Virtual Mentor
American Medical Association Journal of Ethics
May 2008, Volume 10, Number 5: 300-303.

JOURNAL DISCUSSION
Keeping Patients Safe: The Ethics of Quality Improvement
Sara Platte, MD

Lynn J, Baily MA, Bottrell M, et al. The ethics of using quality improvement methods in health care. *Ann Intern Med.* 2007;146(9):666-673.

The quality improvement (QI) movement is not unique to health care. An essential part of business, manufacturing, and engineering, the theories and practice of QI have become incorporated into American medicine out of necessity. Like any complex, multifaceted procedure, health care delivery is not without error or need for improvement. In its 2001 report *Crossing the Quality Chasm*, the Institute of Medicine (IOM) identified six characteristics of quality health care: it is safe, effective, patient-centered, timely, equitable, and efficient [1]. Most QI activities aim to achieve these characteristics by changing either clinical practice itself or the systems of care delivery within which clinical practice occurs. QI has become so critical to medical practice that it is one of the core competencies required of residency training programs by the ACGME (Accreditation Council for Graduate Medical Education) [2]. Further, the American Board of Internal Medicine and other certification organizations require physicians to self-evaluate their practice performance [3].

What could be ethically controversial about quality improvement? Implicit in what I have said so far is that improvement in how medicine is practiced and delivered must be *measured.* And it is the methods by which quality improvements are measured that cause the controversy. Many believe that the distinction between human subject research and QI has not been adequately delineated, and this lack of clarity can lead to ethically complex situations.

In 2003 the Hastings Center convened a panel of experts to set up guidelines for the ethical conduct of QI. Their recommendations were published in the *Annals of Internal Medicine* in 2007 [4]. In this consensus statement, three main questions were addressed [5]:

1. What is QI and what is its role in health care?
2. What ethical standards should QI activities meet?
3. What arrangements must be made to ensure that QI research is conducted ethically?

Clearly defining the purpose and role of QI in health care is the starting point for determining the ethical standards for research. The group defined QI as “systematic,

data-guided activities designed to bring about immediate improvements in health care delivery in particular settings" [6]. They also referred to it as "a form of experiential learning" that "always involves deliberate actions expected to improve care, guided by data reflecting the effects" [6]. This definition makes clear that QI is not a search for new knowledge about a subject but an attempt to apply proven standards to existing procedures. And, as highlighted by the authors, QI has long been a part of health care—although not always formally—and has successfully improved many areas of care [6].

One of the major concerns some have about QI methodology is that, because it observes and documents the effects of newly implemented changes on patients, it should be held to the ethical requirements that the Office for Human Research Protection has set forth for human subjects research; that is, that Institutional Review Boards (IRBs) approve the research methodology. The members of the Hastings Center working group, however, stated that QI should not be held to the same review process as human subjects research because of its inherent alignment with patients' interests and low potential for patient harm. They write, "QI generally aligns with patients' interests, presents lower risks than continuing with usual care…, demands the participation of all to be effective, arises from a responsibility of professionals and patients alike and has no history of ethics scandals" [7]. Instead, they suggest that the ethical oversight of QI should become "part of an enhanced accountability system for professional responsibility and the supervision and management of care" [7].

While the group recommended that this system of professional responsibility remain separate from traditional IRB regulation, health care organizations must have systems in place to monitor the ethical conduct of QI and to recognize when extra precautions, such as specific informed consent from participants or formal protocol submissions to the IRB, might be warranted [8]. The Hastings Center group concluded that, because most QI activities apply existing knowledge to local situations, they do not qualify as research [9]. In situations in which an activity is designed to *both* improve local care and produce broadly generalizable knowledge, however, the more rigorous standards of research ethics should rightfully be applied [9].

Ultimately, the authors advocate further discussion and review by regulatory agencies of the ethical requirements arising from QI activities to ensure that these activities are both ethical and feasible [10]. The group specifically recommended that:

1. Professional organizations and educational leaders emphasize the responsibility of health professionals to engage in QI;
2. Health care organizations clarify the role of QI activities to patients and explain their participation;
3. Leading QI groups develop guidance on methodology and dissemination of results;

4. Health care organizations develop internal management and supervision of QI and overlap projects; and
5. Accrediting bodies expand external accountability for QI and help ensure that it meets ethical standards [10].

This consensus statement continues to provide clear guidelines on the ethical requirements QI activities should meet and is timely because QI activities are becoming a standard requirement of clinical practice. The Centers for Medicare and Medicaid Services started its Physician Quality Reporting Initiative in 2007, offering payment incentives to participating physicians [11]. Although QI activities are becoming a certification requirement, there is still some uncertainty about their implementation. In January 2008, controversy was reported in both the lay and academic presses when an op-ed in the *New York Times* publicized the use of checklists to decrease rates of hospital-acquired infections in ICUs at Johns Hopkins University and the Michigan Health and Hospital Association [12]. Some characterized this form of QI as human research and therefore subject to IRB approval and federal regulation.

Investigation by the Department of Health and Human Services concluded that the Johns Hopkins and Michigan Health and Hospital Association activities had not violated any laws or government standards because "regulations [for human subjects research] do not apply when institutions are only implementing practices to improve the quality of care" [13, 14]. Some areas of the checklist activity *did* require IRB approval, and the checklist controversy remains a prominent example of the confusion that these activities have generated. It illustrates how the Hastings Center group's article can alleviate some befuddlement.

QI is an essential part of clinical practice and, as such, must be held to the ethical standards used to guide patient care. Whether it also must be held to human subjects research standards will be further debated by regulatory organizations. The Hastings Center group has presented a much-needed consensus statement on how health care organizations should approach QI activities. The group's arguments for protecting QI activities from additional external regulation are robust and compelling. Quality improvement activities are at the heart of improving health care delivery, and physicians and organizations should be encouraged to participate in them while adhering to ethical standards. Ultimately, QI is about keeping patients healthy and safe.

References

1. Committee on Quality of Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press; 2001.
2. ACGME Outcome Project. Core competencies. http://www.acgme.org/outcome/comp/compMin.asp. Accessed March 4, 2008.

3. American Board of Internal Medicine. Self-evaluation of practice performance. http://www.abim.org/moc/mocsepp.aspx. Accessed March 4, 2008.
4. Lynn J, Baily MA, Bottrell M, et al. The ethics of using quality improvement methods in health care. *Ann Intern Med*. 2007;146(9):666-673.
5. Lynn, 666.
6. Lynn, 667.
7. Lynn, 668.
8. Protection of human subjects. 45 CFR 46 sec 102(d). http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm. Accessed March 4, 2008.
9. Lynn, 669-670.
10. Lynn, 671-672.
11. Centers for Medicare and Medicaid Services. *2008 PQRI Statutory Authority*. http://www.cms.hhs.gov/PQRI/05_StatuteRegulationsProgramInstructions.asp#asp#TopOfPage. Accessed March 4, 2008.
12. Gawande A. A lifesaving checklist. *New York Times*. December 30, 2007.
13. OHRP statement regarding the *New York Times* op-ed entitled "A Lifesaving Checklist" [press release]. Washington, DC: Department of Health and Human Services, Office for Human Research Protections; January 15, 2008.
14. OHRP concludes case regarding Johns Hopkins University research on hospital infections [press release]. Washington, DC: Department of Health and Human Services, Office for Human Research Protections; February 15, 2008.

Sara Platte, MD, is a clinical associate in the Department of Pediatrics at the University of Chicago. Trained in internal medicine-pediatrics, she is a primary care physician at a federally qualified health care center in Chicago. Her clinical interests are in preventive medicine and transitional care of young adults with chronic health conditions. Dr. Platte is active in resident education and quality improvement in the med-peds resident continuity clinic setting.

Related in VM
Do Secret Shoppers Have a Place in Medicine? May 2008