in *effective information exchange* and teaming with patients, their patients' families, and professional associates."[12]

Perhaps the individuals surveyed in this study would not require explicit informed consent from a physician if they enjoyed an appropriate number of "informational exchanges" with *all* their treating professionals. Their daily treatment plan with its attendant risks and benefits could be discussed in reasonable detail, their comprehension could be elicited through "teach back," and their remaining concerns could be explored through empathic communication techniques. This process, which would fold informed consent into a more elaborate, transparent, and humanistically oriented sharing of information, might ease the tension over autonomy versus time constraints by spreading informational responsibilities throughout the health care system. Achieving that quality of informational exchange, however, will require a serious institutional and

especially educational commitment in our undergraduate and graduate training programs because it is unlikely that most physicians or other health professionals would seek such skill development on their own.

Address for correspondence and reprint requests: John Banja, John and Susan Wieland Center for Ethics, Emory University, Atlanta, GA; E-mail: jbanja@emory.edu

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