

# **HEALTH CARE**

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# **QUALITY IMPROVEMENT:**

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# **ETHICAL AND**

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# **REGULATORY ISSUES**

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EDITED BY

BRUCE JENNINGS • MARY ANN BAILY

MELISSA BOTTRELL • JOANNE LYNN

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## Introduction

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Bruce Jennings, Mary Ann Baily, Melissa Bottrell, Joanne Lynn

Powerful forces of change are at work within the American health-care system. The public debate concerning health-care financing and access to insurance coverage is intensifying. But below the surface, a quieter but ultimately perhaps more significant process of change is under way: the transformation of health-care management and delivery—indeed, health professional work itself—through the learning and change process of health-care quality improvement.

Quality improvement (QI) takes its cue from reform approaches in other industries and is driven especially by studies indicating a shockingly widespread incidence of medical errors and a striking lack of consistency in the standard of care patients receive in different facilities and from different practitioners. These include landmark studies by the Institute of Medicine such as *To Err Is Human* (2000), and *Crossing the Quality Chasm* (2001). It is an innovative, interdisciplinary movement aiming to transform entrenched attitudes, practices, and management styles that no longer serve the needs of patients and families. QI has begun to make substantial improvements in the delivery of health care in the United States. Using knowledge gained from the disciplines of medicine, nursing, health-care management, and medical and health-services research, it attempts to mobilize people within the health-care system to work together in a systematic way to improve the care they provide. In this work, discipline-specific knowledge is combined with experiential learning and discovery to make improvements.

Disciplined and focused QI efforts can increase the effectiveness and safety of health care. Like all facets of medical and nursing practice and health-care management, QI must be sensitive to the rights and interests of patients and must be conducted in an ethically responsible manner. In the past, the ethical dimensions of QI have not been widely addressed, and in particular, the relationship between QI activities and research involving human subjects has not been clarified. Ethical issues arise in QI because attempts to improve the quality of care for some patients may sometimes inadvertently cause harm, or may benefit some patients at the expense of others, or may waste scarce health-care resources. Ethical issues also arise because some activities aimed at improvement have been interpreted as a form of medical research in which patients are used as subjects. If this interpretation is correct, QI would be subject to the same complex review and regulatory requirements that have been set up to govern biomedical and other types of human-subjects research. But is this type of regulation necessary, given what QI involves? Is this the most effective and reasonable way to regulate QI to ensure that it is carried out in an ethical fashion? These are important questions, both conceptually and practically. Current research-ethics regulations and ethical protections may not be appropriate to the circumstances of QI, and if applied incorrectly, ethics regulations may inadvertently

undermine the very protection of patient interests that they are meant to serve. Thus far, however, relatively few attempts have been made to address the interface between research and QI.

Federal agencies with responsibilities in this area have disagreed on where the interface between medical research and QI lies and how it should be handled. The strict ethical rules of oversight, regulation, and patient consent for human-subjects research, including the requirement for institutional review board (IRB) approval, have important implications for the feasibility and cost of pursuing QI activities. More specifically, the mechanism developed to govern ethical conduct in one important area—human-subjects research—could have the perverse, if unintended, consequence of interfering directly with an equally important ethical imperative in another area: unceasing efforts by health-care professionals to make clinical care safer and more effective. The current state of uncertainty about what is ethically and legally required to safeguard participants in QI activities has already become a disincentive to engage in QI, making it more difficult to bring about the health-care system transformation urgently needed if health care is to be made better and safer for patients.

In 2002, The Hastings Center began a project to address these issues and to investigate more generally the ethical and value issues that arise in the theory and practice of QI in health care. The project, titled “The Ethics of Improving Health Care Quality and Safety,” was funded in part by grant #1R13HS13369 from the Agency for Healthcare Research and Quality (AHRQ). This book is one of the outcomes of that project.

The Hastings Center project assembled a group of experts from a number of affected and interested fields and disciplines involved in health-care QI, including medicine, nursing, law, social science, health-care management, medical editing and publishing, health policy and regulation, health-services research, and bioethics. The project group members and other invited guests presented and debated the findings of their own research and drafts of commissioned papers focusing on ethical issues in QI. Those commissioned papers are presented in this volume.

A companion piece to this volume is the final project report entitled “The Ethics of Using QI Methods to Improve Health Care Quality and Safety,” which appeared in the *Hastings Center Report* (July–August 2006) (accessible at <http://www.thehastingscenter.org/research/hchp09.asp>). That report defines QI as systematic, data-guided activities designed to bring about immediate improvements in health-care delivery in particular settings. QI activities are thus more systematic and deliberate versions of normal, ongoing health-care management and operations. Properly conducted, QI can itself be seen as an ethical imperative in health care, something from which both providers and patients benefit and in which they should cooperate. Routine supervision and regulation of clinical practice should include appropriately calibrated supervision of QI activities. After it is assured that appropriate supervision is in place, the question arises of whether or not special review and approval by an IRB should be required of QI projects and activities, as it is currently for non-QI clinical research. In general, the Hastings Center group argues that routine IRB review is neither necessary nor appropriate for most QI activities, and in those few cases when it is, there should be a specialized type of IRB available that has the specific competence necessary to review QI methods and activities.

The papers collected here formed a basis for that final report and also provide more-detailed, in-depth discussions of selected aspects of the ethical and regulatory issues pertaining to QI. Taken together, these complementary publications represent the most thoroughgoing attempt thus far to clarify the ethical responsibilities that health-care administrators and managers, physicians, nurses, and allied health-care professionals—and indeed, patients themselves—have in the context of QI.

The first five chapters tackle the ethical obligations generated by QI for various stakeholders. Matthew K. Wynia and Jacob E. Kurlander argue that a concern for QI has long been an aspect of the ethical obligations of physicians and that current attempts to make QI more explicit, rigorous, and systematic should be seen as part and parcel of professional ethics in medicine. Norma M. Lang addresses this issue from the perspective and history of ethical professionalism in nursing and finds that QI forms an important part of the nurse's ethical commitment to the well-being of patients. At the same time, and precisely because it is so important to patients, it is imperative to distinguish between genuine QI and those financial, organizational, or bureaucratic activities in health care that serve interests other than quality, safety, and the best interests of patients. The responsibilities of health-care management and institutions are addressed by George J. Agich. Finally, the chapter by Nancy Dubler, Jeffrey Blustein, Rohit Bhalla, and David Bernard and the chapter by Margaret E. O'Kane hone in on the patient as both an informed participant in and an integral component of QI activities. By different routes and modes of analysis, these two chapters converge on the conclusion that QI is an ethical responsibility for patients as well as providers and that the existing regulatory system set up for clinical research is not the best way of safeguarding patients' rights and interests in QI.

What alternative forms of oversight and accountability are most appropriate if IRBs are ill-designed and -equipped to manage this task? The remaining chapters in the volume take up this question in various ways.

Frank Davidoff addresses accountability and oversight from the key perspective of the peer-reviewed publication process and the editors who are gatekeepers of medical knowledge and health-systems research. In a brief but fine-grained discussion, he explores the connection between the methodology and approach used in QI studies and the kind of oversight and protection patients may need. QI findings must be disseminated and shared, and the channel of scientific publication must be open to this field without undue administrative burden and regulatory cost.

Karen J. Maschke and Kevin Lawlor discuss various facets of how QI can be facilitated and developed within existing regulatory frameworks. Maschke leads us on a clear guided tour of the privacy protections and regulations associated with the Health Insurance Portability and Accountability Act (HIPAA), which may have a number of direct and indirect effects on the practice of QI and the willingness of clinicians to engage in it. Lawlor addresses the mechanism of organized health-care arrangements (OHCAs), which permit the sharing of personal health information among participating health-care facilities, in line with HIPAA requirements. Such flexibility is one key ingredient in expanding the scope of QI knowledge and reforms beyond the confines of single, isolated facilities.



Rounding out the collection are three chapters providing a general discussion of the ethics of accountability and oversight and specific discussions of approaches taken by two large health-care organizations to develop and professionalize their QI activities and processes. Melissa M. Bottrell presents a far-ranging analysis of the ethical dimensions and the cultural and organizational subtlety and complexity of QI management. This analysis provides a good general backdrop for looking at specific examples of the QI process *in situ* and for understanding QI as a dynamic, flexible process, much as clinical care itself is understood from the perspective of QI. The complex process of developing an institutional commitment to QI at M. D. Anderson Cancer Center is described and analyzed in the chapter by Margaret Holm, Mano Selvan, and their colleagues. In more schematic form, the basic principles and practices of the extensive QI undertaking at Intermountain Healthcare in Salt Lake City are presented in the final chapter by Brent James.

Protection of human subjects of research is a proud achievement of our society's commitment to ethics. Without threatening that achievement, it is also an ethical imperative to improve the quality of health care. The most promising strategies for such improvement use QI methods to guide the enterprise with data and insight. Taken together, this collection of papers and its companion piece provide a framework of key concepts and practices that can ensure responsible implementation of QI activities and also protect persons used as subjects of research. Society needs a period of deliberate innovation and structured evaluation, with the cooperation of many federal and private organizations, to design practices that reliably protect human subjects of research and also reliably engineer a high-quality health-care system.

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## Physician Ethics and Participation in Quality Improvement: Renewing a Professional Obligation<sup>1</sup>

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*Matthew K. Wynia, Jacob E. Kurlander*

### Introduction

A central promise of modern medicine has been innovation to improve the quality of care and health outcomes.<sup>2</sup> Yet studies from the past several decades have shown that physicians use their innovative tools suboptimally. Quality of medical care in the United States lags behind the nation's scientific knowledge base, with evidence showing persistent overuse, underuse, and misuse of health-care services.<sup>3</sup>

While the literature on health-care quality improvement (QI) generally stresses the systemic nature of quality problems,<sup>4</sup> this chapter focuses on physicians. Given their central role in the health-care system, physicians must play a significant role in QI; yet many physicians seem strangely reluctant to take on this mission at the level of delivery.<sup>5</sup> In fact, physicians are often seen as obstacles to QI projects.<sup>6</sup> Michael Millenson notes both a silence of deed—"the repeated failure of physicians . . . to respond with corrective action to studies documenting severe and preventable quality problems"—and a silence of word—"the absence of a thorough discussion of the tragic consequences of that lack of response."<sup>7</sup>

But physician resistance to QI is inconsistent with professional ethical obligations to provide the best care possible, to learn from instances when care falls short of the ideal, and to seek opportunities to improve care.<sup>8</sup> In this chapter, we review the history of physicians' ethical obligations with regard to QI, making special note of recurrent issues that have prevented physicians from becoming fully engaged in QI.

We use "QI" to designate any activity that has an aim of improving quality, not merely the modern concept of QI, i.e., the use of a specific set of management tools to do so. However, as the history unfolds, this broader specification of what comprises QI will be an important theme.

### Quality Improvement: A Long-Standing Professional Duty

While the modern QI movement in health care—the industrial model, using data-driven, planned change projects to assess and improve quality<sup>9</sup>—has developed only in the past few

decades, physicians since antiquity have propounded methods and attitudes that acknowledged the possibility of error in medicine and have embraced opportunities to learn from the trials of everyday practice. At first, it may seem odd to posit a concern with quality in ancient times, when many medical practices, such as bleeding and purging, were frankly harmful, but our concern is not so much with the actual efficacy of medicine in the past as with doctors' perceived obligation to improve the care they provided, even if it was under misguided paradigms of medicine and disease.

In addition, efforts to improve quality of care have always existed in context with professional beliefs relating to, among other things, the nature of the patient-doctor relationship, physicians' obligations toward the community versus individual patients, the status of medical practice as both an "art" and a "science," and the challenges of collaboration with other health workers within systems of care. These beliefs have interfaced with the obligation to improve quality in complex ways. In the selective history presented here, we highlight a few dynamic periods when the practice environment shifted or knowledge and available technologies suddenly changed. At these times, physicians were forced to envision anew what quality means, how best to promote it, and whether to commit to QI despite significant barriers. These historic episodes portend contemporary professional challenges to QI; and understanding this history can help ground a renewed commitment.

## The Hippocratic Tradition: Linking Medical Science to Personal Ethics

Early conceptions of medical quality revolved, naturally, around competence, but also around humility in practice, recognition of the risks of medical treatments, and devotion to the welfare of patients. These conceptions were spelled out in the collection of approximately 60 treatises known as the Hippocratic corpus. Produced by the medical school associated with Hippocrates (c. 460 to c. 370 B.C.E.), these texts figure centrally in the origin of Western medicine's scientific and ethical orientation. Prior to the Hippocratic school, the same person often served as both sorcerer and healer; according to Margaret Mead, the Hippocratics first made the distinction between the two.<sup>10</sup> Also, unlike other practitioners of the healing arts who relied on ritual and magic, Hippocratic practitioners presumed a natural, causal origin of disease based on empirical observation, and they espoused crude theories of etiology and treatment that anticipated modern medical science.<sup>11</sup>

The Hippocratic texts intermingle clinical and ethical observations, underscoring their interdependence by stressing the danger inherent in the practice of medicine and the resultant need for judiciousness and humility on the part of the physician. For instance, the Hippocratic texts outlined diagnostic methods but also detailed treatment failures for the benefit of future physicians. Surgical texts focus on *mathema* (lessons learned), and "the frank discussion of malpractices . . . as a method of instruction . . . [was] incorporated into the teaching of the correct treatment of fractures and luxations [dislocations]. . . . [Because] describing a mistake with all its consequences makes it avoidable . . . safeguard[ing] against repeating it."<sup>12</sup> The most

famous surgical text in the Hippocratic corpus, *On Fractures*, opens with a promise to discuss medical mistakes: “I must therefore mention which of the physician’s mistakes I want to teach you not to do (*apodidaxai*).”<sup>13</sup>

Throughout the corpus, the Hippocratics modestly and cautiously appraised physicians’ powers. One of its most famous aphorisms is, “Life is short, the art is long, opportunity fleeting, experiment perilous, judgment difficult.”<sup>14</sup> Moreover, the ancient Greek word for experiment, *experimentum*, denoted *any* attempted therapy, whether experimental or routine, underscoring two things: first, the degree to which medical treatment was unpredictable and risky, and second, the learning-oriented nature of the humility being advised.

In addition to humility, the other key Hippocratic QI theme is the recognition that since patients are vulnerable and treatment is often dangerous, medical practice entails both science and art and thus assumes explicit moral dimensions. By committing physicians to “follow that system of regimen which, according to [their] ability and judgment, [they] consider for the benefit of patients, and abstain[ing] from whatever is deleterious and mischievous,” the Hippocratic Oath integrates ethical promises into the concept of medical competence.<sup>15</sup>

The personal nature of the oath demonstrates, however, that the Hippocratics were primarily interested in personal virtue rather than group or professional responsibilities.<sup>16</sup> For them, ensuring quality was an individual endeavor, best accomplished through personal competence, a learning-oriented humility, and devotion to their patients’ well-being. The notion of QI as a *professional* responsibility had to wait upon the development of the concept of the physician as a professional.<sup>17</sup>

## Moving Toward Professionalism: Science Becomes a Binding Ideal for all Physicians

We now skip forward more than 1,000 years, to the Middle Ages. During this period, relations between medicine and the church were very important, and illnesses of body and of spirit were seen as connected, giving physicians and priests similar responsibilities to individuals and communities.<sup>18</sup> But with reverence for the ancients and God at the fore, a different version of humility—one might call it servant-oriented humility—became heavily emphasized, with the result that little progress was made in improving the effectiveness of medical practice. It was not until the Renaissance and burgeoning Enlightenment of the 18th century that significant advances were made in understanding illness and disease and in improving treatments. As we shall see, however, this progress ultimately came at the expense of medical humility, including, sadly, the learning-oriented humility of the Hippocratics.

Despite the personal promises in the Hippocratic Oath, by the 18th century, an enlightened John Gregory (1724–1773) perceived personal moral laxity on the part of the medical practitioners in England. At the time, the private market for medical services was unregulated and unscrupulous. To be a member of the medical “profession” meant only that a physician “had undertaken a university education in medicine [for which there was no standard curriculum, as there is now] and so should be the preferred practitioners for the well-to-do sick.”<sup>19</sup> No single concept of health and disease dominated, and doctors offered competing theories

in hopes of attracting patients. To remedy this situation, Gregory proposed improving on the Hippocratic Oath by adopting a professionwide ethic of virtuous service to a greater scientific mission.

Influenced heavily by Scottish Enlightenment thinkers and the methods of Baconian science, Gregory gave the first body of systematic lectures in English on ethics for physicians. He called on physicians to humbly advance the curative mission of medicine. Most notably, he expanded on the learning-oriented humility of the Hippocratics (as distinct from the servant-oriented humility of the Middle Ages), calling this sort of humility “diffidence.” He wrote that the “sense of the present imperfect state of our art, ought to incite us to improve it, not only from a love of the art itself, but from a principle of humanity.”<sup>20</sup> Note the use of the plural, “our art.” For Gregory, diffidence was essentially a personal virtue, part of what he called an “ethics of character.” But shared service to humanity meant that acknowledging mistakes and advancing science were moral duties for all physicians:

I may reckon [that] among the moral duties incumbent on a physician, [is] . . . candor, which makes him open to conviction, and ready to acknowledge and rectify his mistakes. An obstinate adherence to an unsuccessful method of treating a disease, must be owing to a high degree of self-conceit, and a belief of the infallibility of a system. . . . It sometimes happens too, that this obstinacy proceeds from a defect in the heart. Such physicians see that they are wrong; but are too proud to acknowledge their error, especially if it be pointed out to them by one of the profession. To this species of pride, a pride compatible with true dignity and elevation of mind, have the lives of thousands been sacrificed.<sup>21</sup>

This devotion to science and the Gregorian ethics of character were both readily imported to the New World. America’s first professor of clinical medicine, Thomas Bond, who had studied in Britain and France and, along with Benjamin Franklin, established Pennsylvania Hospital, the first incorporated hospital in the United States, argued that a physician’s character is demonstrated in his willingness to admit mistakes and use science to improve quality. Arguing in favor of bedside training of medical students in a 1766 essay titled “The Utility of Clinical Lectures,” Bond wrote:

If the Disease baffles the power of Art and the Patient falls a Sacrifice to it, he [the physician] then brings his Knowledge to the Test, and fixes Honour or discredit on his Reputation by exposing all the Morbid parts to View, and Demonstrates by what means it produced Death, and if perchance he finds something unexpected, which Betrays an Error in Judgment, he like a great and good man immediately acknowledges the mistake, and, for the benefit of survivors, points out other methods by which it might have been more happily treated.<sup>22</sup>

In 1769, Samuel Bard, who founded the Columbia College of Physicians and Surgeons, addressed the first medical graduates of Kings College (now Columbia University) with the following admonitions about their duty to continually improve upon their knowledge:

Your Labours will have no End. . . . Do not imagine, that from this Time your Studies are to cease; so far from it, you are to be considered as but just entering upon them; and unless your whole Lives, are one continued Series of Applications and Improvement, you will fall

short of your duty. . . . In a Profession then, like that you have embraced, where the Object is of so great Importance as the Life of a Man; you are accountable even for the Errors of Ignorance, unless you have embraced every opportunity for obtaining Knowledge.<sup>23</sup>

As a partisan of the Enlightenment, Bard also understood that improving medical knowledge came not merely from studying books, but also from studying patients, both alive and dead:

Whenever you shall be so unhappy as to fail, in your Endeavors to relieve; let it be your constant Aim to convert, particular Misfortunes into generally Blessings, by carefully inspecting the Bodies of the Dead, inquiring into the Causes of their Diseases, and thence improving your own Knowledge, and making further useful Discoveries in the healing Art.<sup>24</sup>

Benjamin Rush, perhaps the most famous American physician of the 18th century, gave similar advice a few years later, in 1789, when he recommended that students

open all the dead bodies you can, without doing violence to the feelings of your patients, or the prejudices of the common people. . . . record the epidemics of every season; their times of appearing and disappearing, and the connection of the weather with each of them. . . . Preserve, likewise, an account of chronic cases. Record the name, age, and occupation of your patient; describe his disease accurately, and the changes produced in it by your remedies; mention the doses of every medicine you administer to him. It is impossible to tell how much improvement facility in practice you will find from following these directions.<sup>25</sup>

Rush had signed the Declaration of Independence and served as physician to General George Washington's troops at Valley Forge. Writing in the year of the signing of the U.S. Constitution (1787), he told his students that if, as physicians, they combined Gregorian personal virtues of openness, honesty, and diffidence (humility) with empirical observation and a commitment to continually improving medicine, they could create a new medicine and a new era of human happiness:

Human misery of every kind is evidently on decline. Happiness, like truth, is a unit. While the world, from the progress of intellectual, moral, and political truth, is becoming a more safe and agreeable place for man, the votaries of medicine should not be idle. All the doors of the temple of nature have been thrown open, by the convulsions of the late American revolution. This is the time, therefore, to press upon her altars. We have already drawn from them discoveries in morals, philosophy, and government; all of which have human happiness for their object. Let us preserve truth and happiness, by drawing from the same source, in the present critical moment, a knowledge of antidotes to those diseases which are supposed to be incurable.<sup>26</sup>

Early American medical leaders, heirs to the Enlightenment views of Gregory, thus embraced ideals of continual medical improvement based on scientific observation and investigation, though still always in the context of personal, rather than group, or professional, moral



responsibility. These ideals of personal virtue were embraced in the charters and codes formulated by American medical societies in the early 19th century (e.g., the 1823 New York *System of Ethics* and the 1832 Baltimore *System of Medical Ethics*).<sup>27</sup>

Similar personal virtues were central to the Hippocratic corpus, but quality was also evolving, from a simple willingness to do one's best and be humble about what medicine can offer toward obligations to share information about errors and learn from one's colleagues. Quality was becoming a group responsibility.

## Professionalization: Quality Becomes a Group Responsibility

At the turn of the 19th century, Thomas Percival, a prominent physician and an author of moral parables in Manchester, England, profoundly transformed medical ethics by construing ethical duties as matters of professional standing rather than personal character. Percival recognized that the old ethic of individual character was insufficient for the new work environment of the hospital: Personal disputes could quickly affect the care of many patients. After several occasions in the late 1700s in which intercollegial disputes disrupted patient care at the Manchester Infirmary, Percival was charged with drafting a set of institutional regulations. In 1803, these were republished under the title *Medical Ethics*.<sup>28</sup> In this work, Percival proposed a distinct realm of group responsibilities which he called "professional ethics," marking the first use of that important phrase. Specifically, he proposed that the ethics governing hospital conduct derived not from individual character alone, but from physicians' fiduciary responsibility, *as a group*, to care for patients and the public's health. "Let the physician and surgeon never forget that their professions are public trusts," he wrote,<sup>29</sup> and he dealt in separate sections with duties to hospitals, conduct in private practice, relations with apothecaries, and duties related to the law.

As part of his recognition that hospital work demanded group responsibility, for example, Percival conceived of clinical rounds in which "the junior physician present should *deliver* his *opinion* first, and the others in the progressive order of their seniority," so that each level provided a check on the knowledge and proposed actions of those at lower levels.<sup>30</sup> Hence Percival moved medical ethics, "into the new world of complex social relationships between professionals with differing competencies working together in an institution within an urban industrial society."<sup>31</sup>

While solo general practitioners were still the norm, hospitals were becoming more important, and Percival's group ethics encouraged doctors to take advantage of the new collegial means of QI that hospital practice offered. Percival called for the creation of a hospitalwide "register" in which all doctors and surgeons could track interesting and extraordinary cases, in the hospital and in their private practices. The register would include tables indicating patients' demographic data, diagnoses, and outcomes. Through analyses of the register, he hoped, physicians would attain "a clearer insight into the comparative success of . . . their practice[s]; and would be incited to a diligent investigation of the causes of such differences."<sup>32</sup> He also recognized the value of collaborating with apothecaries, noting that "the apothecary will regard the free communication of the physician as a privilege and means of improvement" and that

both would be more effective in caring for patients if they cooperated.<sup>33</sup> However, in acknowledgment of physicians' concern that any admission of error could be professionally harmful (another recurring theme of QI in medicine), Percival recommended that the hospital register be open to physicians only.<sup>34</sup>

Despite his adamant belief in professional ethics, Percival still relied heavily on personal character to promote QI, recommending that

At the close of every interesting and important case, especially when it hath terminated fatally, a physician should trace back, in calm reflection, all the steps which he had taken in the treatment of it. This review of the origin, progress, and conclusion of the malady; of the whole curative plan pursued; and of the particular operation of the several remedies employed, as well as of the doses and periods of time in which they were administered, will furnish the most authentic documents, on which individual experience can be formed. But it is in a moral view that the practice is here recommended; and it should be performed with the most scrupulous impartiality. Let no self-deception be permitted in the retrospect; and if errors, either of omission or commission, are discovered, it behooves that they should be brought fairly and fully to the mental view. Regrets may follow, but criminality will thus be obviated.<sup>35</sup>

Though Percival's *Medical Ethics* was never adopted by the British medical establishment, his work is of landmark importance because his orientation of ethics around the profession rather than the individual, essentially creating the notion of medical professionalism, served as a basis for the American Medical Association's (AMA's) *Code of Medical Ethics*, published in 1847. In the "Introduction to the 1847 Code of Medical Ethics," John Bell (1796–1872) acknowledged the ideal Hippocrates had set forth ("The duties of a physician were never more beautifully exemplified"<sup>36</sup>) but strongly emphasized a Percivalian obligation of physicians to work together, especially to promote public health. He wrote, "On them [physicians] devolves, in a peculiar manner, the task of noting all the circumstances affecting the public health, and of displaying skill and ingenuity in devising the best means for its protection," and he called physicians "conservators of the public health"<sup>37</sup> and exhorted them to work with their "professional brethren" on health promotion and to promote "scientific logical medicine."<sup>38</sup>

## The Social Contract: Standard-Setting and Professional Autonomy

This new notion of medical professionalism was built on an explicit social contract. Physicians would agree to certain shared obligations, as written in the *Code of Medical Ethics*, and the public and patients would grant the profession a number of important privileges in return—most notably, the liberty to set professional standards, i.e., professional autonomy. But almost immediately upon the founding of the AMA around its code, tensions arose regarding what "professional autonomy" would mean. Would the profession issue quality standards binding on all practitioners, or would individual physicians be free to set their own standards?

Though shaky at first, the former view would hold considerable sway for many years. Throughout the Progressive Era (1890–1913), "professional autonomy" meant that the profes-

sion set and enforced shared standards for quality practice.<sup>39</sup> Within a year of its founding, the AMA had established committees to set standards on medical education, medical sciences, practical medicine, surgery, obstetrics, medical literature, and publications. Standing committees on anatomy, physiology, materia medica, chemistry, forensic medicine, vital statistics, hygiene, and sanitary measures soon followed.<sup>40</sup> The reciprocal arrangement was clear: Individual practitioners would benefit from professional social privileges garnered by the AMA, but in return, they were expected to follow the dictates of the profession, as set by AMA committees.

The AMA's work to impose uniform standards was sorely needed. Between 1840 and 1849, only 55 of 170 candidates for surgical appointments passed the Army Medical Board examination, which acting Surgeon General H. S. Heiskell, M.D., attributed to "insufficient preparatory education, a hurried course of pupilage, want of proficiency in practical anatomy, in pathology and in clinical medicine."<sup>41</sup> In 1848, one year after its founding, the AMA recommended that medical education be clinical and demonstrative, with cooperation between medical colleges and hospitals, and that hospitals appoint staff based on merit.

### **Cabot's "Ethics of Competence"**

A critical further shift away from an ethic of personal virtue toward group responsibilities was provided by Dr. Richard C. Cabot (1868–1939), a Professor of Clinical Medicine at Harvard Medical School and a Professor of Social Ethics at Harvard College.<sup>42</sup> Cabot was concerned both with humanism in medicine and with the changes it was undergoing at the end of the 19th century, including "the shift of care to the hospital, the use of ancillary professions such as social work in caring for the patient, and the increasing appreciation of science in understanding disease."<sup>43</sup> To Cabot, gentlemanly character was of little concern; what mattered ethically was a physician's ability to effectively treat disease, which often meant working with others, including non-physicians. He called this an "ethics of competence," and in an article titled "Medical Ethics in the Hospital," Cabot stressed the importance of cooperation among the many professionals caring for patients, accurate keeping and analysis of records, and the resolution by committee of disputes over clinical care. While similar ideas had been voiced earlier (including by Percival), Cabot joined his ethics of competence with the ideal of group responsibility and new methods of quantitative analysis to great effect. At Massachusetts General Hospital, he analyzed the autopsies of 1,000 patients and discovered a high rate of diagnostic error. Jonsen writes:

His [Cabot's] publication of this analysis and a later similar study dismayed and angered many of his colleagues, who accused him of the ethical breach of "publicly advertising the faults of the general practitioner." But for Cabot, this *was* ethics: moral practice was competent; incompetent practice was unethical. Clinical competence had moved to the center of medical ethics.<sup>44</sup>

## Standards for Medical Education

Cabot and others recognized that the ethic of group competence would ultimately require a complete overhaul of the education system. But while the AMA had had minor successes in its initial efforts to improve education standards, by 1900 there remained an abundance of poor-quality, for-profit medical schools, despite the growing need for more-sophisticated medical education. As King writes, “By 1900 the growth of science, no longer a matter of scholarly isolation, was actively affecting medical practice and medical education.”<sup>45</sup> Yet at the beginning of the 20th century, the minimum requirement for entrance to medical school was only two years of high school, and even this was not always demanded by for-profit medical schools that were interested in filling as many seats as possible. Only 7 percent of medical students held an undergraduate degree prior to matriculation to medical school.<sup>46</sup> Furthermore, few medical schools were affiliated with universities or hospitals, so most lacked the means to provide a rigorous grounding in laboratory science and clinical medicine.<sup>47</sup>

In 1904, the AMA established its Council on Medical Education “to enhance and standardize requirements for medical schools.”<sup>48</sup> But without broad public awareness of quality problems or support for a solution, it was unable to fulfill its mandate. In 1910, the council sought out the impartial and respected Carnegie Endowment for the Advancement of Teaching to produce a report on the state of medical education.<sup>49</sup> The resulting report, *Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching*, by Abraham Flexner, brought the shortcomings of medical education to wide public attention and, amid great fanfare, Flexner recommended the “drastic reduction in the number of schools from 155 to 31.”<sup>50</sup>

## Art, Science, and New Organizations

In addition to retooling the educational system, realizing an ethic of competence at the turn of the century also involved a reconceptualization of clinical practice. Despite the efforts of pioneers like Bond, in the 1800s the “art of medicine” and the “science of medicine” largely remained separate, at least in America—practitioners focused on the art, researchers on the science. Observation was an important clinical skill, but formal physiologic and anatomic measurements were used little in the day-to-day practice of medicine. This changed with the advent of tools such as the ophthalmoscope, stethoscope, and laryngoscope, as well as techniques to monitor body temperature and hemoglobin levels. Physicians increasingly were becoming scientists, which seemed to conflict with the notion of medical practice as art. In a speech to the AMA titled “The Essentials of the Art of Medicine,” Dr. John H. Musser, President of the AMA in 1904, remarked, “With the incoming of scientific precision there is the outgoing of so-called art. Diagnosis by intuition, by careless ‘rule of thumb’ . . . is as little trustworthy as the shifting sand of the Sahara.”<sup>51</sup>

With these new scientific techniques, physicians were again asked to adopt an attitude of self-questioning and critical judgment; medicine was seeking the diffidence—humility—in medical practice that Gregory, Bond, and the Hippocratics had earlier endorsed. And again,

this was not passive, servant-oriented humility in the face of God's inscrutable ways, but rather a learning-oriented humility, aimed at improving medical science for society and all of humanity.

But, building on Cabot's earlier discovery of high rates of misdiagnosis in hospitals and his understanding of the importance of organizations, some were beginning to question whether doctors alone could fix quality problems in health care. In 1910, Ernest Codman (1869–1940) “noted the need to improve hospital conditions and to track patients to verify that their care had been effective.”<sup>52</sup> Quality demanded the actions of organizations, and especially hospitals. Codman wrote, “Every hospital should follow every patient it treats long enough to determine whether the treatment has been successful, and then to inquire ‘if not, why not’ with a view to preventing similar failures in the future.”<sup>53</sup> Like Cabot, Codman benefited in the early 1900s from statistical methods then becoming available in his pursuit of what he called the “end result idea.” A onetime member of the Massachusetts General staff and the Harvard faculty, however, Codman eventually resigned from the hospital in protest of his colleagues' resistance toward using outcomes as the basis for professional advancement. Still, by 1918, his work led the American College of Surgeons to establish its Hospital Standardization Program. The program called, in part, for standards of staff organization and hiring, medical record-keeping, and supervised diagnosis and treatment within hospitals, including formal case reports of adverse outcomes.<sup>54</sup>

Though he built on a great tradition, following Gregory, Percival, Cabot, Bard, and others, Codman's work is often thought of as the beginning of a new paradigm for medicine: a greater focus on measured outcomes and, later, evidence-based medicine. In addition, Codman's legacy was to solidify the role of organizations in pursuing QI. In little more than 100 years (1803–1918), QI had clearly moved from an individual endeavor based on the personal virtues of doctors, to a shared professional obligation (i.e., a matter of professional ethics), to an organizational challenge for hospitals, albeit with doctors still playing a leading role in this larger scheme.

## **Great Leaps in Quality: Science Succeeds, Humility Fails**

One cannot discuss quality of care without noting that by the end of the 19th century, scientific discoveries had solidly established the germ theory of disease, opening the way for incalculable improvements in the quality of care physicians were able to deliver. It is difficult today even to imagine the impact medicine was seen to have on society during this time. The mid- to late 1800s saw the discovery of the agents of anthrax, tuberculosis, and childbed fever, along with early work on vaccines and antibiotics. And then, within only about 20 years, closing out the 1800s, the infectious agents of amoebic and bacillary dysentery, cholera, gonorrhea, diphtheria, typhoid fever, leprosy, malaria, glanders, and many more diseases were discovered. Early antibiotics provided medicine with miraculous cures, in addition to the profound public health benefits of better understanding of infectious diseases. Between 1900 and 1920—before the widespread use of antibiotics—deaths from the common killers typhoid, diphtheria, and gastritis were cut by more than half, and tuberculosis deaths dropped by one-third, through

physician-led public health interventions. By the 1940s, with the introduction of penicillin and streptomycin, influenza deaths dropped by more than one-half, and tuberculosis deaths were falling so rapidly that the disease was widely expected to be rapidly eliminated. At the beginning of the 1900s, all-cause mortality in the United States plummeted 60 percent, from more than 1,600/100,000/year to less than 1,000/100,000/year.<sup>55</sup> Within a generation—a mere 30 years—physicians had become miracle workers.

In 1926, in the wake of this success, a popular book, *The Microbe Hunters*, made heroes of physicians and microbiologists.<sup>56</sup> With research continuing to yield one medical miracle after another, the United States dramatically increased federal and state funding for hospitals and research,<sup>57</sup> and, as Sullivan writes, “Medicine came to link its reputation ever more closely to its claims to be scientific.”<sup>58</sup>

On the basis of clear, demonstrable improvements in quality, medicine in the early 20th century attained “unquestioned authority.”<sup>59</sup> Patients trusted physicians’ commitment to patient welfare, believed in the miraculous efficacy of new medical treatments, and allowed physicians tremendous discretion. This authority was often well-used, but it also manifested as increasing paternalism and retrenchment from the long-sought-after diffidence in medical practice.

## New Organizations for QI

In parallel with this increasing paternalism, changes in medical practice also brought along wider recognition, as Percival and Codman had implied, that full responsibility for quality lay beyond individual physicians’ immediate reach, requiring organizational action. Medical leaders were coming to recognize that QI was moving beyond the purview of doctors as a group and needed to encompass many other professional stakeholders.

As medicine became more scientific, complex, and hospital-based, entirely new organizations became necessary to monitor quality. The Hospital Quality Program and efforts to reform medical education, noted above, were early examples. As another example, at the turn of the century, drug quality was a limiting factor in quality of care, but Congress had repeatedly declined to exert federal control over the manufacture of drugs, so the AMA waged a campaign to better regulate drug quality.<sup>60</sup> So-called “nostrums” were seen as “an evil that existed within the medical profession itself,” and in 1900, in a series of articles in the *Journal of the American Medical Association*, the AMA vowed to undertake an examination of patent medicines.<sup>61</sup> In 1905, it established the Council on Pharmacy and Chemistry to standardize drug manufacturing and advertising. The next year, the AMA established a laboratory to evaluate substances submitted for approval. Then, in part through the workings of the AMA’s political machinery and its Committee on National Legislation, Congress passed The Pure Foods and Drug Act in 1906, establishing the Food and Drug Administration (FDA) and requiring drug makers to disclose certain of the ingredients of drugs they marketed. The AMA would continue to investigate and publicize information on drug composition through most of the 20th century, in a series of books, *Nostrums and Quackery*, which went through three editions into the 1940s.<sup>62</sup>



Later examples increasingly show the complex interplay of government, the private sector, and the profession to monitor and improve quality. Most notably, in 1952, the American College of Surgeons joined with the American College of Physicians, the American Hospital Association, the AMA, and the Canadian Medical Association to form the Joint Commission on Accreditation of Hospitals (JCAH, now the Joint Commission on Accreditation of Healthcare Organizations, JCAHO). With power derived from both professional and governmental authority (ultimately, Medicare payments hinged on JCAHO accreditation, for example), the Joint Commission's focus on quality assurance evolved rapidly to QI; initially, it surveyed hospitals on a set of minimum standards, but in 1966 it opted for "optimal achievable standards," in recognition of the advances in techniques to measure and improve quality.<sup>63</sup>

### Modern Outcomes Movement, Ancient Conflicts

In the 1970s, the "outcomes movement" gained substantial momentum both from rising health-care costs and from new research on health-care utilization that "cast doubt on the existing knowledge base for medical practice,"<sup>64</sup> including unaccounted-for variations in medical-practice patterns in similar populations.<sup>65</sup> The basis of the movement, derived from Gregory, Cabot, Codman, and others, was the idea that "probabilistic studies are the best evidence of what works, and that better medical practice will result from the direct application of research findings by individual physicians."<sup>66</sup> As statistical evidence showing correlations between procedures and outcomes amassed, modern evidence-based medicine (EBM) was born. Outcomes studies were designed to serve as the basis for practice guidelines, which could provide explicit, statistically sound treatment recommendations for specific conditions.

In 1986, Congress created the Agency for Health Care Policy and Research (AHCPR, now the Agency for Healthcare Research and Quality, AHRQ), in part to create clinical practice guidelines that could guide physician decisionmaking, standardize practice, and improve health-care quality. Evidence- and population-based medicine would also become the cornerstones of managed care, with its emphasis on cost-containment and access to voluminous patient data.<sup>67</sup> The notion, as Chervenak and McCullough put it, was that "large institutions can . . . [assume] responsibility for patient care and can collect and analyze data in ways not feasible in the now passing, decentralized, cottage-industry world of medical practice."<sup>68</sup>

AHCPR almost immediately ran into difficulty over its guidelines program, however, which has subsequently been transformed into a clearinghouse rather than having a standard-setting function.<sup>69</sup> Likewise, managed care continues to struggle with implementation of clinical practice guidelines.<sup>70</sup>

Considering the history of QI, it was virtually inevitable that the outcomes movement, at least as manifested in guidelines, would meet with resistance among physicians; not because physicians are uninterested in improving quality, but because of the way guidelines challenge what and how physicians know. The conflict is clear and long-standing, if not intractable. The "art" of medicine values physicians for their ability to treat each patient individually based

on the accretion of clinical judgment, not simply the ability to follow instructions provided by massive clinical studies.<sup>71</sup> But—as a founder of the EBM movement, David Sackett, put it when asked to speak to the effect of artfulness in medicine—according to EBM, “Art kills.”<sup>72</sup>

## The Guidelines Rebellion

Doctors were not alone in seeking to retain the art in clinical care and pushing back against population-based guidelines, which became widely referred to as “cookbook medicine.” Concomitant with the growth of the outcomes and EBM movements, which sought to prescribe optimal treatment programs for individuals based on data from populations, three interrelated opposing movements arose; taken together, they comprised a widespread rebellion against the use of guidelines to improve quality.

The first driver of the guidelines rebellion was the conflation of QI and cost control. Dramatic increases in health-care costs had led to the strong need to curtail expenditures, and guidelines can be used to constrain unnecessary care and thus reduce costs. Of course, guidelines could also lead to increased use of effective care, which might cost more, but this was rarely noted, as guidelines were sold to payers and policymakers almost solely on the promise of reducing costs. Unfortunately, this led inevitably to the conflation of the cost-control and QI movements, which greatly heightened physician and patient wariness about QI and whether its proponents were really interested in raising quality or whether reducing costs was the primary objective.

Second, following the Vietnam War and Watergate, many individuals had begun to question authority—including medical scientific authority—and to place tremendous value on individual autonomy.

For patients, this trend took form in the bioethics revolution, laws and regulations enforcing the ideals of shared decisionmaking and informed consent, and the growth of medical consumerism. Paternalism, whether on the part of individual doctors or of large systems of care, was under assault. Some patients questioned doctors’ authority as it became clear that some “scientific medicine” was not really based on science. But many patients also wanted something beyond science; they wanted their individual desires and health beliefs to inform their medical care. Of course, respecting individual autonomy can be a driver of QI, insofar as patients want scientific information to inform their decisions, but unfettered consumerism in health care also leads to the use of alternative and unorthodox therapies—as was seen in England in Gregory’s time and in America at the time of the founding of the AMA, and is seen to a certain extent today. More broadly, individualism naturally rebels against the standardized, population-based decisionmaking that EBM represents.

For physicians—who, based on their history of paternalistic ethics since 1847, might have argued for standardized scientific decisionmaking—the increasing importance of patient autonomy as an ethical principle meant that medical ethics became increasingly associated with strict advocacy for individual patients’ needs and desires. In 1984, Dr. Norman Levinsky wrote, “Physicians are required to do everything that they believe may benefit each patient, without regard to costs or other societal considerations.”<sup>73</sup> Concerns about inappropriate cor-



porate or state controls over medical care played neatly into this trend, the end result of which was that many physicians came to believe they were obliged to reject nearly any social role (and especially a cost-containment role) if doing so would help a patient obtain a health benefit—as defined by the patient.

Finally, and perhaps most important among physicians, an old tension within the profession reappeared, but this time the individualists came to prominence. “Medical professionalism” mutated from entailing the right of the profession as a group to set and enforce standards for practice (which could have supported the movements toward professionally created practice guidelines) to being construed as conferring on individual physicians the right to choose what therapies to offer each patient. In effect, “professional autonomy” came to be understood as a license to practice without meaningful oversight, even by one’s peers.<sup>74</sup> This reading of professionalism might be an understandable reaction to the surge in autonomy as a primary ethical principle and to wariness of the corporate cost-control mandate. But it could hardly be more different from the initial understanding of professionalism as requiring groupwide standard-setting, which, not coincidentally, is how physicians won the right to professional self-regulation to begin with.

Thus, both patients and physicians have been involved in rebelling against the perceived interference of QI projects, or at least those that result in enforceable guidelines for clinical practice. Yet these ethical, practical, and professional qualms over QI would ultimately need to succumb to mounting scientific evidence of significant, avoidable problems with quality of care in the United States.

### Quality at the Crossroads: Adopting a Systems Approach to QI

In 1996, the Institute of Medicine (IOM) unveiled a massive Quality Initiative to assess and improve the nation’s health-care quality, and in 2000, it released *To Err Is Human: Building a Safer Health System*,<sup>75</sup> which summarized earlier findings regarding medical errors in detail (noting, most famously, that as many as 98,000 Americans might die each year as a result of medical errors) and dramatically brought health-care quality problems to public attention.<sup>76</sup> The week the report was released, editorial pages took note: *The New York Times* pointed out that, according to the report, the casualties from medical errors were the same as if “three jumbo jets filled with patients crash every two days,”<sup>77</sup> and *The Washington Post* reported that “the sheer scale of the loss of life should act as a spur across the system.”<sup>78</sup>

Indeed, the “system” has been spurred. Numerous professional organizations have now formally embraced systematic approaches to QI. For example, in 1999, the Accreditation Council for Graduate Medical Education issued six core competencies that all residency training programs must teach young physicians.<sup>79</sup> Among these are *professionalism*, which is to be related to “practice-based learning and improvement.” Residents must be able to “analyze practice experience and perform practice-based improvement activities using a systematic methodology” and “obtain and use information about their own population of patients and the larger population from which their patients are drawn and specifically included.”<sup>80</sup> In 2002, the American Board of Internal Medicine (ABIM), the American College of Physicians–American

Society of Internal Medicine, and the European Federation of Internal Medicine issued “The Charter on Medical Professionalism.” Among its nine professional responsibilities were the following:

Physicians must be dedicated to continuous improvement in the quality of health care. This commitment entails not only maintaining clinical competence but also working collectively with other professionals to reduce medical error, increase patient safety, minimize overuse of health care resources, and optimize the outcomes of care. Physicians must actively participate in the development of better measures of quality of care and application of quality measures to assess routinely the performance of individuals, institutions, and systems responsible for health care delivery. Physicians, both individually and through their professional associations, must take responsibility for assisting in the creation and implementation of mechanisms designed to encourage continuous improvement in the quality of care.<sup>81</sup>

The AMA’s Principles of Medical Ethics (the nine core statements on which the Code is based) were revised in 2000 to include the statement, “A physician shall continue to study, apply and advance scientific knowledge, maintain a commitment to medical education . . . and participate in activities contributing to the improvement of the community and the betterment of public health.” Similar statements appear throughout the Code and in many other professional-association policies, documenting the commitment among the profession’s leaders to modern systems-based methods of QI. And these documents are being followed with action, such as the Physician Consortium for Performance Improvement, which is led by professional associations and dedicated to developing and implementing quality measures for medical practice.<sup>82</sup>

Such recognition of QI as a professional social obligation holds great promise for physicians as professionals. Writing about the Physician Charter, Brennan notes, “The principles underlying civic medical professionalism [shared obligations toward communities] derive from traditional professional values, but they extend the accountability of the profession from dutiful action on behalf of individual patients to the social contract with the public.”<sup>83</sup> In fact, although “civic medical professionalism” is a relatively new term, it reflects a concept of professionalism dating at least to 1847. Indeed, it is this concept on which physicians’ social status largely rests, even though it was neglected for several decades. And its reemergence has coincided with a new appreciation of the fact that individual physicians cannot improve health care working alone. Like Percival, Cabot, Codman, and the AMA’s 1847 Code, the American College of Physicians’ Physician Charter and similar documents, including the *Declaration of Professional Responsibility* (AMA Code, p. xx) are intended to mobilize physicians, in aggregate *and* working with other stakeholders, to fulfill their end of the compact between medicine and the public.

## Bringing All Stakeholders into QI

Before closing, we must note an important counternarrative to the theme of an evolving civic-minded, professional teamwork approach to improving health-care quality: that of the market as the primary driver of quality. According to this alternative—but very commonly held—view, the putative professional is understood fundamentally to be an interchangeable purveyor of expert skills and services. The norm that it advocates is one of sophisticated technicians working in groups and overseen in some fashion by managers who can harness market forces to drive quality. Physicians are seen foremost as “providers” who should compete on parameters such as hospital days per thousand patients, formulary use, and rate of immunizations.<sup>84</sup> By monitoring performance, and assuming a good supply, poor-quality providers can rapidly be swapped out for better performers.

The influence of this market-driven model is reflected, for example, in efforts at public reporting on individual physician performance and in many of the most common pay-for-performance programs. Tensions between these two potential drivers of QI—professional collegial action and market-based competition—are important. Scholars of the professions note that selling technical expertise (even if it is sold within a well-functioning market, which is far from assured in health care) is insufficient grounds for maintaining some of physicians’ current social prerogatives. Dr. William Sullivan writes, “Historically, the legitimacy, authority, and legal privileges of the most prestigious professions have depended heavily on their claims (and finally their demonstration) of civic performance, especially social leadership in the public interest.”<sup>85</sup> It is partly in recognition of this fact that some are now calling for a revival of civic, or “social-trustee,” professionalism in medicine.<sup>86</sup>

We raise the market approach here not to discuss these tensions,<sup>87</sup> but rather to note that the market model, in fact, tends often to be in alignment with professionals on the goals of QI. As a result, some private purchasers have shown great interest in supporting QI initiatives. The Leapfrog Group, for example, has organized more than 150 organizations that provide health-care benefits and is working to identify patient-safety problems in hospitals and reward players in the health industry for coming up with solutions.<sup>88</sup>

Government purchasers are also aligning toward QI. Medicare, for example, works with peer review organizations (PROs), now known as quality-improvement organizations (QIOs), throughout the United States “to make sure patients get the right care at the right time.”<sup>89</sup> And multi-stakeholder efforts such as the National Quality Foundation (NQF) and the Ethical Force program have joined older players, including JCAHO, the AMA, and the American Hospital Association, in bringing organizations together to address QI across the health-care system.

## Conclusion

QI in medicine has evolved from an individual concern based on personal virtue and duties toward patients to a collective (professional) concern driven by a shared devotion to science, and finally to a systemic concern involving many stakeholders.

Considering the long, evolutionary history of physicians' ethical commitment to improving the quality of care patients receive, the tremendous accomplishments derived from this commitment, and the numerous current statements of support by professional organizations, it is disappointing that physicians are still too frequently seen as obstacles to implementing QI projects. Yet, given the history we have reviewed, it should not be surprising.

Understanding the evolution of QI from an individual to a professional to a systemic activity is important to understanding that certain recurrent factors will continue to pose challenges to full physician participation in QI. The profession must grapple with ongoing tensions between humility (Gregory's "diffidence") and pride in meaningful accomplishments. Admitting to quality problems is the first step in QI, but barriers to such admissions (including both the threat of lawsuits and personal shame) are pervasive. Questions remain about how to balance professional social obligations and obligations toward individual patients. In fact, some physicians do not see or admit to a social role for the profession, and many do not belong to the professional associations that should establish quality standards. Wariness of cost-control masquerading as QI remains common. And medical practice continues to become increasingly complex, demanding greater and greater teamwork, even though physicians are often poorly trained in how to work within a team.

We have shown, however, that despite these barriers, there is ample historical precedent for physician leadership in QI. This is an especially crucial time for physicians to step up to the challenge. Both ethical and prudential arguments favor doing so. Ethical arguments are reflected in numerous statements, dating as far back as the Hippocratic era, that physicians must admit errors and engage in QI as fundamental duties. Pragmatically, the social promise to promote QI lies at the base of the public's trust in physicians and thus physicians' authority, as a group, to self-regulate and enjoy other social privileges.<sup>90</sup> By taking this promise seriously, physicians can improve their patients' care and simultaneously regain some of the autonomy they have recently lost to the government and to managed care.<sup>91</sup>

Capitalizing on this opportunity will require reciprocal changes in some physicians' wary attitudes toward QI *and* in certain top-down-management, "cookbook" approaches to QI. Physicians in all settings should be leading QI as an integral part of routine patient care, rather than having QI initiatives imposed upon them as external, burdensome, irrelevant, or even risky tasks. Recognizing that health care today is complex and team-oriented, physician leadership in QI does not mean that physicians bear the full burden of solving all the problems. But it does mean that physicians must show clear resolve and renewed leadership in their endeavors.

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## Notes

1. The views and opinions contained in this chapter are those of the authors and should in no way be construed as representing official policies of the American Medical Association.
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## Health Care Quality Improvement: A Nursing Perspective

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### Introduction

The very heart and soul of the nursing profession is the ethical sense of responsibility to people in nurses' care. In return, those served express respect and trust. It is not surprising that nurses top Gallup's annual survey on the honesty and ethics of various professions.<sup>1</sup> Nurses have been the highest publicly rated profession since first being included in Gallup's Honesty and Integrity Survey in 1999, with the exception of 2001, when firefighters outranked them in the wake of the September 11 terrorist attacks.

So imbedded in nursing is the case for morality that it is sometimes hard to address morality, ethics, and nursing separately. This is further confirmed by a review of nurse definitions, education, and practice. Quality has always been at the forefront of nurses' practice. Historically, the individual nurse and the nursing collective carry a strong ethical obligation to provide necessary care and to not cheat or harm the recipients of that care. Nursing embodies the moral principle of beneficence (doing good) and its complementary principle, non-maleficence (doing no harm), as well as justice, confidentiality, and fidelity. These obligations are and always have been inherent in the work of nurses. It is not often that nurses talk about personal financial returns or gains for providing care, and the silence is sometimes to their detriment. Nurses do, however, often speak about what care patients, families, and communities need and are often seen as the advocates for care in a society that limits care. They also serve as advocates for those who have difficulty accessing care.

There are more than 2.7 million professional registered nurses (RNs) in the United States, making them the largest group of health-care professionals in the nation.<sup>2</sup> In addition, registered nurses provide supervision and accountability for a very large number of assistive personnel. Nurses practice in nearly every conceivable health-care, business, educational, and community setting. They occupy positions in clinical practice, administration, management, research, policy, education, and business. About 60 percent of RNs practice in hospitals; 20 percent practice in public/community health, including home care; and the remainder practice in other sites, such as ambulatory care, nursing homes, school health, occupational health, and schools of nursing.<sup>3</sup> The reach of nursing care throughout health care is immense, and so is their impact on the quality of health care.

Nurses are involved in quality assurance, quality assessment, quality improvement (QI), and research, both from the perspective of nursing and as leaders or participants in systemwide projects. Indeed, most historians credit Florence Nightingale with being the first person to conduct formal quality studies to improve health care.

This chapter discusses the strong social contract with society that nurses have as individuals and as a group, the inherent caring characteristics manifested in their individual clinical practice, and the leadership they provide for QI, including professional accountability within the organizations and systems in which they work. Finally, it presents thoughts about the unanswered quality and ethical dilemmas that nurses face.

## Ethical and Moral Responsibility for Nurses to Participate in QI

### A Collective and Individual Mandate

Nurses are collectively and individually committed to quality health care. Expressions of this commitment are found in documents from the Nightingale Pledge to current publications of the American Nurses Association (ANA), the largest organization representing registered nurses.

Nursing and ethical concern for quality health care have coexisted since the time of Florence Nightingale, a pioneer who stressed moral obligation and commitment. Specific statements of character requirements are contained in the Nightingale Pledge, composed by Lystra Gretter, an instructor of nursing at the old Harper Hospital in Detroit, Michigan, and first used by its spring 1893 graduating class. The pledge, adapted from the physicians' Hippocratic Oath, is as follows:

I solemnly pledge myself before God and in the presence of this assembly, to pass my life in purity and to practice my profession faithfully. I will abstain from whatever is deleterious and mischievous, and will not take or knowingly administer any harmful drug. I will do all in my power to maintain and elevate the standard of my profession, and will hold in confidence all personal matters committed to my keeping and all family affairs coming to my knowledge in the practice of my calling. With loyalty will I endeavor to aid the physician, in his work, and devote myself to the welfare of those committed to my care.<sup>4</sup>

Historically, nursing candidates were selected on the basis of strong character traits that were reinforced both during their education and in their nursing practice. Adherence to standards of care and detailed procedure manuals were the requirements for nursing practice. Early nursing also had strong associations with religious and military groups, whose influence may have provided the roots of some of these characteristics. The title of Nelson's 1992 book *Say Little Do Much: Nursing, Nuns, and Hospitals in the Nineteenth Century* is descriptive of the period. Most of the 19th century ideas of the obligations and commitment of nurses emerged from the religious context and from pious, socially conscious Protestant women like Rebecca Strong<sup>5</sup> and Alice Fisher,<sup>6</sup> who worked at nursing. Certainly, one can see the emergence of strong character traits such as honesty, moral obligation, and commitment in the skills required in early schools for nurses' training.

For almost two centuries, the nursing profession has demonstrated an ethical commitment to those who are in their care and to the improvement of that care. The long-standing commitment of the ANA to the ethical responsibility of nurses, including QI, is reflected in several statements, including *Nursing's Social Policy Statement*,<sup>7</sup> *The Code of Ethics for Nurses with Interpretive Statements*,<sup>8</sup> the *American Nurses Association Bill of Rights for Registered Nurses*,<sup>9</sup> and *Nursing: Scope and Standards for Nursing Practice*.<sup>10</sup> The Social Policy Statement and the Code of Ethics contain several specific references to these professional responsibilities. ANA's statements embody the principle that the quality of professional nurses' practice is an essential part of their professional roles and professional ethics.

The Social Policy Statement<sup>11</sup> expresses the social contract between society and the profession of nursing. The statement, revised several times, includes and continues to promote the values that Page wrote of:

Societies determine, in accord with their different technological and economic levels of development and their socioeconomic, political and cultural conditions and values, what professional skills and knowledge they most need or desire. . . . Logically then, the professions open to individuals in any particular society are the property not of the individual but of the society. What individuals acquire through training is professional knowledge and skill, not a profession or even part ownership of one.<sup>12</sup>

Similarly, the ANA policy statement includes a belief often referred to by nurses over the years:

Society grants the professions authority over functions vital to itself and permits them considerable autonomy in the conduct of their affairs. In return, the professions are expected to act responsibly, always mindful of the public trust. Self-regulation to assure quality in performance is at the heart of this relationship. It is the authentic hallmark of a mature profession.<sup>13</sup>

The ANA Code of Ethics originated in 1893 with the Nightingale Pledge. The current version has nine provisions, each of which can be correlated with the assurance of quality nursing care. For example, Provision 1 deals with respect for human dignity, and Provision 3 has specific reference to protection of participants in research, standards, and questionable practice. Provision 4 references the accountability of nurses, and Provision 8 outlines responsibilities to the public. Provision 3 specifically addresses QI:

Nursing is responsible and accountable for assuring that only those individuals who have demonstrated the knowledge, skill, practice experiences, commitment, and integrity essential to professional practice are allowed to practice.

The nurse has a responsibility to implement and maintain standards of professional nursing practice. The nurse should participate in planning, establishing, implementing, and evaluating review mechanisms designed to safeguard patients and nurses, such as peer review

processes or committees, credentialing processes, quality improvement initiatives, and ethics committees. Nurses must bring forward difficult issues related to patient care and/or institutional constraints upon ethical practice for discussion and review.<sup>14</sup>

In 1994, the ANA issued its *Guidelines on Reporting Incompetent, Unethical, or Illegal Practices*. Grounded in the previously described codes and standards, the guidelines offer definitions and parameters of incompetent, unethical, and illegal behavior and the process to be used when reporting such practices

The American Hospital Association's Patient's Bill of Rights<sup>15</sup> is found in most sites where care is given. In an interesting parallel, the ANA issued a Bill of Rights for Registered Nurses in 2001, which includes the following statements detailing the intent to protect the dignity and autonomy of nurses in the workplace:

Nurses have the right to practice in a manner that fulfills their obligations to society and to those who receive nursing care.

Nurses have the right to a work environment that supports and facilitates ethical practice.

Nurses have the right to a work environment that is safe for themselves and their patients.<sup>16</sup>

Individually, nurses have an ethical responsibility for the care they provide. Much of nurses' activity is direct patient care. Each patient encounter requires that nurses, as well as physicians, behave in a certain way. In hospitals, collectively, nurses stay with their patients 24 hours a day, seven days a week. They do not abandon patients; they carefully "hand them off" to each other. Sometimes, nursing is referred to as the "glue" that holds everything together for the patient.<sup>17</sup>

The very definitions of nursing are instructive about the essence of the profession. In Nightingale's *Notes on Nursing: What It Is and What It Is Not*, originally published in 1859, nursing is defined as to have "charge of the personal health of somebody . . . and what nursing has to do . . . is put the patient in the best condition for nature to act upon him."<sup>18</sup>

The nature of nursing is contained in a frequently used definition:

To assist the individual, sick or well, in the performance of those activities contributing to health or its recovery (or to a peaceful death) that he would perform unaided if he had the necessary strength, will or knowledge. And to do this in such a way as to help him gain independence as rapidly as possible.<sup>19</sup>

Aydelotte, who carried out studies on the quality of nursing care in the 1960s and later served as the Executive Director of the ANA, described nursing this way: "Nursing encompasses an art, a humanistic orientation, a feeling for the value of the individual, and an intuitive sense of ethics, and of the appropriateness of action taken."<sup>20</sup> Another major leader in nursing, Scholtfeld, expressed the concept of nursing's concern as being with human health-seeking and coping behaviors as people strive to attain, retain, and regain health.<sup>21</sup>

The ANA currently defines nursing as “the protection, promotion, and optimization of health and abilities, prevention of illness and injury, alleviation of suffering through the diagnoses and treatment of human response, and advocacy in the care of individuals, families, communities and populations.”<sup>22</sup>

Benner, Hooper-Kyriakidis, and Stannard identify the *ethic of responsiveness* as a part of nursing’s clinical wisdom—the term means “responding to the concerns, needs, and tendencies of the patient and/or family in a timely manner.”<sup>23</sup> The authors define *ethos* as “the characteristic spirit or attitude of a person, group, community, or culture that reflects moral worth (e.g., notions of good and that which is harmful, that which is sacred, and that which is profane).”<sup>24</sup>

All these definitions carry common themes: protection, humanism, valuing, ethics, advocacy, the right action. These definitions and codes are authoritative and serve to guide nurses in practice. A strong case can also be made that implicit ethical values are the very heart of the nursing profession.

### **Licensed and Assistive Nursing Personnel**

Ethical responsibilities of professional nurses have been documented over the decades. But what about the various levels of licensed and assistive nursing personnel? One cannot talk about the ethics and accountability of the profession or the individual nurse without also recognizing that many thousands of assistive personnel other than RNs are classified under “nursing.” Clark and Connolly estimate that there are about 700,000 practical nurses and 1.3 million unlicensed assistive personnel in the United States.<sup>25</sup> Who in this mix is responsible or accountable for the care provided? Those lines of responsibility and accountability are not all that clear. The sheer magnitude of the numbers and ratios between professionals and assistive personnel produces complex relationships, especially given the incessant restructuring that takes place. This problem is particularly prevalent in large nursing homes, home health care, and mental-health institutions. Professional nurses are implicitly responsible for all nursing personnel. This responsibility must be assumed by professional nurses, and clarity must be established for lines of authority, responsibility, and accountability across all levels of nursing care.

At the time of this writing, Ethel Mitty raised an interesting question: When do patient rights come into the picture when organizational change is under way?<sup>26</sup> She describes the following concern regarding nursing delegation and unlicensed assistive personnel (UAPs):

We do not ask patient permission to have them tended to by UAPs—let alone UAPs performing skilled nursing acts. We did a social experiment (i.e., substitution of UAPs for nurses without asking patient consent) and we had a hypothesis regarding cost containment and neutral quality outcomes, yet, despite many studies, it remains to be proven.

It is indeed an interesting quandary. Parents question the qualifications of a teacher and the size of a class before leaving their child in a classroom. Yet these same parents may not ask

about the qualifications of the nurses caring for their child or the number of patients the nurse cares for. Every patient and family member has the right to ask these questions—and perhaps to ask for a financial adjustment to the bill if staffing is short or substitutions are made.

As the structure of health care has changed, lines of responsibility have become opaque. Organizational restructuring, especially in hospitals, has in the past decade or so run the gamut from mergers to staffing changes to process reengineering. Financing of health care has also been in flux. The explicit goals of restructuring and reengineering were to build teams of “care personnel” and blur the identification of RNs. As some institutions removed the title RN from name tags, it became very unclear as to who was the caregiver and who was accountable. The stress that this created for nurses rose to an intolerable level, and the nurses left. Evidence is growing that industry restructuring and reengineering has failed to achieve better quality of care or financial stability.<sup>27</sup> A statement heard from nurses: “I love to care for patients, but I hate my job.”

Perhaps because of this failure of reengineering, many hospitals are looking to regain positive work environments and thus restore the presence, influence, and accountability of nurses. This movement is most notable in the rising number of hospitals that have sought and are seeking magnet status through the American Nurses Credentialing Center’s Magnet Nursing Services Recognition Program. Among the 14 key forces of magnetism, two specifically address quality:<sup>28</sup>

One force is *quality improvement* where quality improvement activities are viewed as educational. Staff nurses participate in the quality improvement process and perceive the process as one that improves the quality of care delivered. Another force is *quality of care* when nurses perceive that they are providing high quality care to patients. Providing quality care is seen as an organizational priority as well, and nurses serving in leadership positions are viewed as responsible for developing the environment in which high-quality care can be provided.<sup>29</sup>

### Studies of Ethical Factors and Nursing

Practicing health-care professionals today encounter serious ethical problems at the clinical, managerial, and social levels.<sup>30</sup> At the clinical level, ethical questions center on the dimensions of the patient-provider relationship. Ethical problems in clinical practice affect outcomes of care by creating the potential for conflicting obligations in the workplace, moral distress in health-care providers, and a lack of clear focus on meeting patient and family needs. Nurses’ duties to protect patient autonomy and confidentiality have been challenged by value-laden decisions related to technology, the right to die, the right to live, the limits of intervention, and quality-of-life issues.<sup>31</sup>

Many nurses have found themselves faced with an increasing number of ethical dilemmas.<sup>32</sup> When nurses confront ethical issues, they tend to rely on intuition and instinct to settle them quickly. Mitchell, Uehlinger, and Owen maintain that although nurses are able to identify ethical issues quickly, they sometimes believe themselves powerless to initiate a formal ethical discussion because they feel they lack an adequate theoretical background in ethics.<sup>33</sup> Ironically, nurses have also felt powerless or inadequate to institute substantial changes in



patient outcomes as a result of what they perceived as inadequate knowledge of QI theory as well. It is imperative that support and education about ethical decisionmaking be provided to nurses and other health-care professionals.<sup>34</sup>

Several studies have concluded that nurses believe they have limited influence on decisions. Penticuff and Walden reported that 127 neonatal nurses perceived themselves to be limited in influencing patient care.<sup>35</sup> In another study, the majority of 254 nurse practitioners in the state of Maryland were experiencing ethical conflict in their practice, with nearly two-thirds (64.1 percent) indicating that their ethical concerns were not heard. Only 16.6 percent of the sample reported that administration was concerned with ethical care. Although nurse practitioners were able to recognize the intensity of the ethical issue, they did not have information on the administrative channels or available resources to deal with those concerns.<sup>36</sup> Similarly, McDaniel and Stumpf reported on a sample of 450 nurses primarily employed full-time in acute inpatient settings.<sup>37</sup> Nurses who were 40 or more years of age and in practice longer generally perceived the working environment to be more negative than those younger and in practice less than five years. Findings from this study indicate that nurses were concerned about the ability to engage in ethical dialogue regarding clinical care, administrative support with respect to ethical care, and the appropriate structures to uphold ethical practice. In unpublished work, Corley and associates investigated the relationship between the ethical work environment, nurse moral distress, and patient satisfaction with participation in treatment decisionmaking for 106 nurses from two large medical centers in 2000. Participants perceived the ethics environment as neutral, which suggests that they did not perceive the hospital environment as supportive of ethical practice. Moreover, 25 percent of the sample left a clinical position due to distress.

Ludwick and Silva surveyed a self-selected group of 1,386 RNs about experience with clinical errors or incidents, whether they believed their own or other nurses' errors were related to the nursing shortage, and whether they felt any resultant moral distress. They found that 78 percent of the respondents had experience with an error, 69 percent believed this error to be related to the shortage, and 73 percent felt moral distress as a result.<sup>38</sup> Redman and Fry found that nearly 39 percent of nurses in leadership roles experienced ethics and human rights issues at least one to four times a week.<sup>39</sup> One of the five human rights issues reported was "respecting or not respecting informed consent to treatment."<sup>40</sup>

Preliminary findings of a recent study of nurses and social workers in the United States revealed a number of ethical concerns among nurses.<sup>41</sup> Nurses are worried about how to protect patients' rights and about lax informed consent and conflicting professional obligations to the patient, institution, and/or profession, as well as about staffing problems, confidentiality issues, and end-of-life care.

According to Davis, "Ethical dilemmas confronting health care professionals are here to stay in one complicated form or another. In the present and the future, all health care professionals need to be able to take a more *reasoned* stance regarding several interrelated areas: (1) clinical ethical issues; (2) human subjects in research; (3) allocation of scarce medical resources; and (4) health policy both at local and national levels."<sup>42</sup> All four are relevant for nursing, especially if quality underpins each.



And finally, Huycke and All offer broad ethical considerations in relationship to quality health care.<sup>43</sup> As they address inequities in access, scope, and choice, they propose ethical principles of prudence, autonomy, beneficence, justice, and non-maleficence.

### **The Challenge of Measuring Caring**

One of the challenges in studies about nursing practice is how to weight the many intrinsic and implicit factors that contribute to good patient outcomes. Caring is difficult to define. Mustard describes 200 actual cases of what caring and competence are not. He proposes a “nurse hospitalist competency model that goes beyond a description of clinical skills to other factors that will ensure quality patient care. The humanistic attributes of nursing described by Gerteis et al.<sup>44</sup> treat the patient, the family and the system beyond the minimum requirements of licensure and regulatory standards.”<sup>45</sup>

Nurses deal with clinical problems that are not always amenable to reductionistic quantification.<sup>46</sup> Such attributes as “being there,” continuous surveillance, and trust are not easily measured, yet they are thought to be major factors in the rate of adverse events, complications, and outcomes. Benner, Hooper-Kyriakidis, and Stannard point out that the complexity and rapidity of nursing-care changes, especially in acute-care settings, require frontline monitoring, the development of cumulative wisdom, and immediate expert intervention.<sup>47</sup> Complex situations and ambiguities in everyday practice do not lend themselves to easy QI-type measurements.

Professionals are always confronting uncertainty because of the incredible variety of situations they face daily. The question remains as to how to balance what is quantifiable with factors that cannot be “put in a box.” At the minimum, all who are involved in QI studies and the use of the results of those studies must be mindful of this question.

### **Nurses as Leaders in Quality Improvement**

Nurses have not only expressed a strong commitment to the ethics of care, including quality health care, in recent decades, they have also excelled as leaders of efforts to measure and improve the quality of health care. Again, this leadership can be traced to Florence Nightingale, the first health-services researcher, first statistician, first quality-focused researcher, and founder of modern nursing.<sup>48</sup>

Nurses have always been involved in quality assurance, quality assessment, and quality improvement, both from the perspective of nursing and as leaders or participants in system-wide QI projects. The nursing literature has for years cited nursing studies, including nursing audits, changes in clinical practice, and organizational characteristics. At least one nursing journal, the *Journal of Nursing Quality Assurance* (published from 1986 to 1991, then renamed and published as the *Journal of Nursing Care Quality*), is dedicated to quality care. Numerous books on the quest for quality in nursing have been published in recent decades, including *The Nursing Audit: Self-Regulation in Nursing Practice*<sup>49</sup> and *Quality Patient Care Scale*.<sup>50</sup>

An entire issue of *Nursing Administration Quarterly* in 2003 focused on quality assessment, assurance, and improvement. Editor B. J. Brown defines quality assurance in the “consumer

world as the accountability of a product—a warranty or guarantee.”<sup>51</sup> She further describes greater predicaments and quandaries of nurse administrators who are attempting to provide a solid professional practice environment for quality patient care, including the limitation of expenditures, cost containment, and the need to provide adequate or quality nursing care.

Extensive nursing QI activities routinely occur in all types of health-care organizations. A small percentage of these efforts are reported in the literature, most of them as *QI studies*. Nurses have long contributed to the QI literature, which includes their own professional journals dedicated to the topic. Nursing textbooks on the improvement of quality also exist.<sup>52</sup>

Not only do nurses lead and contribute to QI studies, they also bring ethical considerations to the work. Mitchell, Uehlinger, and Owen elaborate:

As members of the health care team, nurses have traditionally viewed patient advocacy as a hallmark of their profession. It is imperative to preserve this aspect in the current climate. Knowledge of the ethical concepts of autonomy, beneficence and non-maleficence, and distributive justice is a core competency for nursing. Nurses need to embrace an ethic of care as we participate in quality improvement and reengineering groups that assume responsibility for the development of critical paths based on research that helps identify appropriate and inappropriate practices. Then there is hope that this knowledge and advocacy will bring an ethical dimension to the process.<sup>53</sup>

### **QI Topics Are Broad and Varied**

What does a QI project look like from the perspective of nursing? QI topics run the gamut from the very specific to the very broad; they cover the full continuum of care, including hospitals,<sup>54</sup> home care,<sup>55</sup> nursing homes,<sup>56</sup> mental-health care,<sup>57</sup> primary care,<sup>58</sup> and all of the other organizations in which nurses work. To illustrate, a sampling of QI studies can be found on the prevention of decubiti,<sup>59</sup> transport of patients,<sup>60</sup> chemotherapy administration,<sup>61</sup> quality indicators,<sup>62</sup> benchmarks,<sup>63</sup> use of guidelines,<sup>64</sup> development/use of protocols,<sup>65</sup> and presence of visitors.<sup>66</sup> Others include sedation,<sup>67</sup> sleep management,<sup>68</sup> telenursing,<sup>69</sup> transitional care,<sup>70</sup> intravenous therapy,<sup>71</sup> complementary/alternative therapy,<sup>72</sup> infection control,<sup>73</sup> patient falls,<sup>74</sup> wound healing,<sup>75</sup> nurse injury,<sup>76</sup> use of restraints,<sup>77</sup> patient satisfaction,<sup>78</sup> pain management,<sup>79</sup> safety checks,<sup>80</sup> rounds,<sup>81</sup> patient teaching,<sup>82</sup> documentation systems,<sup>83</sup> nurse empowerment,<sup>84</sup> purchasing supplies,<sup>85</sup> noise control,<sup>86</sup> support systems,<sup>87</sup> discharge planning,<sup>88</sup> patient satisfaction,<sup>89</sup> and nurse satisfaction.<sup>90</sup>

The QI processes and methods are as varied as the topics. These may include direct observation, retrospective audit of individual records, administrative directives, clinical directives, analysis of routinely collected administrative and clinical data, and implementation of administrative or clinical protocols. Data may include information on structure, process, or outcomes. Studies may be unit-specific or may cover the entire health organization. With the increase in computerized clinical information systems, study methodologies have begun to include data mining. The creation of two large nurse databases holds promise for studies to contribute to the development of evidence-based policy and for study of the effects of nurse

staffing on clinical and service outcomes. They are the California statewide nursing quality-measurement database<sup>91</sup> and the ANA database<sup>92</sup> collected and aggregated from more than 200 hospital sites across several states.

### **Management of Organizationwide QI Activities**

Nurses not only conduct QI activities for their own practices, they also frequently lead and staff the QI programs of entire health organizations. Nurses also carry out much of the work required for overall institutional external reviews such as the Joint Commission on Accreditation of Health Organizations (JCAHO) and have a major role in specific processes, such as preventing sentinel events.<sup>93</sup> It is also noteworthy that studies authored by nurses are increasing in number and breadth and that many of the articles cited above appear in interdisciplinary journals.

### **Dramatic Increases in Research**

Research conducted by and about nurses and nursing practice has increased dramatically within the past two decades. Major work has focused on the clinical management of patients, management of enterprises, and organizational characteristics in which nursing practice takes place, as well as basic biomedical research and human behavioral responses:

The period of 1960 to 1999 was an era of evolution and rapid growth of scientific research in the discipline of nursing during which specific knowledge realms, or subfields of the discipline, emerged and scientific breakthroughs occurred.<sup>94</sup>

One of the breakthroughs identified by Donaldson is research utilization. Three decades of work aimed at translating research to practice are thought to be the basis for practice-guidelines development in nursing. This type of research is closely related to QI activities that are aimed at implementing best practices in clinical and administrative settings.

### **The Weaving of Research, QI, and Ethics**

Within university and medical centers, nursing research is reported to and undergoes review by human-subjects committees in the university, the respective health-care organization, or both. It is less clear how quality studies are reviewed in academic medical centers and community health-care organizations.

Nurses are often principal investigators (PIs) on studies, being responsible for all aspects of the research. Other nurses may work as “research nurses” who recruit subjects and administer protocols of research projects for physician and other scientist PIs. A research nurse has responsibility for a specific part of the research protocol, such as recruitment and retention of subjects, administration of the protocol intervention, or data management. Nurses in both capacities—as PIs and as research nurses—have raised ethical questions and have been “whistle blowers” in serious human-subject violations.<sup>95</sup>

The literature includes a few discussions of the ethical standards applied to QI activities from a nursing perspective. As previously described, ethical standards are usually implicitly woven into the actual fabric of nursing. Likewise, some discussion occurs within nursing about when QI activities are considered QI and when they are considered research. There is little

question that nurses as a whole include QI and clinical innovation in their personal and professional mandates. What is not as clear from the literature is the extent to which nurses compare the goals, methods, and probable effects of nursing QI and research on human subjects. Some authors (e.g., Mayhew) call for Institutional Review Board (IRB) review when studies are prospective, have potential scientific merit, and have application beyond the study setting.<sup>96</sup>

An interesting approach to assuring ethical considerations as part of QI is to combine the QI program with the ethics committee, particularly in a changing medical environment increasingly driven by financial considerations.<sup>97</sup> Integrating ethics and QI in the transitional/extended-care setting is described by Piette et al.<sup>98</sup> They established an Ethics Resource Team and two councils—the Clinical Ethics Quality Council and the Operational Ethics Leadership Council—thus making “ethics and values a part of what every person does every day, rather than being present only in the formal ethics decisions at an institution.”<sup>99</sup>

Another interesting approach is to use what Mitchell, Uehlinger, and Owen call the synergistic relationship between ethics and QI.<sup>100</sup> Using a case study of restraint use, they posit that the original impetus for their study was ethical in nature in that it is an issue of patient autonomy. As the QI study progressed, it became “clear that the decreased use of restraints led to improvements in the patients’ physical condition as well. Thus the caregivers were at risk for harming the patient even as they attempted to render aid. This was a reversal from the generally accepted belief that it is necessary to restrain patients to prevent harm.”<sup>101</sup>

In 1989, the U.S. Department of Health and Human Services’ National Center for Nursing Research (now called the National Institute for Nursing Research) held a conference on Bioethics and Clinical Practice: Examining Research Outcomes and Methods. Conference participants emphasized that bioethical issues for nurses are not a subset of medical ethics, but are unique, partly because of the unique relationship of nurses with patients and the health-care establishment. They recommended more bioethics research to evaluate the effectiveness of ethics programs in hospitals, nursing homes, and other clinical settings; research involving several health-care institutions; and preparation of future ethics researchers.<sup>102</sup>

### **Worth of QI and Research**

Tension exists between researchers and practitioners. Some believe that there should be no gap between theory and practice, even though research knowledge and clinical knowledge are developed in different contexts and each follows its own logic.<sup>103</sup> Others feel that there are huge gaps between research, theory, and practice in nursing. This strong feeling is reflected in a question from a respondent<sup>104</sup> to Larsen and colleagues: “Are the satisfactions in the self-contained world of research sufficient to compensate for the fact that the life’s work of most researchers is unlikely to make nurses or patients better?”<sup>105</sup> The question reflects a clinician’s view of the worth of research.

Even though there is considerable literature reporting research, research-utilization, and quality-type studies, only a few publications discuss related ethical and human-subject considerations. Not unlike authors in the United States, some Australian authors comment that “the difference between QI and research is not always clear-cut and . . . when in doubt some investigators pursue the path of quality improvement for expedience, because approval is easier, quicker.”<sup>106</sup>

In discussing the differences between research and QI, King and Teo advocate the blending of clinical quality-improvement (CQI) strategies to bridge the research-practice gap.<sup>107</sup> They recommend that for retrospective reviews, research ethics boards may be proxies for patients when the record is in the custody of an institution, and they recommend that prospective studies have the consent of participants. They propose that clinical QI strategies be used as a mechanism to enhance the connection between research and practice. Practitioners can play a critical role in identifying problems in daily practice for which QI initiatives can be targeted; are ideally suited to act as or with researchers to plan, implement, and reevaluate the specific initiatives made to improve care; and can help generate clinically relevant questions for further research.<sup>108</sup>

Reinhardt and Ray proposed four criteria that can be used to differentiate QI and research and thus assure the evolution of patient-care practices and appropriate procedures for safeguarding participants: intervention, risk, audience, and data source.<sup>109</sup>

A stronger stand is taken by Byers and Aragon, who clearly state, “Healthcare quality improvement studies are systematic analyses of processes and outcomes. As such, they meet one of the federal regulatory criteria defining research. They also meet the second criterion in many instances, generalizability of findings, even if it was not the study’s original intent.”<sup>110</sup>

### QI and Ethics in the Curriculum

Many experienced nurses would probably attest that the teaching of ethics was strongly emphasized in their educational training, where a theologian or philosopher often taught courses in moral theology or medical ethics.<sup>111</sup> In 1905, Isabel Hampton Robb, an international leader in nursing, wrote *Nursing Ethics for Hospital and Private Use*, a book describing nursing situations and offering moral suggestions. In the early 1900s, the *American Journal of Nursing* provided a forum for nurses to discuss and explore many of the ethical issues of their newly created profession. In the 1930s and 1940s, the National League for Nursing Education specified that ethics was to be included in the nursing curriculum.

Twenty-five years ago, the ANA Committee on Ethics held conferences and published papers entitled “Ethics in the Nursing Curriculum: Why? What? How?” and “Ethical Decision Making in an Interdisciplinary Setting.” These papers were published as a monograph, *Ethics in Nursing Practice and Education*.<sup>112</sup> Ethical theory, moral concepts, ethical decisionmaking, clinical examples, and teaching strategies were suggested for inclusion in the nursing curriculum.

Stanley defined ethics as “concern with a logical, systematic and critical reflection on human conduct and decisions in relation to moral principles of what is judged right or wrong, good or bad,”<sup>113</sup> and morality as “behavior according to generally accepted standards, custom, or tradition of goodness or rightness of conduct in society.” She wrote extensively on the teaching of ethics and lamented that nurse educators had failed to prepare leaders and decision-makers of the future to stand alone to support rights and convictions. Rather, schools of nursing emphasized obedience to authority and the virtue of a harmonious relationship with the institution.<sup>114</sup>

Textbook series such as those by Thompson and Thompson<sup>115</sup> offer extensive ethical content and suggestions for teaching ethics to nurses and other health professionals.

QI is a standard part of textbooks on ethics, e.g., Ellis and Hartley.<sup>116</sup> The following example is found in a chapter on legal and ethical responsibility and accountability for practice:

Commitment to the nursing profession requires that each individual nurse be concerned not only about personal performance, but also about how nursing is practiced.

The main purpose of evaluation is to maintain consistent high-quality nursing care. This is an ethical, professional obligation.

Formal evaluation of nursing care is occurring in most settings under the title of quality assurance and quality improvement. Quality assurance is a planned program of evaluation that includes ongoing monitoring of the care given and of outcomes of care.<sup>117</sup>

Likewise, ethics is part of QI textbooks. A widely used nursing QI textbook has a chapter on “Improving Quality Care: An Ethical Imperative in a Time of Change,”<sup>118</sup> and another has a chapter on “Ethical Dilemmas in Nursing Quality Assurance.”<sup>119</sup>

## Unresolved Dilemmas

While nursing has had a long and strong history of leadership in quality efforts, some dilemmas remain unresolved. The top three are the blurred accountability for quality, the concern for adequate staffing with competent nurses who have differing educational backgrounds and experience, and the challenge of the invisible practices and interdisciplinary relationships.

### Uncertain Lines of Accountability

Accountability for clinical practice in nursing, as well as for QI, is not always clear. In the preceding section, the nursing profession, through the ANA, makes it clear that there is a social mandate for nursing to be accountable to the public and to patients and families. In practice, accountability to hiring organizations and to physicians is added to the social mandate. Nurses find conflict in these accountabilities, and the profession faces many dilemmas in its attempt to fulfill ethical obligations to provide quality care. Situations in which the nurse knows the intention and decision of the patient and is unable to influence either the physician or the organization are rife today. Examples are choice of medical treatments, costly interventions, comfort for dying patients, interactions with family, and insufficient resources for care.

### Concern for Adequate Staffing

**Unsafe Staffing and Work Environments.** The concern over inadequate staffing and the environment in which nurses practice is well documented. A safe environment and an efficient organizational structure are essential for both patients and nurses. Discussions of nurse-to-patient ratios or nurse staffing bring quivers to most health organizations. Yet research findings support the conclusion that inadequate numbers of nurses<sup>120</sup> and fatigued nurses<sup>121</sup> imperil patient safety. In a self-report study that measured moral distress,<sup>122</sup> nurses experienced negative emotional feelings (e.g., anger) and/or symptoms (e.g., headaches) when it was impossible to take the morally right course of action. A large percentage of nurses report moral distress.



Inadequate nurse staffing creates a domino effect whose consequences—all well documented in the literature—have been catastrophic to patients, nurses, and the health-care system. Staff reductions force fewer nurses to work longer hours, often as forced overtime, and to treat more patients. Studies have shown that working long hours causes fatigue and burnout, reduces productivity, and greatly increases the risk of making a mistake that will endanger a patient.<sup>123</sup> Research has also found that when nurses on medical-surgical floors are assigned more than the optimum four patients, each additional patient creates a 7 percent greater chance of someone dying a preventable, unnecessary death.<sup>124</sup>

Staffing cutbacks and chronic shortages plague nursing practice and are a major concern in the national debate on quality of care. How any reasonable quality reforms can be expected in the face of this persistent trend defies comprehension. Mounting expensive QI programs while continuing to systematically reduce the number of RNs, often replacing them with unlicensed health-care workers, flies in the face of mounting public-safety concerns and the research that proves that poor staffing and forced overtime are imperiling patients' health and well-being, if not their lives.<sup>125</sup>

In the past decade, professional nurses have been “slashed and burned” in major health-care-system restructuring activities. From the level of vice president to that of floor clinical staff, organizations have encouraged nurses to identify themselves not as nurses, but rather as “care coordinators,” in the belief that this might better integrate them with teams of many kinds of caregivers.<sup>126</sup> Concern for patient care only recently has coincided with a concern for an adequate supply of competent nurses, a situation that has created significant tension for nurses.

**Variation in Education and Competency.** An essential part of quality health care and QI is the quality of education and preparation for practice. Yet considerable variation exists in nurses' educational preparation (both basic and graduate), continuing professional development, experience, and competency level. Who holds the ethical obligation for ensuring that nurses are well prepared? One could posit that it is the responsibility of the clinician, the profession, and society to make sure that nurses are capable of doing what they are supposed to be doing.<sup>127</sup>

Approximately half of today's RN workforce will be eligible for retirement in the next 15 years. At current rates, a shortfall of one million RNs is predicted by the year 2010; by the year 2020, a 20 percent nurse deficit is expected.<sup>128</sup> Dr. Dennis O'Leary, JCAHO president, has made the statement that probably the most significant threat to quality is the present and future lack of numbers of professional nurses.<sup>129</sup> Compounding this problem is that the average age of nursing faculty is 51 years. Moreover, schools do not have enough new faculty, and the number of graduates from master's and doctoral programs is declining.<sup>130</sup> The reasons for this decline are complex but probably reflect the competition from other opportunities, lack of support for the required graduate education, and low salaries.

Only 43 percent of nurses hold a baccalaureate degree; fewer than 15 percent have earned a more-advanced degree. At a time when most health professions (e.g., medicine, pharmacy, physical therapy) have increased their academic requirements to meet increasingly complex practice demands, nursing has the largest percentage of practicing RNs and newly graduated nurses whose degrees have not kept pace with the complexity of health



care. Graduates of two-, three-, four-, and five-year programs are eligible to sit for exams for the RN credential. The American Association of Colleges of Nursing (AACN) recently approved a resolution to prepare clinical nurse leaders at the master's level and at the doctoral level.<sup>131</sup> It will be essential to identify the scope of practice and competency requirements for each of these levels. The variation in education added to the variation in years of practice raises serious questions about the quality of care that can be expected. Many nurses find themselves in practice without the appropriate basic or inservice education.

A stronger warning is given by D'Antonio, who argues that the "deterioration of the educational background of U.S. nurses relative to that of all U.S. women jeopardizes the clinical and social roles of the profession."<sup>132</sup>

Adequate funding and other support for urgently needed nursing education at the baccalaureate and higher-degree level are almost nonexistent.

### **Invisibility and the Need for Better Data**

**Invisible Practices.** When viewing QI from a nursing perspective, several issues are especially important. Paramount is the persistent invisibility of nursing, especially in interdisciplinary, system, and nationwide studies. This invisibility is surprising, considering the pivotal role of nurses at the bedside. Nurses often know that quality of care is inadequate, but they either lack the power to make the changes or fear reprisals for questioning unsafe practices. It is difficult to find the nursing data in the current QI databases and systems because most aggregate data systems include organizational data, physician data, and payment data but no nursing-specific data.

It is fair to point out that some nurses prefer anonymity, for various reasons. Nurses are often the "good soldiers" who take orders and don't "talk back." Some nurses prefer anonymity because they don't want to take the blame for their own actions or for actions over which they have little control. If a group has responsibility, then no individual is clearly responsible.

In hospitals, costs for nursing care are included in the bed and board room rate. There are no incentives or even expectations built into the payment system to encourage optimal staffing of nurses or even safe care.<sup>133</sup> And in primary care, nurses are often included in physician charges. Much of the nursing plan of care and documentation is not easily retrievable for further study. Invisibility of the work of nurses continues to pose a challenge in QI studies.

Likewise, medical and health-care databases and literature frequently refer only to physicians. Nurses often are invisible in the databases used for QI. This is true for a full range of data, from the number and qualifications of nurses to the interventions nurses use in caring for patient problems that they have identified. Yet nurses have a language that is useful in helping to describe the many dimensions of patient care.<sup>134</sup> Interdisciplinary studies could be strengthened through the inclusion of nursing interventions that correlate to patient outcomes.

In most of the general literature on quality, QI, and quality research, the absence of references to the nursing literature is striking. Silos exist not only in practice, but in the QI, research, and science world as well. For example, although the nursing literature has long been replete with discussions of the importance of patient-centered and coordinated care,<sup>135</sup> in current health-care management and policy discussions, patient-centeredness reads like a concept newly discovered.

Since the patient, family, and community function as whole entities, one goal should be to integrate all data pertaining to them. QI studies might be of more benefit to the patient if they were not cut into pieces of separate medical diagnoses, the multiple types of treatments by several health disciplines, and multiple settings for care, all of which claim an effect on outcomes.

**Interdisciplinary and Interprofessional Relationships.** Further discussion of the multifaceted patient problem and treatment dilemma requires dissection of the true meaning of interdisciplinary. Among QI researchers, discussion abounds regarding teams and interdisciplinary goals. Cronenwett's description of a major issue, the nature of interdisciplinary leadership, is helpful here:

Nursing's position within respect to other dominant players in health care—medicine and health care administration. Neither embraces nursing as a full partner. After several experiences where a team's accomplishments are attributed to physician or administrative leaders, nurses sometimes retreat to work on problems of a narrower scope that do not require interdisciplinary work.<sup>136</sup>

Physicians view quality as mortality, morbidity, and specific treatments/interventions for a specific medical diagnostic category, and they strive to keep the rates consistent with regional and national norms. Nurses view quality of care more holistically and are concerned with processes and outcomes of safety, comfort, patient teaching, mobility, and symptom control that cut across many medical diagnoses. Added to these two views is that of the administrator who is concerned with management and costs. And of course, the patient and families, as well as external payers and accrediting bodies, have still different values. These very different approaches bring up conflicts as to the “worth” of each professional. Each group needs to clarify its own values and then contribute to an environment in which these potentially conflicting values can be discussed.

Poor interprofessional relationships have created situations in which the quality of care is compromised.<sup>137</sup> It is even more disturbing to have a large group of nursing professionals who are often categorized as “non-physician” or “mid-level personnel.” On the other hand, good communication between physicians and nurses has a positive effect on patient care and outcomes.<sup>138</sup>

A recent study<sup>139</sup> identified the following ingredients for success in influencing hospital quality: the right culture, recruitment and retention of the right people, the right in-house processes, and having the right tools to do the job. All of these relate to good interdisciplinary relationships among all health professionals and staff.

## **Access and Payment—A Systemic Dilemma**

Ethical issues remain in situations where the best practice is unattainable because of lack of patient access, funding limitations, or refusal of patients. Ethical principles include justice that mandates equal access to care and equal level of care without regard to race religion, gender, financial status, cultural background, or sexual orientation.<sup>140</sup> In other words, justice requires

that care be reasonably accessible. Kassirer argues that a health-care system without equity is “in fact, already unethical.”<sup>141</sup> The problem of health disparities among groups is currently receiving emphasis among policymakers. The gaps in care for the chronically ill are well documented.<sup>142</sup> Some maintain that most care is provided at home,<sup>143</sup> and the question remains, Do we as a society really care about quality health care across the board, or do we just care about it in the acute-care setting?

An individual nurse may find herself in a major conflict, as illustrated by the following anecdote. An RN was being recruited to a position within a large nursing home. She would be the sole RN for the 300-bed facility, which included persons requiring nursing care. It would be fine if she slept there; the facility needed only to confirm that there was an RN on the premises for 24-hour coverage. There were a small number of licensed practical nurses, but most of the staff were unlicensed personnel. The RN had the option of accepting the position at a higher salary than she was able to earn elsewhere. What difference could one person make in system that is so flawed? Nurses consistently find themselves in this type of ethical conflict with the system. In a sense, personal ethics become moot, because there is no way to operate in such situations.

Problems of access to and payment for nursing services remain an unresolved dilemma. This is especially true outside of the acute-care setting. Home care, nursing-home care, school health, occupational health, and primary care remain woefully underfunded. Even where there is significant evidence that nursing interventions make a cost-effective difference, payers are reluctant to add nurse providers or nursing care to the already highly expensive medical care. Erlen encourages nurses to be key players as they inform and help shape health-care policy, especially in situations where there are limits on health-care resources.<sup>144</sup>

“The deeply embedded ethic of responsiveness further compels advanced practice nurses to return to the tradition of community health, push to extend care, and work on closing gaps by going into underserved communities.”<sup>145</sup> For years, Frontier Nursing Services provided maternal- and infant-mortality data that supported the effectiveness of nurse midwives. Still, questions abound in this country about the use of midwives even when patients are receiving no prenatal, delivery, or postnatal care. Likewise, ample data are available to explain the benefit of advanced nurse practitioners in primary care, chronic illness,<sup>146</sup> and high-risk prenatal care.<sup>147</sup> Similar data are available on the cost-effectiveness of nurse practitioners in nursing homes.<sup>148</sup> In its strategies document, JCAHO includes reimbursement incentives for advancing the practice of nursing.<sup>149</sup>

Distributing limited health-care resources is a daunting challenge. Finding appropriate solutions requires that all stakeholders be involved in the choices. Because of their special knowledge, nurses can bring essential information to the discussion.

## Conclusion

As the largest group of health professionals in the United States and the world, nurses have a far-reaching effect on the care people receive. An ethical and moral concern for quality health care has always been at the heart of the nursing profession.

We cannot parse quality, especially quality related to nursing, as though it were an item on a spreadsheet. But even though the essential caring interventions of nurses are among the most difficult to quantify, it is important to recognize the centrality of these interventions as major determinants of health, well-being, and peaceful death.

Nurses historically have been leaders in QI for nursing and health care in general. It is surprising, therefore, that data about nurses and nursing care are often not included in data used for quality measurement and for deciding public policy. Data about nursing have great promise to yield considerable knowledge in the future about the improvement in the quality of health care.

Nursing is the sleeping giant in health-care quality. Nursing expertise affects a patient's chances for survival and quality of life. Accessible, suitable, safe care, especially nursing care, is not available for enough people—indeed, for many people. This is certainly the case for the elderly, those who have chronic conditions, and those who suffer from mental-health problems or have limited financial means.

Quality should always be the first thing we think about and the last thing we sacrifice.

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## Health Care Organization Responsibility for Quality Improvement

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George J. Agich

Do health-care organizations (HCOs) have a responsibility to improve the quality of the care they provide? This question is particularly pertinent today because of the dynamic changes caused by alterations in the system of reimbursement, medical practice patterns, the introduction of new technologies, and health-professional shortages. This chapter answers the question affirmatively, arguing that a consideration of the nature of health care, the role of HCOs in its delivery, and social and economic conditions of contemporary health-care delivery provide a firm foundation for concluding that improving patient-care quality is a fundamental responsibility of the HCO. This argument does not imply that the HCO is uniquely responsible. However, fully integrating—and perhaps reconciling—the HCO responsibility for quality improvement (QI) with the responsibility of others, e.g., health professionals, is beyond the scope of this discussion.

### The Role of the Organization in the Delivery of Health Care

The term *health-care organization* applies to a wide range of organizations, including hospitals, provider organizations such as Preferred Provider Organizations (PPOs) and Health Maintenance Organizations (HMOs), physician group practices, visiting-nurse associations, nursing homes, and home-care agencies, as well as organizations that support the infrastructure wherein health care is delivered, e.g., claims processors. Addressing such a heterogeneous group of organizations complicates our question but does not invalidate it. Although HCOs have a variety of different organizational structures, operational processes, business models, and agendas, they share a family of normative commitments that ethically differentiate them from other social entities. In a similar way, although improving quality can serve a variety of purposes, such as increasing efficiency, reducing costs, or increasing market share, there are distinctively ethical reasons for improving the quality of care. These reasons derive from the pivotal, but often underappreciated, role that HCOs play in the delivery of health care.

While it is true that individual health-care professionals provide health care, it is a profound mistake to think that HCOs do not. Consider the delivery of surgical services. Contemporary surgery is inconceivable without anesthesia, intraoperative monitoring, post-surgery anesthesia recovery, the availability of appropriate operating facilities, sterilized spe-



cialized instruments and devices, immediate postoperative care, and recovery support, including rehabilitation. Although many individual health professionals provide these services, they are provided *in a coordinated fashion* that delivers more than the sum of the parts.

Surgical care is thus best understood not as a performance by virtuoso individuals, but as the product of the complex efforts of a surgical team. Just as there are team sports and individual sports, surgical care—and much of contemporary health care—is best thought of as a team rather than an individual sport. To press the sports analogy further, a group of talented players does not automatically make a successful team, as the performance of the U.S. basketball team in the 2004 Summer Olympics showed. The players must *play well together*. They have to perform *as a team*. They have to pursue a *team* goal, not just individual goals. Because contemporary health care involves the delivery of services that are produced by groups of individuals acting cooperatively and in a highly coordinated fashion, contemporary health care is a *social* enterprise.

For this reason, the HCO is a central player in the development and delivery of contemporary health care. Although improving health care can involve something as straightforward as improving the design of an instrument used in a particular procedure, even such improvements must be integrated within the operational environment. For example, a medical instrument must not only perform the specific task for which it was designed, it must be fabricated from a material that will not harm the patient, and it must be tested and approved for use. In addition, it must be available and ready for use when needed. A cascade of actions and adaptations by multiple individuals is entailed in the introduction of a new instrument. These actions are social in nature. Because coordination of services is integral to contemporary health care, it is natural to regard HCOs as agents or entities that have responsibility for improving the quality of care. Contemporary scientific health care is a *social* action that embodies a commitment to the ideal of a progressive improvement.

## HCOs and Medical Ethics

Ethical analyses of health care have customarily focused on health-care professionals rather than organizations. Indeed, organizations, particularly Managed Care Organizations (MCOs), have been mainly regarded as agents obstructing the delivery of ethical health care, and they have been roundly criticized, for example, for providing financial incentives for reducing care, creating conflicts of interest for physicians, and breaking down the traditional trust in physician-patient relationships.<sup>1</sup> Relatively little attention has been given to the positive ethic of the HCO. In fact, organizational ethics is a relatively new field of interest that is only beginning to define the ethical responsibilities of the HCO.<sup>2</sup>

The continuing dominance of the traditional physician-patient relationship in the health-care ethics discussion continues to deflect attention not only from team-delivered care, nursing, and allied health-professional relationships with patients, but from the HCO as well. The driving ideal of contemporary scientific medicine, however, is inherently collaborative and progressivist. The production and delivery of contemporary care are driven by the hope that discoveries will improve patient care.<sup>3</sup> The HCO provides and coordinates the capital, fiscal,



human, and information resources essential for this style of health care. For these reasons, HCOs are structurally and functionally central in contemporary health care, and they are the natural focus of responsibility for improving the quality of care.<sup>4</sup>

## Responsibility of Organizations

Talk of HCO responsibility for improving the quality of health care might sound odd to the ears of those who are skeptical that organizations, much less HCOs, are the sorts of entities that can bear responsibility. At least since the work of Max Weber,<sup>5</sup> a common view of formal or bureaucratic organizations is that they create a structure that stifles moral accountability.<sup>6</sup> The alternative view that formal organizations are bearers of ethical responsibility is a distinctively recent development. It can be traced to work on the nature of accountability of corporate businesses in the 1970s and 1980s that argued that corporate moral responsibility is a valid concept.<sup>7</sup> In the view of Peter French, agency is required for the attribution of responsibility. An organization has agency if it has an internal structure that organizes knowledge and the motivations of the individuals who constitute it.<sup>8</sup> More recently, critics have focused on the way in which French derived metaphysical propositions about the nature of organizations from semantic propositions concerning the way we talk about organizations. While there is an extensive literature on the nature of agency that organizations manifest and the meaning and foundation of organizational responsibility,<sup>9</sup> there is general agreement that the concept of organizational responsibility is meaningful. Many thinkers now simply accept that a distinctive responsibility devolves on organizations.<sup>10</sup> Because the practice of attributing responsibility to an organization is reasonable,<sup>11</sup> we can accept that it is semantically sound to say that organizations can bear responsibility. This conclusion, however, does not directly answer a further set of questions that naturally arise, namely, Does HCO responsibility include improving the quality of care? If it does, what definition of quality should guide the HCO commitment to QI? or What is the relationship between HCO responsibility for improving the quality of care and other important organizational goals?

## HCO Responsibility for QI

Because of their function in providing health care, HCOs have responsibility for QI. Contemporary health care is inherently unstable and dynamic. It functions on the cusp of change, driven as much by normative commitments to improving the quality of patient care and extending its effectiveness in the treatment of disease as by well-recognized financial, regulatory, scientific, social, and technical factors. Therefore, QI embodies the normative commitment at the heart of contemporary health care—a commitment to improve the well-being of patients, not just to increase scientific knowledge. This practical, normative commitment is essential to contemporary scientifically based health care. HCOs are the primary institutional agents that carry out this social ideal. Because the HCO is the essential agent in the progressivist enterprise of contemporary health care, QI is one of its essential responsibilities.

Even if improving the quality of care were viewed as an activity best carried out by health professionals, the management of QI would involve social processes that logically belong to

the organization. Providing the accepted standard of care may have been a justified ethical expectation for an individual physician in the conservative atmosphere of traditional medical practice or in the context of malpractice litigation, but it is an utterly inadequate norm for contemporary medicine that aims at the progressive improvement in care. It is especially important that this normative commitment provide a signpost in the dynamic environment of fiscal, regulatory, scientific, and technological change that dominates contemporary health care. A normative framework that links the commitment to the progressive improvement in the quality of patient care and the social nature of health care is needed. In this context, it is thus natural to look to the HCO, rather than the individual physician, as the primary locus for improving the quality of care.

### A Definition of Quality

Grant E. Steffen has pointed out that *quality* has two different meanings: first, in a metaphysical sense, quality is identical with the properties of an object and does not imply preference or value; second, in a preferential sense, quality is identical with the capacity of the properties to achieve a specific goal.<sup>12</sup> Contemporary health care involves the pursuit of quality in both senses. The metaphysical sense underlies the idea of contemporary scientific medicine committed to the progressive application of technical and scientific knowledge to improve patient care. Commitment to the preferential sense of quality is implied, but in an unspecified way—Avedis Donabedian has insisted that “quality is a property that medical care can have in varying degrees.”<sup>13</sup>

Claiming that QI is an essential feature of contemporary scientific medicine does not imply that there is agreement regarding the definition of *quality* worthy of pursuit or the specific types of activities that constitute improvements in care. Our claim is simply that improving quality is built into the idea of medicine as a progressive enterprise founded on the application of scientific and technical knowledge. That this commitment is linked directly with the HCO, because contemporary health care is delivered in complex institutional and organizational settings. However, concluding that improving quality is a responsibility of the HCO is important, but it does not take us very far. We need to inquire how this responsibility can be discharged and what conditions complicate its enactment. These questions are important, because improving quality is but one of a complex range of responsibilities that fall to HCOs. Some prioritization of the responsibility for QI must be made among the many HCO responsibilities, and this responsibility must be assigned and evaluated within the HCO leadership.

It is important to put the question of HCO responsibility for QI in a positive light, because it is not primarily about calling HCOs to account for failing to achieve quality measures; rather, it is about the positive responsibility for improving the quality of care. Viewed in this way, quality of care is a normative ideal that is fixed only to the extent that the idea of quality involves distinctive normative elements that define the domains that contribute to the definition of ideal quality. The implication is that the term “quality improvement” admits a range of definitions in actual use which are dependent upon a variety of operational and value judgments made by HCOs. Even a cursory review of the literature on quality of care and QI shows that these concepts are plastic and depend on a shifting constellation of factors and values.<sup>14</sup> Their definition relies on context-specific commitments that reflect interests and concerns that

vary over time and across practice and institutional settings. In defining the HCO responsibility for QI, we thus need to avoid platitudinous recommendations. Instead, it is important to identify the structural and procedural features that *in general* define that responsibility.

### **Toulmin's Negative Assessment**

Stephen Toulmin provides an important but negative assessment of the health-care institution in the context of responsibility.<sup>15</sup> Toulmin took the hospital as the paradigm HCO, arguing that a variety of forces have historically transformed it into an organization that tyrannically limits professional authority and discretion. Instead of encouraging professional judgment and moral commitment, which Toulmin regards as central ethical values in health care, HCOs are motivated to articulate rules to constrain professional action and discretion in deference to cost control and promotion of their economic agenda as businesses.

Toulmin articulated a Weberian view of the HCO as a bureaucratic entity that ultimately stifles individual health-professional responsibility. The upshot is that the activities of physicians and other health-care workers are demoralized, because the sphere of moral and personal commitment is inevitably corroded as it is placed under the control of bureaucratic structures and organization rules that are driven by market concerns. Stressing professional integrity as an important ethical value that is threatened by the bureaucratic (and profit-maximizing) functioning of health-care institutions, Toulmin laments that the responsibility of physicians in these organizations has been transmuted into delivering “the best medical goods that collectivity of medicine has yet devised.”<sup>16</sup> In his view, this objective, which seems remarkably consonant with many of the objectives of QI, causes the physician to lose independent moral autonomy and professional authority. As a result, the traditional commitment to the well-being of the individual patient is sacrificed on the altar of business expediency; the physician becomes “more like a sales rep” for a large corporation than a true professional exercising independence of judgment.<sup>17</sup>

This assessment represents an important challenge to thinking that HCOs should be responsible for QI. Even under a more favorable view of HCOs, the inevitable potential for conflicts between organizational and professional concepts of quality of care and among the competing definitions of quality reflecting competing goals and interests, especially within complex organizations, needs to be considered. Even if these concerns are overblown, they suggest a critical question, namely, What normative ideals should constrain the pursuit of quality, and what degrees of control over these processes should rest with the HCO managers and health professionals?<sup>18</sup>

### **Normative Constraints**

There are three main areas of substantive concern in the HCO responsibility for QI: respect for professional integrity, respect for patients, and respect for workers.<sup>19</sup> As with all responsibilities, using these normative guides will require judgment.

### Respect for Professional Integrity

Respecting professional integrity in QI involves the following elements:

- Respect for legitimate exercise of professional judgment and discretion;
- Support for interprofessional communication and respect; and
- Shared leadership.

Toulmin's concern that HCO decisions in pursuit of QI will efface or override professional discretion, especially when decisions are taken for economic reasons, is widely shared, as the literature on managed care and futility attests.<sup>20</sup> One way to avoid this problem would be to involve health professionals in the management and administration of the HCO, especially in the processes of QI.

Involving health professionals and allowing for professional judgment is a critical requirement for HCOs in carrying out QI initiatives. When health professionals are regarded as mere employees, they are likely to be given marching orders and forced to follow rules that constrain their professional judgment. This can be avoided by insisting that HCOs include health professionals in QI initiatives. Here, the issue is less one of control than one of leadership and the kind of judgment that should guide the QI process. Managers have a responsibility to focus on the fact that their business is health care; the concern for quality of care should be the prime driver of QI efforts.

Health professionals are trained to focus on the immediate clinical needs of individual patients. That focus can lead them to overlook the relation of their work to ultimate outcomes or to the organization as a whole. This tendency is compounded when HCO leadership fails to positively define a wide concept for the professional's QI responsibility. HCO leadership must articulate a clear expectation that health professionals will undertake and support improving patient care beyond their immediate professional concerns. We do not assume that health professionals are disinclined to participate in QI or that they lack a responsibility to do so, but establishing the conditions for health-professional involvement in QI is a responsibility of HCO leadership, which includes the leadership of the medical staff. Including *participation* in QI in performance evaluations could create positive incentives for health professionals to be so engaged. It does so, perhaps even more effectively than rewarding the achievement of quality *per se*, given the potential perverse incentives in so-called "pay-for-quality" schemes, e.g., the incentive to avoid caring for patients who are likely to have bad outcomes.<sup>21</sup>

### Respect for Patients

The HCO responsibility to respect patients is an important ethical constraint on QI. This responsibility includes

- Respect for patient values and rights, such as informed consent, confidentiality, and privacy;
- Incorporation of patient values and preferences in the assessment of quality; and
- Transparency of process consistent with the organizational mission and structure of the HCO.

A corollary of the previous section is that the responsibility for preserving professional integrity is itself bound up with the value of promoting and pursuing patient welfare. Respecting patients is a separate normative consideration in QI even if one argues that the pursuit of patient welfare is primarily assured by maintaining professional integrity. HCOs cannot delegate the duty to respect patients to direct-care providers and allow organizational operations to function on the basis of cost containment or to be driven by other business values. Respecting patients is such a core value in health care that the HCO must itself assume this responsibility. The HCO must similarly accept this as a normative constraint in QI. It is well established that whenever health-care professionals fail to maintain or pursue patient welfare, HCOs can be assigned independent responsibility to assure patient welfare. Cases such as *Darling v. Charleston Hospital*<sup>22</sup> have shown that both health-care organizations and individual health-care professionals have legal accountability for actions that harm patients.<sup>23</sup> In addition to responsibility in the negative sense of *liability*, organizational responsibility for QI has the important positive aspect that is a component of the overall organizational ethic. Respect for patients is a key feature of this ethic and should be part of the organization's mission that guides its operational practices.

In QI, respect for patients has to involve more than respecting the universally acknowledged rights of patients, such as confidentiality, informed consent, and privacy. It must also include the responsibility to actively identify and accommodate patient assessments of designed changes in care. Ideally, improving patient care should involve achieving outcome objectives that are broadly in agreement with patients' values; but since this is an empirical issue, HCOs have a responsibility to incorporate patient values and preferences into QI.

### **Respect for Workers**

Given the complexity of contemporary health care, even workers who are not, strictly speaking, health professionals have a stake and a role in QI. This role is often overlooked in discussions of the ethics of HCOs and QI, but it is an essential concern for responsible managers. Respect for workers in QI includes at least the following:

- Participation and buy-in of employees;
- Open and honest communication and trust; and
- Fair share in the benefits and burdens of process improvements.

Contemporary health care would not be possible without the services of multiple support personnel. These workers have an important but often overlooked role to play in improving quality of care. Resources and services must be available in the settings where need has been identified. Because hospitalized patients are increasingly transported to various departments for services, a complex transportation and distribution system that involves multiple non-health-professional workers is essential in contemporary HCOs. Effective QI within an HCO will thus impact operations, and some changes will most directly affect support personnel. Attention to the impact of these changes should be a key managerial concern. Failure to address them effectively will limit the organization's ability to carry out QI, particularly improvements that require coordination beyond the unit level.

Many health professionals occupy dual roles in HCOs. They are both health professionals and employees of the organization. In many instances, protection of professional integrity will assure protection of worker rights, but this is not always the case. Other health-care workers who are not health professionals are less well paid and more vulnerable, because they fill jobs that have low entry requirements, and they are thus more easily replaced. Custodial services, transport, materials-handling, clerical and secretarial support, data entry, food service, and so on are essential to the operation of HCOs, yet these functions are provided by the most vulnerable workers. Improving quality of patient services should ideally be conducted in ways that protect the rights and welfare of workers, not only those who provide direct patient care, but those who provide support services as well. Some improvements in patient-care quality entail alteration in scheduling or duties. These changes can cause worker dissatisfaction, contributing to overall decreases in productivity and morale that can have adverse effects on patient care. Even positive change that improves the quality of care is not necessarily less stressful or disruptive for workers than changes caused by economic exigencies. Keeping workers aware of and committed to the HCO mission and maintaining their commitment to QI within the framework of the mission is an important responsibility of HCO leadership. Educating health-care workers about the contribution that they can make to the overall mission of the institution and the connection between their functions and patient outcomes is critical for maintaining worker morale and commitment.

## Pursuing Quality

How might these considerations be incorporated by HCOs in pursuing QI? First, the decisionmaking process for QI should be institutionalized in such a way that there is open participation. QI should include not only health professionals, but workers and patients as well. Accepting and adapting to the changes that result from QI require trust and transparency of process. The values and goals that drive the process should be clear to patients, workers, and health professionals. The HCO needs to accept the fact that health-care workers, health professionals, and patients are all stakeholders and that their involvement in QI should have institutional support.<sup>24</sup> Support involves providing resources, release time, and appropriate recognition in annual performance evaluations. As a managerial responsibility,<sup>25</sup> QI cannot be responsibly managed from the top down; rather, the commitment to quality needs to be part of all structures within the HCO culture, and it should permeate administration and support services as well as patient care. In this regard, HCO management has the overall responsibility to provide leadership in the commitment to quality and QI. Clearly, administrative styles and processes associated with QI will vary from one HCO to another, depending, in part, on institutional mission and culture. Despite the variety of ways that QI might be institutionalized, a common expectation for HCO leadership in QI is that it match actions and decisions to words. Fairness and openness of process are critical for the success of QI.

Although some QI involves small-scale, noncontroversial projects that are evolutionary solutions to unit-level operational difficulties, other improvements, such as implementing consensus guidelines for managing complex clinical problems, can have a revolutionary impact on



an organization. Such change can be achieved best in organizations in which the leadership exhibits high levels of trust, openness, and integrity.<sup>26</sup> The commitment to QI needs to be articulated and supported by the governing board of the institution and incorporated into the evaluation of personnel at all levels. Even when QI is not conducted as a delegated responsibility, such as within a defined department in the organization, e.g., a QI officer or office, a fully responsible leadership will accept accountability for improving quality and will carry this message throughout the organization. At all levels, QI has to be seen as *our* responsibility rather than *their* responsibility. From a management perspective, the quest for quality must be seen as a fundamental organizational goal accepted at the highest levels and institutionalized in ways that positively shape the daily operations of the organization.

These conclusions are consistent with the recommendations of the Institute of Medicine in *Crossing the Quality Chasm: A New Health System for the 21st Century*.<sup>27</sup> Ten rules are offered in this report:

1. Care based on continuous healing relationships.
2. Customization based on patient needs and values.
3. Patient is source of control.
4. Shared knowledge and the free flow of information.
5. Evidence-based decisionmaking.
6. Safety as assisted property.
7. The need for transparency.
8. Anticipation of needs.
9. Continuous decrease of waste.
10. Cooperation among clinicians.

These ten rules might be viewed as defining two thematic domains. The first theme includes the elements of relationship, knowledge and information, and patient welfare; the second includes the concerns of patient values and preferences, health-care-professional integrity, and worker rights. Rules 2, 3, and 7 clearly place the patient at the center of health-care delivery and at the center of efforts for improving quality of care. Permeating both thematic domains is a concern that services be provided effectively and efficiently. Rule 9 is best read as saying not simply that waste should be avoided for the financial benefit of the HCO, but that there is a positive and continuous responsibility to decrease waste of all sorts of resources, not only financial resources but even patients' time. This commitment is important, because one worry about organizational commitment to QI is that the underlying motive for management in pursuing QI is simply to reduce cost and increase efficiency without regard for preserving the integrity of the professional relationship, the well-being of employees, or the rights and welfare of patients, families, and communities. This criticism, however, needs to face up to the legitimate responsibility for managing resources that rightly falls to HCOs.<sup>28</sup> In acknowledging this responsibility, the Institute of Medicine re-balances the scale on which the pursuit of quality in health care will be weighed. The Institute of Medicine Report is an important document that comes to terms with both the complexities of QI in health care and the complex nature of pursuing quality in the contemporary environment.



## Conclusion

This chapter has argued that improving quality of care is an important responsibility that falls to the HCO because of its historically distinctive place in the delivery of health care. Because complex contemporary health care often must be delivered in and through health-care institutions, the HCO is properly regarded as having responsibility for the quality of care. The concepts of quality of care and QI, however, are not fixed or static; rather, they reflect purposes and values that are, in part, context-dependent. It is thus to be expected that HCOs will pursue quality in a variety of ways. The differences are justified if they reflect differences in mission, community setting, resource base, and place in the health-care system, but they are not justified if they reflect managerial lack of interest or commitment. The HCO has affirmative responsibilities for quality, and management should be held accountable for the overall quality of the HCO. Worries like that of Toulmin that HCOs can structure health care in ways that erode professional values can be somewhat allayed by insisting that the commitment to quality of care and QI is not optional for HCOs; it is an essential responsibility not only for health professionals, but also for management. Health professionals and the institutions within which they practice should be partners. HCO leaders should seek out and join other stakeholders—patients, families, and the community at large—in the pursuit of quality and should work cooperatively with those regulatory agencies that oversee and measure patient care.

Our discussion of HCO responsibility for QI has focused on what might be termed the *internal responsibility of HCOs for QI*. We have not addressed the responsibility of HCOs in a competitive environment to avoid the diminution in the overall quality of care provided to communities as competitors are driven from markets, creating gaps in service and coverage. Such organizational-ethics issues are beyond the scope of this essay, but the corrosive effects that HCO decisions in competitive markets can have on the overall quality of care within a community need further analysis.

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## Notes

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3. The view that scientific research and knowledge should have practical benefits for society is hardly new. It can be found as early as the 16th century in the work of Francis Bacon (F. Bacon, *Novum Organum*, 1620, in Peter Urbach and John Gibson, eds. (Peru, IL: Open Court Publishing Company, 1994)). The granting of licensure to physicians, beginning in the late 19th century, was based on medicine's claim or commitment to the application of scientific methods and knowledge in the traditional physician-patient relationship. By the late 20th century, however, this commitment had evolved into a complex system of care featuring multiple, interdependent, and technology-mediated social relationships. The traditional solo-practice-based, dyadic physician-patient relationship was effectively replaced by group practices and team- and institution-based systems of care. Thus, HCOs emerged as the social structures within which health care is produced and delivered.

4. Although I have argued for the key role of HCOs in health-care delivery, one might object, citing the fact that scheduling, staffing, custodial services, maintenance, utilities, and continuing education are variably distributed across HCOs. Although it is clear that the management of these supportive services is essential to the provision of everyday health-care services, these services are not health care properly regarded. Just as the tailor, grocer, and buggy maker who helped clothe, feed, and transport the solo practitioner so idealized in traditional medical ethics cannot be said to be agents in the provision of health care, so, too, the objection goes, HCOs at most create and sustain the environment within which health care is produced, but individual health-care professionals provide that care. To say otherwise would involve a category mistake, confusing the actual delivery of health care, which essentially involves interpersonal relationships, with its supportive social structures.

This criticism must be taken seriously. It is true that health professionals are involved at all stages of patient care, but insofar as this care is technologically mediated and cooperatively delivered, it is a mistake to see the individual health professionals involved as the prime agents by which health care is delivered. Even if they were, they often function collaboratively to such a degree that the care in question is actually delivered by the collective and not by the individual agents.

A sports analogy might help to make this point. Although it is true that not all players score in team sports, it is a mistake to say that only the players who score win games. The team wins because the nature of the team sport requires their

collective action. Without collective action, there would be no football or baseball game. Similarly, without technology, training, and supplies, health care could not be delivered in its present form. A physician does not compound his own medications; he relies not only on pharmaceutical manufacturers, but also on distributors. More remotely, the physician relies on basic and clinical researchers to develop the medications and to test them and the subjects who participate in the clinical trials. Clearly, contemporary health care is a social, or collective, product.

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21. This point was made to the author by an anonymous reviewer.

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25. This does not mean that the responsibility for QI belongs solely to management. However, exploration of the relationship of HCO responsibilities for QI and, for example, physicians is beyond the scope of this chapter.

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## **Informed Participation: An Alternative Ethical Process for Including Patients in Quality-Improvement Projects**

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### **Introduction**

Quality improvement (QI) is an essential component of the medical enterprise. This chapter argues that QI is a morally mandatory element of medical care, both for institutions to design and pursue and for patients to acknowledge and embrace; the need for QI is one facet of excellent medicine, a reality that physicians, patients, and medical organizations should integrate into the delivery of health-care services. The case is presented for the regular education and involvement of patients in projects that pursue quality medical services. Structures for implementing and testing advances in care and improved service-delivery systems demonstrate a commitment to excellence in medical practice and fidelity to patient well-being. Institutions with robust systems for improving quality reflect ethical commitments to patients' best interests and support for integrity in clinical decisionmaking.

In designing projects in pursuit of quality, however, the line between QI and clinical research is relatively permeable, and it is sometimes difficult to determine with precision whether a project should be considered QI or research.<sup>1</sup> It is important that these realms be distinguished, to the degree possible, so that areas ripe for QI can be identified, data can be collected, and interventions can be tested and improvements instituted in a timely fashion. The QI process must be subject to some recording or review to ensure that the intervention is itself a quality product, but the underlying systems should be flexible and swift, without substantial barriers to design and implementation.<sup>2</sup> It is equally important for Institutional Review Board (IRB) review of medical research that is not QI to continue. This is needed to enable clinicians and scholars other than principal investigators to make a determination that the risk of the research is reasonable in light of the benefits and to scrutinize the document that supports the prospective subjects' informed consent. While in most cases, QI activities and clinical research are distinct, some projects fall into overlapping or gray areas that seem to have features of both. In these cases, those responsible for research and QI should share standards and create procedures together, cooperate in review, and communicate regularly to determine the effectiveness of the linkage.

Distinguishing QI and research is becoming a focus of scholarly work and federal regulatory policy because of the significant consequences that result from a project's designation.<sup>3</sup>

This distinction appears to be necessitated by the apparent similarity between, and the methodological alliance of, these two processes, given the tools they use and their formats and structures for gathering data.<sup>4</sup>

## Matters of Definition: Quality Improvement and Disease Management

The application of QI principles in health care is rooted in industry, primarily through the pioneering work of Walter Shewhart, a statistician at Bell Laboratories, and W. Edwards Deming, an industrial consultant. More than 50 years ago, they utilized methods and principles of *total quality management* and *continuous quality improvement* as mechanisms by which to improve industrial processes and shape core organizational functioning.<sup>5</sup> These principles have been assimilated in health care to varying degrees in recent decades, as shown by the fact that the nation's primary agency accrediting health-care organizations, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), bases its accreditation decisions in part on the ability of the requesting organization to successfully demonstrate adherence to the process and practice of continuous QI.<sup>6</sup> JCAHO's *2005 Comprehensive Accreditation Manual for Hospitals: The Official Handbook* includes a chapter in Section II, Organizational Functions, devoted entirely to standards for "improving organization performance."<sup>7</sup> JCAHO favors the more all-encompassing term *performance improvement*, which it defines as "a continuous process. It involves measuring the functioning of important processes and services, and when indicated, identifying changes that enhance performance. These changes are incorporated into new or existing work processes, products or services, and performance is monitored to ensure that the improvements are sustained."<sup>8</sup>

The Institute of Medicine (IOM) has also offered a definition for quality in health care. It defines quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."<sup>9</sup> In its landmark report, *To Err Is Human*, the IOM focused significantly on lapses in health-care quality by calling attention to the problem of medical errors and compromises in patient safety.<sup>10</sup> This work noted that up to 98,000 Americans may die each year as a result of medical error.<sup>11</sup> While the accuracy of the figures reported has been questioned, the report firmly established the sheer prevalence of quality and safety lapses in health care and indicated that medical errors may rank among the leading causes of death in the United States.<sup>12</sup>

In a subsequent report, the IOM focused on a remedy for these deficits in health-care quality and safety. *Crossing the Quality Chasm* set forth six aims for the 21st century health system.<sup>13</sup> These included making health care safe, effective, patient-centered, timely, efficient, and equitable.<sup>14</sup> The scope of these goals illustrates how pervasively QI is being viewed as a mechanism to achieve change in health care. The traditional regulatory approach, which rewards health-care organizations mainly for engaging in the practice of QI, is being replaced by more-aggressive programs known as "pay-for-performance" programs.<sup>15</sup> These programs provide financial incentives or disincentives toward various quality objectives and may specify desired quantitative results.



This approach is illustrated by provisions within the Medicare Modernization Act of 2003,<sup>16</sup> which called for, among other goals, a reduced reimbursement rate for hospitals failing to collect and report specific quality measures related to care of patients with acute myocardial infarction, congestive heart failure, and pneumonia.<sup>17</sup> Data on these measures are also being reported publicly, adding to a growing number of “report cards” for public use.<sup>18</sup>

These developments provide a context within which QI initiatives are occurring. Perhaps most germane to the ensuing discussion, this context demonstrates the broad scope of QI activities in health-care organizations, the increasing prominence of these efforts, and the considerable public pressures on health-care organizations to improve quality quickly. The following are some examples of QI projects:

1. *Reducing potential medication errors caused by automatic expiration.* Multiple cases of adverse events caused by medications automatically expiring and being removed from the patient’s list of medications have been brought to peer-review committees. In these cases, the primary-care physician has not been aware of the discontinuation. This QI project studies the medication orders in an attempt to determine the intent of each one that auto-expires and then quantify the orders that unintentionally auto-expire during the test period. A solution is then proposed.
2. *Managing congestive heart failure.* This QI project offers home telemonitoring for selected congestive heart failure (CHF) patients in the ambulatory-care setting. The patients are provided with a precision electronic scale that records their weight and prompts them to answer specific wellness questions. The information is then automatically transmitted to a computer server located in the case-management organization, with a “red-flag” system to identify patients who require early contact and intervention. These patients or their physicians are contacted to apprise them of the situation and discuss treatment alternatives.
3. *Improving the care of diabetic patients.* In this QI project, patients are assessed by a diabetes-nurse case manager who contacts them and their physicians to gather baseline medical and general information that can impact treatment and assist in the identification of potential interventions. Patients are then stratified according to risk level. Ongoing monitoring is implemented to determine the effectiveness of interventions or changes in status. A multidisciplinary disease-management team meets to review the program’s performance relative to its targets, and modifications are made as necessary. Feedback from both physicians and patients is gathered through periodic satisfaction surveys and ongoing interactions. Any new advances in the care of such patients are identified and incorporated into the program.

Disease management, illustrated by the CHF and diabetes projects, is a leading type of QI process. It relates largely to the quality of techniques for managing chronic disease and primarily concerns managed-care organizations that absorb the full risk of care for patients. Several recent reports, including two by the IOM, show that the management of chronic illness is inadequate.<sup>19</sup> Approximately 125 million persons in the United States,<sup>20</sup> and 88 percent of those aged 65 years or older, suffer from at least one chronic condition.<sup>21</sup> Four diseases—

asthma, CHF, depression, and diabetes—affect nearly half of those Americans who have a chronic disease.<sup>22</sup> These diseases are directly responsible for approximately 140,000 deaths each year in the United States,<sup>23</sup> and they generate at least \$173 billion in annual costs.<sup>24</sup> In a recent extensive study that examined the proportion of recommended care provided for chronic conditions overall, such care was found to have been delivered in only 56.1 percent of the cases examined.<sup>25</sup> Yet these are conditions for which scientific evidence suggests that organized, proactive care-management processes for patients can improve the quality of health care.<sup>26</sup>

Numerous reasons have been suggested for today's inadequate care.<sup>27</sup> Indeed, notable variation in practice patterns by different providers for the same disease, punctuated by the frequent lack of best-practice care, has led to the suggestion that the implementation of disease-management processes will be an effective way to close the quality chasm between current and optimal practice.<sup>28</sup>

Disease management is aimed at ensuring that the best practices known to medical science are implemented with little variation by all caregivers across the entire continuum of care. As such, it encompasses acute-care delivery in the hospital and chronic-care management in ambulatory-care and home-care settings.<sup>29</sup> In order to achieve its greatest impact on improving health-care quality, such a process must involve all providers, including primary-care physicians, specialists, acute-care medical teams, and home-care providers, at all sites of care, including ambulatory offices, emergency departments, and acute-care and subacute-care hospital facilities.<sup>30</sup>

In recent years, several institutions have shown that a disease-management approach, in which a patient is co-managed by a team focused on delivering evidence-based, best-practice care, significantly improves patient satisfaction and quality of care.<sup>31</sup> The primary objectives of such programs are to

- Improve overall quality of life;
- Reduce morbidity and mortality;
- Ensure that patients receive evidence-based care for their particular chronic illness;
- Improve patient and family understanding of the particular chronic illness;
- Reduce inpatient admissions and length of stay;
- Reduce emergency-room visits;
- Ensure rapid inclusion of new advances into daily clinical practice;
- Reduce costs.

The key components of these programs are

- Patient identification, assessment, and stratification;
- Continued physician compliance with best-practice standards;
- Patient and family education and empowerment;
- Ongoing monitoring of patients' health status.

## Analysis and Measurement of Outcomes of Quality Interventions

QI provides the basic platforms for identifying less-than-adequate medical service-delivery systems and for pursuing improvement. The informed-consent process required by the federal rules governing research<sup>32</sup> is preeminently unsuited to a process that is continuously changing and responding to new data, new literature, and accumulating experience.<sup>33</sup> QI requires self-aware patient-provider interaction, constant data-monitoring of interventions, and consistent reformulation as the process either shows success or proves irrelevant to the problem. Flexibility is key to this process. In contrast, research depends on a developed hypothesis and the gathering of data according to a fixed plan, which can, at the end of the protocol, be measured to determine whether the hypothesis was proved or disproved.<sup>34</sup> During the course of a research plan, only a data safety monitoring board (DSMB) can break the blind and examine the data to evaluate whether the data collection needs to be terminated because clearly less-effective care or actual harm attaches to one arm of the study.<sup>35</sup> If the practice that governs consent to research were imported into QI, “modifications” to the informed-consent document might need to be detailed to the IRB each week. It is clear that if these new forms also required renewed patient agreement, chaos would ensue and it would be impossible to conduct QI projects.

The urgent need for reform is clear. What is not yet agreed upon in the scholarly literature and in government guidance is how this push to improvement will be coordinated with prior notions of patient and subject information and choice.

## Distinguishing Features of Quality Improvement and Research

The projects described above are particularly instructive in that they have carefully prepared plans for monitoring quality. They include inclusion and exclusion criteria, propose specific measures to be used to assess results, and employ a stratification plan to test different interventions in varied patient populations. These characteristics point to the fact that there are many similarities between QI and research endeavors. Both QI and research

- Involve human participants;
- Are concerned with inquiry;
- Are processes in which empirical or systematic inquiry generates a question that data collection is designed to answer;
- Propose a set of outcome measures that will satisfy the design;
- May involve testing of an apparent solution to evaluate the value of broader implementation;
- Involve critical evaluation of data to determine the efficacy or effectiveness of an intervention.

However, in some exceptionally important ways, QI and research differ substantially. Most important, QI activities do not comport with the federal definition of research in that they are not designed as “a systematic investigation, including research development, testing

and evaluation, designed to develop or contribute to generalizable knowledge.”<sup>36</sup> Rather, organizations conducting QI activities have decided that they are under a regulatory, professional, and ethical mandate to do so. They engage in specific and aggressive QI because, if it is successful, interventions will be put in place. The Health Insurance Portability and Accountability Act (HIPAA) views QI activities as necessary for “health-care operations.”<sup>37</sup> From a more practical perspective, QI and research also differ in staffing, evaluation, and review mechanisms. For purposes of clarity of thought, we have attempted to distinguish quality improvement and research on a number of discrete aspects, shown in the table below:

Aspect	QI	Research
Risk to subjects	Minimal	Variable
Benefit to subjects	Often direct	Variable
Level of subject knowledge and participation	General awareness	Individual informed consent
Degree of necessity for health-care operations	Implicit	None
Assignment of interventions	“Piloted”	May be random
Nature of intervention	Unclear effectiveness	Unclear efficacy
Review mechanism	Organizational leadership	IRB
Publication imperative	Secondary	Primary

While research and QI have some important similarities, QI is directed primarily at finding cost-effective solutions to problems for populations served because of necessity, while research is concerned primarily with contributing to generalizable knowledge. This does not mean that the results of QI activities might not be generalizable or of interest to others. Indeed, publication of such results in a journal may be of significant immediate value to the health-care community at large. We would merely argue that intent to publish is not a morally relevant distinguishing characteristic.<sup>38</sup> The ethical aspect that is missing from the above is an articulated process for review and a sense of how the agreement of the patient will be solicited, secured, and recorded.

As noted earlier, classifying QI projects as research would trigger traditional regulatory provisions for individual informed consent, except in circumstances where the IRB is permitted to waive this requirement. But a “research-reflecting” informed consent before participation in QI interventions will not serve the purposes for which the informed-consent requirement for research was created and will be a major deterrent to flexible, effective QI. Different levels of review and supervision are required for QI and clinical research so that research subjects are adequately protected and patients who participate in QI are assured that projects to improve quality are instituted and results are applied in a timely fashion. As distinctions are made between research and QI, one issue that must be addressed is whether complex QI projects, especially those that utilize techniques of randomization and prospective intervention with the support of electronic databases, require the individual informed consent of prospective participants.<sup>39</sup> We argue that if the data are adequately protected to address issues of individual privacy, individual informed consent should, in general, not be required.

Scholars, regulators, researchers, managers, and QI practitioners at each institution must agree on the criteria for distinguishing QI and research and on the relevant structures and committees that must be established to record, scrutinize, and supervise each effort. It is to be hoped that a national consensus will emerge on these issues and the relevant government agencies will provide guidance for health-care systems. We propose that for most QI projects, patient information, agreement, and, in certain circumstances, the ability to opt out can protect the individual's interests. We make these assertions in the context of the general agreement that the present integrity and effectiveness of the informed-consent document and process has been severely compromised by the capture of documents and the process by company sponsors and by institutional risk-management concerns. Furthermore, we assume that while participation in research is not morally mandatory, participation in QI can ethically be required of patients.<sup>40</sup>

### **Ethical Analysis: Cooperating with QI**

As the basis for the reciprocal obligation described above, we now consider in more detail whether it is morally imperative for patients to participate in and promote QI initiatives. We argue that while reasons can be given for participating in and promoting research, the case for doing so is considerably weaker than the case for participating in quality/performance improvement. Participation in and promotion of QI projects is supported by compelling ethical arguments, whereas arguments in support of an individual's obligation to participate in research are controversial at best.

In general, participation in research is morally imperative only if the research itself is, so we can approach the issue by asking whether research on human subjects is morally imperative. Before doing so, however, it is important to head off a possible misunderstanding. Some, perhaps many, might answer "No" to this question on the grounds that it is wrong to compel individuals to participate in research against their will, especially when doing so involves more than minimal risk. But it does not follow from the claim that research is morally imperative (assuming this has been established) that people may be conscripted into participating in it. It may still be appropriate, indeed morally required, to place conditions on individual participation, such as informed consent and a favorable risk/benefit ratio. The question about moral imperative applies to the research enterprise, either as a general activity or in specific areas, not to the individual's participation in the enterprise.

In his often-cited paper "Philosophical Reflections on Experimenting with Human Subjects,"<sup>41</sup> Hans Jonas takes up and criticizes two arguments advanced on behalf of an ethical obligation to participate in biomedical research. According to the first, participation in research is justified because of its essential role in preventing future harms as well as promoting health and well-being. It is justified, in other words, because science is a necessary instrument of medical progress and research is a necessary instrument of science. Moreover, since there is an obligation to *advance medical progress*, participation in research is morally imperative. Jonas counters that while research is undeniably an important social interest, participation in it is

morally “gratuitous.” Were research necessary for society’s very survival, the moral calculus might/would be different. But most medical research is not of this sort; most of it falls in the category of improving society.

The second argument construes an obligation to participate in research as a form of repayment for benefits received from research conducted in the past. According to this view, *justice* requires that the beneficiaries of past research do their fair share to extend these benefits to future generations, hence that they accept an obligation to participate in research that is likely to do this. Jonas responds that if we owe anybody anything, it is gratitude for the altruistic acts of past research participants. But we have still not shown what we set out to show, since “gratitude is not an enforceable social obligation.”<sup>42</sup>

These two arguments—one based on the vital social interest in the progress of medicine and the other on a requirement of justice—are the ones most frequently used in defense of a moral imperative to participate in biomedical research, and we do not believe that Jonas’ rejoinders have completely disposed of them. Many would dispute the claim that medical progress is in no instance morally imperative. In the case of certain diseases—serious life-shortening diseases for which there is currently no cure, such as Alzheimer’s disease and various types of cancer—people’s reactions may go in a very different direction. Of course, important questions will need to be asked about who should participate in research to advance medical progress and under what conditions. But the intuitive case for research participation to advance medical progress in these specific areas is quite strong.

With respect to Jonas’ second rejoinder, the implied distinction between justice and gratitude is too simple. To be sure, gratitude is not a debt in the same way that repayment of a loan is a debt, but gratitude may nevertheless be morally obligatory in some circumstances. Further, the problem of enforcement, which Jonas focuses on, raises an issue very different from whether there is a moral obligation in the first place, and he seems to confuse these issues.

We do not want to suggest that the justice argument for research participation is not problematic. Arguably, only those who have had a fair opportunity to enjoy the benefits of past research can be said to have an obligation to participate in research to benefit future generations. In this view, members of marginalized and disadvantaged groups who have not had equitable access to health care have either no obligation or a much weaker obligation to participate in research than the well-off members of society have. The important point is this: There are different versions of the justice argument for a moral imperative of research participation, and some may be more plausible than others.

In any event, we will not take a stand here on who has the better arguments. Thoughtful arguments can be presented on both sides, and they deserve much more attention than we can pay them here. Turning to QI, however, we believe it would be inappropriate to adopt this ambivalent stance, since the case for a moral imperative for patients to participate in and for medical institutions to conduct such projects is clear and much stronger than any opposing arguments.

Quality improvement is morally imperative in three interrelated respects: First, it is imperative for medical professionals to *conduct* performance-improvement projects; next, it



is imperative for individual health-care organizations to *support and promote* such efforts; and finally, it is imperative for active patients to *participate*, under certain circumstances, in QI efforts.<sup>43</sup>

The obligation of medical professionals derives in part from the moral admonition “Above all, do no harm.” An important part of QI is the monitoring, uncovering, and elimination of medical errors, and every professional is responsible for minimizing the likelihood of errors in his or her own practice. Beyond this, the beneficence obligation of medical professionals supports a moral obligation to conduct QI projects aimed at improving the standard of care. While not every professional can or should conduct such QI projects, at least every one should give moral support to the QI enterprise.

The obligation of health-care organizations to support and promote QI projects flows from their responsibility, as moral agents in their own right, to protect and enhance the quality of care provided under their aegis.<sup>44</sup> Health-care organizations are not merely loci of clinical practice; they are themselves agents within the health-care arena. But the fact that they comprise health professionals who have their own professional obligations has significant implications for the policies, decisionmaking procedures, and strategic plans that organizations may adopt. In the most general terms, health-care organizations are required to create the sort of environment and infrastructure that enables health professionals to do their work well and that sustains them in their efforts to do so. Among other things, this means that they are charged with monitoring the effectiveness and quality of clinical interventions and facilitating the efforts of medical professionals to improve the quality of care they deliver.<sup>45</sup>

The obligation of active patients to participate in performance-improvement projects is our central concern here. As argued above, in theory—and often in fact—individual subjects of biomedical research receive no benefit from that research. The benefits are reaped by future patients, individuals, and society in general.<sup>46</sup> In contrast, QI often creates an immediate benefit for individual participants, their families, and the communities in which they live, in the form of increased efficiency and effectiveness of service, better use of limited health-care resources, and fewer errors in the provision of medical care.

We are increasingly recognizing that patients not only have rights, they have *responsibilities* as well. Some of these responsibilities can be justified on grounds of benefit to self—patients have a responsibility to cooperate with the plan of care to which they have agreed. Participation in QI projects can be viewed in the same way, since the results of those projects often provide a direct benefit for the participants themselves.<sup>47</sup> But there is a growing awareness that patients also have responsibilities to others, for example, a responsibility to not consume limited medical resources wastefully and to consider the interests of their involved family members in deciding about treatment. We believe a similar notion of responsibility to others justifies participation in QI projects.

Quality improvement projects, at least those that interest us here, involve active patients, that is, patients who are receiving ongoing care. As such, they are not being asked to forgo further treatment or to be randomized to different treatments so that others may benefit by their participation. Nor do QI projects typically impose greater than minimal risk. Our claim is that under these conditions, a compelling case can be made that patients should participate in QI projects. However, to say that participation in QI is morally imperative is not to imply

that individuals should be involved in QI projects without at least the understanding that their institution engages in QI activities, nor does it imply that they should be coerced or compelled to take part against their will. In the next sections, we describe the possible designs of QI projects, distinguish them from more traditional notions of research, and suggest how to balance the need for continuing QI with protection for the rights of prospective participants.

Inherent in our argument is the notion that standards of care in the diagnosis and treatment of disease are constantly changing. Medicine incorporates new knowledge, keeps pace with the constant evolution of best practice, and reflects new safety measures. Thus, the underlying ethical commitment of medicine is not to a fixed entitlement or to a fixed notion of best practice, but rather to the idea of evolving and improving practice, which provides the ethical basis for and the ethical imperative of QI.

## Informed Consent to Research

Informed consent is the primary mechanism used to incorporate prospective subjects' preferences, values, fears, and expectations into decisions about enrolling in or continuing in research. The doctrine of informed consent to research is allied to but different from that governing informed consent to medical care. The requirements for obtaining informed consent to medical care were honed by state courts and state legislatures in the late 1950s and early 1960s as patients struggled to establish the prominence of their decisions in the face of a long-standing tradition of medical paternalism; courts and legislatures articulated standards under which physician practice and patient demands be could fairly assessed. The physician was urged to disclose to the patient the information that was material to the patient's decision.<sup>48</sup> This disclosure would clearly require a prior relationship and focused discussion. In fact, most jurisdictions then moved to a less rigorous standard, one of disclosure of what the reasonable patient would want to know in the circumstances—a standard that required far less specific knowledge of this particular patient's needs.

The principles governing informed consent to research emerged from review of the Nazi concentration camp experiments,<sup>49</sup> the Tuskegee syphilis study,<sup>50</sup> and other truly abusive and demeaning uses of humans for research or so-called research. These modern principles evolved from the Nuremberg Code—actually, the opinion of the court in the Nuremberg trials—and from the work of national and international ethics commissions and working groups.<sup>51</sup> The community of researchers in the United States, however, smugly assumed that this was a European, and specifically a German, moral issue. But the exposé by Beecher of conscripted research subjects in 1966<sup>52</sup> and the report of the Tuskegee experiments in 1972 dispelled this complacency and led to the National Research Act and the Code of Federal Regulations Governing Research with Human Subjects.<sup>53</sup> For purposes of informed consent to QI, suffice it to say that the rules for research and treatment were honed in the crucible of scandal and professional failure to advance autonomous decisions in care and research. This is an important element to assess, as the oppositional nature of the informed-consent requirement in both

treatment and research assumes that the patient/subject must be protected from potentially injurious interventions that may be hidden if they are not clearly identified, highlighted, and exposed.

This particular history and the principled analysis it spawned are now incorporated into the federal regulations governing human-subjects protection. As these two related notions of informed consent have developed, each has been affected by the other. Courts and state legislatures have addressed informed consent to medical care;<sup>54</sup> federal regulations have specified the elements of informed consent to research.<sup>55</sup> In both clinical care and research, the doctrine was refined to ensure that the patient/subject was capable of making a decision and that his or her consent was based on sufficient disclosure of the risks, benefits, and alternatives to the intervention and was uncoerced and voluntary.<sup>56</sup> The paradigm was the informed and empowered individual who offered a personally appropriate decision after reference to personal values and in response to individual history, goals, and desires.

In both research and clinical care, regulations, statutes, and judicial opinions have contributed to a fundamental shift in the relationship between researcher and subject and between physician and patient. The excessive exercise of physician authority in clinical care and the abuse of subjects in research led to fundamental shifts in review and regulation and, at least in theory, in power. These experiences with informed consent to clinical care and research, however, do not fit comfortably within the ethical confines of QI. This is especially the case when QI is designed to inform patients and produce results which, if positive, are implemented for their benefit and that of like patients in the cohort. In contrast to clinical care and research, QI is, or should be, a transparent process that informs, involves, and improves the care of patients with their knowledge that these interventions—in general—are always under way.

### **Exceptions to the Informed-Consent Requirement**

During the early history of biomedical research, the primary purpose of informed consent was to protect subjects from coercion, deception, and/or abuse and from being involuntarily burdened with the dangers inherent in research protocols. Additionally, informed consent was intended to minimize the potential for discrimination and the imposition of an unfair burden of research upon socially undervalued populations.<sup>57</sup>

However, under certain specified circumstances, an IRB may approve research protocols that do not include informed-consent procedures.<sup>58</sup> To waive the requirement to obtain informed consent, an IRB must find that (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.<sup>59</sup> There are also regulatory exceptions specifically for research in the public benefits or service sector.<sup>60</sup> However, we think that it would be unwise to shoehorn QI and research into a structure that is not designed to recognize the ethical and practical differences that distinguish the two realms. Doing so would subject QI to the IRB process, which might be fatal to flexibility and responsiveness.

Food and Drug Administration (FDA) regulations have additional informed-consent exceptions. Since 1996, the FDA has acknowledged that an exception to informed-consent

requirements is needed for subjects “who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition and who do not have a legally authorized person to represent them.”<sup>61</sup> The exception is specific to potential life-saving therapies used in emergency situations that, under standard treatment, typically have poor outcomes.<sup>62</sup> Additionally, the FDA has allowed exceptions due to the infeasibility of retaining informed consent and the need for immediate use of experimental interventions, e.g., in research with large populations of military personnel during Operation Desert Storm.<sup>63</sup>

Finally, there are broad carve-outs from the doctrine of informed consent for certain sorts of research, such as epidemiological research, where the requirement for consent would negatively affect the validity of the results by possibly injecting biases into the data. For large epidemiological studies where there is no possibility of the breach of confidentiality and where the quality of the data might be compromised by the imposition of an informed-consent requirement, this right/obligation has been waived.

### **The Case for Informed Participation**

Most physicians, managers, and scholars assume that the only way to protect the rights of patients both in complex QI interventions and in research is by extending to them the right to consent to or refuse participation within the confines of present research informed-consent regulation and practice. Complex QI proposals seem naturally to fall under the ethical logic and regulatory mandate of individual protection and choice. As the previous sections have argued, however, forcing QI projects into the research informed-consent paradigm will disable QI interventions from going forward. Given the ethical importance of pressing forward with QI activities, the minimal risk of most QI interventions, and the obligations assumed by institutions and organizations to implement positive results, we contend that a process other than the standard notion of research informed consent is necessary to meet the ethical, legal, and practical needs of a robust notion of QI.

This conclusion comes partly from the lack of fit between the theory of informed consent and QI activities and partly from the reality of what the informed-consent process has become in practice in clinical settings today. The governing perspective of this chapter is that the practice of informed consent in research has been ethically deformed and intellectually debilitated by the successful self-interested efforts of medical institutions, commercial sponsors, and government agencies to control their possible future liability. Risk management rather than patient empowerment is now the evident—and in some instances, the only—goal of the process. Informed-consent forms have become unreadable; they act not as supports for education, understanding, and the exercise of autonomy, but rather as barriers to those goals. If a coherent and widely accepted notion of a *process* of informed consent were to exist as a support for interpretation and discussion of forms, the actual forms would be less important. If there were a widely accepted, clearly effective process that engaged the patient in an exploration of the research, its likely or possible effects on his or her lifestyle, patterns of work, leisure, and relationships with others, then the form would be far less critical. Unfortunately, however, elaborated, in-depth discussion of the forms and supportive engagement with the prospective subject rarely take place. Therefore, the informed-consent document is the major component

of an ethics policy in disarray. Why would we take a less-than-adequate process and apply it to a new area such as QI, thereby making that area bear an even greater ethical burden? We should not do so.

We have demonstrated that the process of improving health care to enhance patient well-being and improve effective service delivery is ethically mandatory. But the ethical demands of this process, in contrast to the demands of research, exert a responsibility upon both patients and institutions; both have ethical obligations to engage in the process of improving quality. This chapter argues for a process parallel to that of research informed consent, a process that we have labeled *informed participation*, by which institutions design QI interventions and educate and engage patients about their obligations to help improve quality. This process would involve patient education to alert patients about the notion of QI projects that are designed to improve their health and the health and well-being of the similarly situated members of their medical cohort or health-practice group. This process would allow the vast majority of QI projects to go forward without triggering the presently required components of informed consent of the subject to research and without the review of an IRB.

The informed participation process should begin as soon as a relationship is forged between a patient and the hospital, ambulatory-care, home-care, or managed-care setting. Patients should be told about the organization's ongoing obligation to engage in QI and should receive materials that explain that the health-care network engages in continuous QI. They should be told that projects to determine the effectiveness of the care they receive and to review the care of other patients are always ongoing. They should be assured that if any QI project were to impose a burden or require a major change in schedule or behavior, they would be informed about the goal and methodology of the QI intervention and asked to accept or refuse participation.

## Recommendations

For the purposes of the recommendations presented below, the factors that characterize QI are

- The origin of the plan and its flexibility and oversight;
- The use of *plan, pilot, analyze, and implement* methodology, rather than a research design with a *fixed hypothesis*, in which assumptions and data will not be reexamined until the end of the data-collection phase of the research;
- The primary intent is to use the data to improve services if the data demonstrate a cost-effective route to change;
- Source of funding—a National Institutes of Health (NIH) application under a request for proposal (RFP) or a request for application (RFA) that makes clear that the design is research disposes of the issue and classifies the intervention clearly as research.

We recommend that an institutional QI program must have

1. An oversight structure that reviews QI projects and determines that
  - Projects are well designed and justify the use of resources (mere elements of randomization, prospective data collection, creation of new knowledge, and intent to publish do not, in and of themselves, make the design one of research and not QI; conversely, an examination of cost-effectiveness does not, in and of itself, make the project QI);
  - Projects do not pose more than minimal risk to patients, or if they do so, they are accompanied by a robust informed-consent process;
  - Projects protect collected data appropriately and have addressed HIPAA issues;
  - Projects do not overly burden one setting or patient population—which would be wrong in and of itself and might interfere with the collection of useful and accurate data—and priorities have been set sequencing data collection in specific populations;
  - The department or division (including long-term care, step-down units, ambulatory systems, clinics, and home care) responsible for the patient population is accountable for the design and conduct of the project and has the authority to implement findings;
  - The process is as transparent as possible to all patients and providers and is specifically explainable to any patient who requests QI-specific information.
2. An ability to provide information to patients in all settings (inpatient, ambulatory, long-term, and home) and to employees about the ongoing obligation to engage in QI:
  - In contrast to research, which almost all agree is not morally mandatory, QI is an essential moral and practical component of a functioning health-care system;
  - Disclosure to patients and employees about the frame of the QI system is essential for creation of an ethical basis for QI that may, in many cases, make individual informed consent unnecessary.
3. A structure for institutional disclosure through a Notice of Informed Participation:
  - The institution must make clear in basic patient materials that QI projects are a regular part of fulfilling its obligation to patients;
  - The institution must notify patients that a list of current QI projects is available at the Office of Quality Improvement and must provide the contact information;
  - The levels of patient information are
    - a. General institutional announcement
    - b. General description of the project in question when requested
    - c. Specific description of the project in question whether requested or not as the precursor to a focused informed-consent process, when appropriate
    - d. Informed consent of the patient.
4. A structure of accountability for the QI process.



There is not, as of this moment, a fixed set of criteria that clearly distinguish between research and QI. What is hoped is that the Office for Human Research Protections (OHRP) will review any plan and will conclude that a good-faith effort is the most important contemporary element of compliance. It is also clear that developing an institutional “common law” of research and QI is critical. An institution will need to decide, for defensible reasons, why it has placed any project under one jurisdiction or the other. The OHRP has stated that using the IRB regulations with their enormous burden of documentation is not in the interest of flexible QI projects.

Acknowledging some overlap between QI and research will provide a reality base for the process that is created. The choices will be review by a QI committee, review by an IRB, or, in some cases—hopefully few—review by both a QI committee and an IRB.

## Conclusion

The first goal of this chapter has been to distinguish appropriate QI projects from similar interventions that might constitute research. This effort is critical, as the present apparatus for research review—the IRB system—and for soliciting the informed consent of the patient will, we fear, so burden the process of QI as to make it ineffective for the purposes for which it is needed—ferreting out bad systems and practices and creating better ones. For minimal-risk QI projects (almost all QI projects are in this category), institutions that have a commitment to QI and to explaining QI to their patients should be able to have patients included without triggering the expensive and burdensome process of IRB review and without the comprehension-defeating present litany of informed-consent components. Clearly, for projects that involve greater than minimal risk and that create a burden that would be unknown but for an informed-consent process, such a process must be created.

A second goal of this chapter has been to argue that QI is a new and growing field, and there will be violations of patients’ interests and, perhaps, dangerous interventions unless some oversight is provided. The fact that these projects will not be reviewed by an IRB demands that some person or committee have effective oversight. An alternative supervision process is morally and practically demanded. Each institution or organization has the obligation to be cognizant of developing projects and to supervise the general progress of QI.

Because of the moral and practical place of QI, every institution, hospital, and health-care organization that chooses to engage in QI must have a regular way of communicating with patients and families about the QI projects that are under way and those that are completed. One possible mechanism for informing/disclosing is a regularly scheduled newsletter. Another might be an information sheet in waiting rooms that describes projects that are under way and completed projects that have been implemented. Informing patients about the process of QI, the end results, and the implementation of completed projects is a critical part of the disclosing and informing obligation of the institution.

The foregoing paragraphs raise some practical and public-relations issues that are beyond the scope of this chapter. Institutions may, understandably, find it uncomfortable to inform patients that they have reduced the number of unnecessary deaths caused by the improper use

of IVs, the improper sterilization of instruments, or other deficient practices that are, unfortunately, still too common but are rarely known to most patients. Whether and how much to disclose is an interesting issue for organizational ethics, one that we are certain will be explored in the future. As an institution gains expertise in QI projects and is increasingly able to demonstrate that data collected and efficacy documented have resulted in improvements to patient care, the community of patients should be more willing to trust the process and to participate in future projects.

The health-care organization has the obligation to continually monitor its QI protocols: *plan* (by planning), *do* (by testing), *check* (by assessing), and *act* (by implementing). It must assure the timeliness of interventions, the fairness of formulas for resource allocation, and the implementation of findings that have improved patient outcomes. Any negative outcomes that are reasonably related to QI projects should be reported to the oversight person or committee for evaluation. This process will comport with current trends in QI to standardize measurements, utilize prospective methods, define interventions, publicly report findings, and reward providers who perform excellently.

The results of QI initiatives might usefully be submitted to the relevant scholarly literature for publication. Even though QI is not designed to produce “generalizable knowledge,” the process and findings of individual projects in specific institutions might be instructive to other organizations similarly situated with comparable illness patterns, wellness profiles, and patient populations. Eventual publication should not be the reason for required submission to an IRB. Journals should recognize that there is a new field with different rules that is engaging in projects that will be of interest to others in the field.

It is the obligation of the institution or organization to have, before the data-collection phase is instituted, a plan for acting on the results of the QI process as a way of improving patient care. This obligation serves as one basis for arguing that the participation of patients is morally mandatory. Without this commitment, there is no moral basis for varying the cumbersome informed-consent process that is stipulated in the federal rules governing research with human subjects. Organizational commitment to change is the rationale for assuming patient cooperation. Patient self-interest is the component that allows the imposition of this obligation.

Finally, protections must be in place to shield any personal or private information related to the patient and to ensure that none of the data are used for purposes outside of and ancillary to the QI process.

Quality improvement is the ethical corollary to efficient management. It is a practice that affects the care of patients in the present and seeks commitment to that care as the basis for soliciting patient involvement. Informed participation is proposed in this chapter as a term and as a process that can be considered the counterpart to the notion of informed consent in the context of research. It grows out of a notion of mutual moral obligations and a joint effort to improve care.

## Notes

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## Do Patients Need to Be Protected from Quality Improvement?

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### Introduction

Recent advances in understanding of health-care quality and the practice of quality improvement (QI) have generated discussion about the ethics of QI and the relationship between QI activities and Institutional Review Boards (IRBs). Published articles describing QI initiatives have raised questions about whether and under what circumstances QI activities should be reviewed by IRBs.

Some analyses of this set of issues have attempted to extend the current IRB framework for the protection of human subjects to QI. What has been missing is a broader perspective that recognizes the current state of quality, the ethical imperative to improve it, and the current state of organization of QI. This chapter suggests some of the elements of that broader perspective. It then proposes a way of thinking about the relationship between QI activities and protection of human subjects. It posits the need for the primary creation of a framework for QI and then explores the intersection of that framework with the current framework for the protection of human subjects in research.

### The Current State of Health-Care Quality

The quality of health care in the United States is not acceptable. Research has documented deficits in the quality of American health care for more than a century,<sup>1</sup> and there has been a steady increase in compelling evidence that patients often do not get the care they need;<sup>2</sup> that they get unnecessary care, with accompanying unacceptable risks; and that even appropriate care is often poorly executed. In 2000, the Institute of Medicine’s (IOM’s) landmark report, *To Err Is Human*, carefully documented the toll of preventable medical errors in dollars and lives and cited estimates of annual deaths ranging from 44,000 to 98,000.<sup>3</sup> The report states, “More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516). . . . Total national costs of preventable adverse events (medical errors resulting in injury) are estimated to be between \$17 billion and \$29 billion, of which health care costs represent over one half.”<sup>4</sup>

Providing optimal care by using the best health-care systems could lead to additional savings in lives and health care costs, as well as increased productivity.<sup>5</sup> The National Committee for Quality Assurance calculated the likely benefits that would be realized if all Americans

received the quality of care provided by health plans that perform in the top 10 percent of commercial plans reporting quality performance in the Health Plan Employer Data and Information Set (HEDIS). It was estimated that from 39,000 to 83,000 lives could be saved, with reductions in direct medical costs from \$12.8 billion to \$4.2 billion and 83.1 million fewer sick days.<sup>6</sup>

The underperformance in health care is pervasive. While there is geographic variability, the range of performance is dismal.<sup>7</sup> Nowhere in the country are patients adequately protected from harm, nor can they be assured of receiving the benefits of medical knowledge delivered systematically, effectively, efficiently, and compassionately.

It is important to note that some individual physician practices, institutions, and systems have achieved impressive levels of performance—the Mayo Clinic, SSM Health Care headquartered in St. Louis, Intermountain Healthcare in Utah, and the Veterans Administration Health System, among others, have documented unprecedented levels of performance in a variety of clinical areas through a commitment to QI and investments in information technology and process reengineering.<sup>8</sup>

Failures occur in all health-care settings—physicians' offices, medical groups, hospitals, nursing homes, outpatient surgery centers, and patients' homes. Because there is often no coordination among providers, failure often happens in the transition from one setting to another or when several providers are treating the patient independently. Fisher and Wennberg have documented a negative correlation between the number of specialists seen by patients in the last six months of life and the quality of the care they receive.<sup>9</sup> Even within the walls of institutions, many errors result from a failure to coordinate across multiple specialists and among caregivers in general.

In 2001, the IOM released a second landmark report, *Crossing the Quality Chasm*, which proposed a vision of health care for the future that is safe, timely, effective, equitable, efficient, and patient-centered.

Policymakers and the public increasingly recognize that a vigorous agenda of transparency, the enabling of excellence through information technology, and a redefinition of outmoded concepts of professionalism, liability, and accountability are urgently needed if Americans are to receive the excellent health care that current spending levels should be delivering. It is critical that ethical constructs relating to treatment of human subjects be reframed in a way that strengthens these important forces, and that they not become an impediment to the changes in health-care delivery that are so urgently required.

## Types of Failure

*Crossing the Quality Chasm* eloquently and exhaustively describes the ways in which health care currently fails:

- *Failure to apply clearly beneficial medical treatment.* This may occur because of a lack of awareness of the potential benefit, a failure to have important clinical information at the time of treatment, a failure to plan the care that an individual needs, or the lack of a single

entity or individual who is responsible for the care being delivered or offered. Examples include the failure to provide beta-blockers to those who have suffered a heart attack or to provide influenza vaccinations to populations at risk.<sup>10</sup> There are numerous examples of waste and suffering because of failure to provide critical treatment.<sup>11</sup>

- *Failure to apply a beneficial treatment effectively.* Examples are poorly executed surgery due to suboptimal individual performance and complications of surgery caused by system failures. Another example is an inadequate course of antidepressant medication for a new episode of major depression. In some cases, poor outcomes may occur simply because no single provider or entity is ensuring the care of the whole patient. Poor performance on antidepressant medication treatment is likely a result of poor coordination among general medical- and behavioral-health providers.
- *Applying a treatment that is not clearly beneficial and that poses risks to the patient without careful consideration and explanation of those risks and potential harms.* One example might be performing bypass surgery on a frail elderly patient at substantial risk for a stroke or serious complications without a frank and detailed discussion of the potential risks and harms of such surgery. Another example is inappropriate use of imaging procedures in patients with low back pain. These procedures contribute to costs of care without demonstrated benefits for the quality of care or patient outcomes.
- *Applying unproven treatments to patients outside the context of research.*
- *Caring for patients in a way that fails to recognize their needs for responsiveness, compassion, respect, and pain management.* While consumers rate communication with their personal doctors as high, they report more problems in getting the help they need to manage their health problems.<sup>12</sup>

A pervasive theme in the literature on quality and patient safety is that errors are most often the result of poorly designed or failing systems of care. In other words, the solution lies in better-performing systems that perform consistently, that thwart potential human error, and that make it easier to do the right thing than to make a mistake.

The position of this chapter is that it is the ethical responsibility of health-care providers—institutional as well as individual—to manage the quality of the services they deliver. While it is likely that few would disagree with this proposition, current policies and mechanisms designed to ensure quality—public and private, within delivery systems and external to them—are incomplete and inadequate for the complexity of health care today.

## What Defines Quality-Improvement Activities?

Quality management is a systematic approach to monitoring and reporting on the performance of an entity—a physician practice, a medical group, a hospital, an ambulatory surgery center—coupled with strategic efforts to raise the quality of that performance. As might be expected, QI often consists of the identification of opportunities for improvement and the design of systems that consistently do better. While there are some examples of problems with

individuals, true cases of incompetence or deliberate mischief are much rarer than failures that could have been prevented by better process design.

It is useful to describe how quality management efforts in health care generally work. Quality management includes the following functions:

- *Design of important processes of care.* Observational research has consistently shown variation in care processes that has no clinical justification. In some cases, a standard of care is not being adhered to. In many other cases, there may not be a clear standard of care, but examination of practice patterns and outcomes will reveal that there is no consistency of process. In some cases, analyses can reveal a “best process” that ought to be translated into a standard of care, a treatment protocol, or a practice guideline.
- *Monitoring to detect conformance with important standards of care.*
- *Surveillance to detect bad outcomes, both predictable and unexpected.* Examples include monitoring of infection rates, examination of “sentinel events,” and monitoring of surgical outcomes.
- *Reporting to individual clinicians and staff about the performance of the unit or group or their individual performance.*
- *Measuring and improving the humane—i.e., patient-centered—aspects of care.*

A key element of a quality-management system is, of course, action to improve performance. None of the activities described above would make sense without the understanding that deficits in performance and opportunities for improvement will be discovered, prioritized, and acted upon. These actions constitute QI.

## The Current State of Health-Care Operations

In considering the ethics of QI, we must acknowledge that there is no bright line between health-care operations, quality assurance, and QI. Let us define health-care operations as the constellation of clinical services that the provider (institutional or individual) renders to the patient. In the current health-care environment, there is a high degree of variation in most health-care operations.

In the normal course of health-care operations today, processes often vary greatly even where there is a clear standard, and this variation has dramatic implications for patients.<sup>13</sup> This is true with regard to both clinical processes (such as ensuring that patients about to undergo cardiac surgery receive the appropriate antibiotic at the appropriate time) and supporting management processes (such as ensuring that medical equipment is appropriately cleaned and stored, that soap dispensers are filled, and that providers are washing their hands). Similar variations exist in clinical processes in ambulatory care, such as ensuring that patients with diabetes receive appropriate monitoring of glucose and lipid levels, as well as supporting advice and help for managing diet, exercise, and weight control. In all of these examples, the variability means that many patients are receiving care that is suboptimal and that may be harmful.

There are other sources of variability as well. Management decisions might affect the ratio of nurses to patients at any given time. For example, increased use of temporary nurses might cause disruptions in care patterns, even when the patterns are defined. Attending physicians or house staff may trade coverage in ways that allow for uneven backup and supervision. Physicians may have different ideas about what constitutes the appropriate standard of care. Emergency rooms may have highly variable triage procedures and may lack protocols for critical clinical processes. In ambulatory settings, there is also high variability of process and abundant evidence that important standards of care are not being met.

The lack of systematic processes may have an even greater impact on ambulatory care, where patient disease registries, computerized order entry for pharmacy and laboratory services, and reminders to clinicians about potential drug interactions or abnormal laboratory values have been linked to improvements in quality and outcomes of care.<sup>14</sup> Planned interventions to improve quality occur in a context where variation and nonstandardized processes are the norm, not the exception.

Traditional approaches to quality assurance have often accepted this variability but sought to identify bad outcomes, discern their root causes, and eliminate them. Often these have involved identification of individual providers and interventions ranging from notification to education to sanctions or terminations. Sometimes they have involved development of a new standard process to ensure better outcomes in the future. However, because management structure and accountability around quality are often uneven, QI “projects” are often limited in scope, and improvements that are achieved are of short duration. Typically there is an ad hoc quality to these initiatives with little priority setting and inadequate structures to ensure their long-term success. Because they tend to focus on “sentinel events” or known errors, they often do not involve redesigning existing processes. In addition to being ineffective, this type of decentralization of quality management could conceivably result in patients being harmed by poorly conceived quality interventions by inadequately supervised practitioners.

## **Most Management Structures Do Not Support Integrated Quality Management**

Exacerbating the situation is the cleavage that exists between the management and the clinical leadership of hospitals and other provider organizations, resulting in a bifurcation of quality activities between hospital quality assurance/quality improvement and medical staff or departmental initiatives. Nursing may have its own quality activities. There is no framework for accountability for quality for the organization as a whole. (One proposed solution to this particular “chasm” is the creation of a subcommittee of the Board of Directors that oversees quality at the institutional level.) Reinforcing this division are state peer-review laws, many of which protect from disclosure the proceedings of quality-assurance committees that are composed of practitioners only.

More forward-looking institutions have embraced more comprehensive approaches to quality management. These approaches typically involve comprehensive definition and monitoring of processes, clearer definition of clinical process and supporting management processes,

and widespread and systematic monitoring and analysis of outcomes. These organizations have an infrastructure for prioritization and improvement and for changes in existing management and clinical practice. In the best circumstances, the organizations use clinical data systems and electronic health records that enable detailed scrutiny of clinical process. Quality improvement initiatives are typically attempts to standardize processes in order to achieve better outcomes. Rather than exposing patients to higher levels of risk, they seek to mitigate the risks and harms of chaotic and uncoordinated treatment environments. While practitioners and workers in the setting are involved in the design and execution of the systems that can most effectively support them, they do so in a context that is supervised by management, which is ultimately accountable to the highest levels of the entity, including the governance.

### Good Quality Improvement Shares Important Characteristics with Research

Well-designed, well-implemented QI activities are similar in many ways to human-subjects research, especially as it is defined in the Common Rule: “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”<sup>15</sup> Steps in research and QI include identifying an eligible target population; observing or intervening with individual patients, staff, or systems; gathering data in a systematic fashion; and conducting appropriate statistical analyses.

Similarly, QI and research share ethical underpinnings. The basic principles underlying research with human subjects identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research are<sup>16</sup>

- *Beneficence*. Requires that risks are minimized in relation to anticipated benefits.
- *Justice*. Demands that the risks and benefits of research are shared equally among different groups of patients.
- *Respect for persons*. Requires that individuals give informed consent to participation.

It should be noted that informed consent is not solely about protecting individuals from research risks; it is a requirement that ensures that the right to self-determination is realized—that is, that individuals “be given the opportunity to choose what shall or shall not happen to them.”

Quality improvement, and indeed medical care generally, shares the goals of providing the greatest benefit with the least harm, providing equitable access to help to all, and ensuring that individuals have a right to participate in decisions regarding their care. However, QI occurs in the context of providing health care to patients who have consented to treatment explicitly or implicitly (by presenting for care). Health-care providers have a responsibility to provide appropriate treatment.

The same ethical principles that are applied to potential research subjects—beneficence, justice, and respect for persons—guide health-care providers in their efforts to ensure that patients receive care that conforms with current medical knowledge (leaving aside for the moment issues of coverage and benefits) and that care is effectively delivered. Therefore, they



have an ethical responsibility to monitor the care they are delivering and to improve it where it is deficient. If there is an ethical responsibility to undertake QI efforts, there is also a responsibility to manage and conduct QI effectively and well. Unfortunately, QI activities in many organizations are decentralized, fragmented, and ad hoc, lacking a reliable structure of management of and accountability for quality.

## How Can Patients Best Be Protected?

Having discussed in some detail the considerable risks that patients face in nonresearch environments, and having argued for a more comprehensive framing of the ethical responsibility to manage and improve quality, this chapter now argues that QI requires oversight by a responsible structure accountable to senior management and the governance of the institution. This will not only protect patients from ad hoc or poorly conceived QI projects, it will also ensure that the institution has a vigorous and strategic agenda to improve the quality of its care. Ideally, this agenda should be managed cooperatively by the clinical and the administrative leadership of the organization, reporting ultimately to the Board of Directors through a quality committee.

## Why IRBs Are Not Well Suited to This Responsibility

There are a number of reasons why IRBs are not the best solution to the oversight of QI:

- *QI interventions should be part of an overall quality-management strategy that is centrally linked to the operations of the entity.* Quality management should not be viewed as a set of projects, but as the heart of the operations of any institution. These projects need to be strategically chosen and, once completed, embedded in the organic functions of the organization.
- *QI initiatives should involve clinicians and workers in the design of the systems in which they will work.* This is true both because these individuals are intimately familiar with the details of their work environment and because they will need to work with the new systems that are designed to improve it. While clinicians and workers need the support of quality experts to optimize possible improvements, their participation in the process of redesigning their work has repeatedly been demonstrated to be crucial to success.
- *IRBs were designed to consider the impact of research on research participants.* While high-functioning IRBs are expert in research and science, they were not created to design clinical and management processes.
- *IRBs are often overworked and backlogged.* Given the urgency for improvement in the quality of health care, it is counterproductive to contemplate delays in the important business of redesigning the nation's health-care system by overloading already heavily burdened IRBs with the review of activities for which they were not designed.

## Is Quality Improvement Ever Primary Research?

Determining the boundaries between QI and research is challenging. A useful distinction was made by Brook and Lohr between the efficacy of a given intervention (does it work under ideal circumstances, i.e., the closely controlled circumstance of clinical trials?) and its effectiveness (how well does it work in XYZ hospital?).<sup>17</sup> Usually, there is a gap between efficacy and effectiveness—in other words, a gap between care provided under ideal circumstances and care provided in the real world of a health-care institution. QI goes one step further by seeking to intervene so that health-care activities that are of proven efficacy under ideal conditions and effectiveness in real-world settings get implemented in routine care. QI attempts to bring the performance of an organization closer to the ideal.

It should be noted, however, that QI efforts can sometimes provide evidence of the effectiveness of treatments. For example, QI activities designed to reduce variations in the timing of antibiotic administration for surgical patients have demonstrated that administration of antibiotics in the two-hour window prior to surgery is associated with improved patient outcomes.

In general, if the goal is to determine the efficacy of a given clinical treatment intervention or its effectiveness in a real-world setting, it is research. If the goal is to incorporate treatments of proven efficacy and effectiveness in a particular hospital, it is usually QI.

## The Current Framing of What Constitutes Research Is an Impediment to Innovation

Applying the Common Rule's definition of research too liberally to QI activities has the potential to stifle innovation and excellence in QI efforts. Such misapplication is embodied by decision rules such as, "If it results in 'generalizable knowledge,' it is research," or, "If it is going to be submitted for publication, it would need to go through IRB review."

There are many ways of producing generalizable knowledge through QI efforts. For example, epidemiological analysis of patterns of infection in hospitals is crucial to reducing infection rates. Mining of observational data and examination of practice patterns and outcomes provide an opportunity to identify aberrant practice patterns or to standardize around best practice. Interventions to design an effective process where none has previously existed likewise will result in more-effective healing. QI activities often produce knowledge that will be useful to other practitioners and institutions<sup>18</sup> and that becomes a mainstay of evidence-based practice. The more sophisticated the quality-management system, the more potential generalizable knowledge will be generated in the course of its efforts to improve quality. This can be true without a single patient ever being exposed to risk as a result of the analysis. Ultimately, many patients will benefit when a QI intervention has been successful. The explosion of the health system's capacity and need for these QI activities was probably not anticipated by the original framers of the Common Rule, which appears to be most relevant to clinical-trials research and the paradigm of the individual patient dealing with a single physician, as opposed to today's complex health-care system which involves multiple clinicians and staff and often coordination across different institutions.

This type of learning that occurs in QI activities is precious and should be disseminated to the broad practice community as effectively as possible. The more effective the quality management system and the more successful the QI intervention, the more urgent it is to get the knowledge out to a broader audience. The alternative path precludes shared learning and requires each provider organization to “invent its own wheel.” Meanwhile, patients in more-average settings will continue to receive suboptimal care. The rule of thumb that defines the possibility of publication as a trigger for IRB review not only provides no added value to the patients whose treatment provided the nexus of the QI intervention, it creates an important barrier to the dissemination of knowledge that could save lives and improve the care experience for millions of other patients.

This raises the question of where such triage to IRBs ought to occur. The structure that governs quality management and improvement may be the appropriate entity to discern an intervention that is a departure from the desired standard of care and that should undergo the kind of weighing of risks and harms that IRBs were developed to conduct. Such a committee should ultimately be accountable to the governance of its institution.

### **The Special Case of Efficiency**

Efficiency needs to be thought of in a broader ethical context that recognizes that higher cost is not necessarily associated with superior quality. Although Medicare spends, on average, about 60 percent more per enrollee in Miami than it does in Minneapolis,<sup>19</sup> there is no evidence that the quality of care is superior in Miami. The evidence actually suggests that the quality is slightly worse. (Non-Medicare use and expenditure patterns are similarly skewed. In a health-care environment where escalations in health-care costs are demonstrably associated with increases in the rate of uninsurance, true efficiency improvement should be at least an implicit goal of health care.)

Nevertheless, there seems to be particular energy in some ethical circles around the argument that interventions intended to improve efficiency (same outcome at lower cost or better outcome at the same cost) often are performed under the banner of QI. (This may be related to the fact that the word “efficient” is often used interchangeably with “less expensive.”) Implicit here is the idea that cutting costs may put patients at risk. Sometimes this may be the case, but where the proposed intervention is built on well-established evidence (for example, where it is proposed that a therapeutically equivalent generic drug will be substituted for a more expensive brand-name drug), it should fall under the category of health-care operations and be considered a prerogative of management and physician leadership. Neither QI committee nor IRB review should be necessary. Because the Food and Drug Administration has already established therapeutic equivalency, there is no quality or ethical issue at stake.

On the other hand, in cases where the organization is considering tradeoffs between costs and quality, consideration of the ethics of the proposed change is warranted.<sup>20</sup> Some proposed changes in process that lower costs are likely to fall into a gray zone of unknown impact on quality. These kinds of tradeoffs should be considered by the same infrastructure that is managing the issue of overall quality.

## What About Privacy?

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) created vigorous new requirements for the protection of patient privacy. This is an important issue, and there is no doubt that QI, like other management activity, can result in the inappropriate exposure of confidential patient information. Therefore, privacy concerns related to research should probably continue to fall under the purview of IRBs, and privacy concerns related to quality should be the responsibility of the quality-management infrastructure.

That being said, it can be argued that some organizations have an outmoded way of thinking about privacy. Fundamentally, the way privacy is considered depends on how the clinical relationship is framed. While there is a new understanding in the health-policy and health-quality communities that quality is enhanced by systems, teamwork, and enhanced communication, the framing of privacy issues is still often driven by an old paradigm of a dyadic relationship between a patient and a physician. This is particularly problematic, because we know that transitions between treatment settings and even among practitioners within the same institution are points of high risk for medical errors of omission and commission. It is more useful and practical to frame the relationship in a patient-centered paradigm, between the patient and all the providers who are providing care for him or her in a particular setting. While this does not solve the problem of patients being cared for by multiple specialists working independently, it does make privacy concerns less of a barrier for integration of care and QI within institutions. The risk of being injured or of receiving suboptimal care presumably outweighs the risks of breaches of privacy that are associated with moving beyond an excessively narrow definition of the clinical relationship. Needless to say, there is a concomitant responsibility to ensure that all members of the team having access to personal health information are vigilant about ensuring that patient privacy is protected. It is also reasonable to inform the patient that information will be shared across providers and QI staff as necessary to ensure a consistent level of quality.

## Conclusion

It is important to remember that patients are harmed and their opportunity to heal is reduced when the quality of care provided to them is not what it could be. Patients are “human subjects” who may receive health care that is not safe and effective. While it is certainly conceivable that a QI intervention might pose an undue risk to patients, patients receiving care in a setting that accepts mediocre results poses risks to their well-being that are real and substantial and likely of much greater magnitude. The potential benefits of medical knowledge have been gained through the cooperation of hundreds of thousands of human subjects in thousands of studies. Fulfilling the promise of this knowledge through state-of-the-art health-care delivery is an important part of ensuring the value of those subjects’ legacy.

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## Publication and the Ethics of Quality Improvement

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*Frank Davidoff*

Publication is generally seen as playing a supporting role, rather than that of a protagonist, in the drama of scientific and scholarly work. But as the “information age” continues to unfold, the hidden powers of publication have begun to emerge. Nowhere is this clearer than in publication’s relationship with medical quality improvement (QI). One particularly compelling aspect of this relationship, which might be called “the tyranny of generalizability,” is the subject of this chapter.

The legions of people now hard at work to improve the quality of health care face a curious “improvement-publication paradox”—a distressing and rather Kafka-esque double bind. On the one hand, they feel an obligation to share publicly the information they have gained in doing their improvement work—ideas, methods, results—as widely as possible, particularly by publishing them. On the other hand, they are coming to understand that publishing accounts of QI may put them at risk of serious public censure, as happened recently to a group of clinicians in Pittsburgh,<sup>1</sup> hence bringing QI efforts to a halt. Indeed, it is quite clear from the Pittsburgh case that if the authors of the paper in question had simply gone about quietly improving their care processes and had not made the extra effort to write it up and publish it, they would have avoided these academic and administrative difficulties. How did publication become the instrument of frustration and obstruction?

“Unceasing movement toward new levels of performance”—that is, continuous improvement—is arguably the core element of all professionalism.<sup>2</sup> Consequently, as suggested elsewhere,<sup>3</sup> failure to publish the results of medical improvement work undermines professionalism in a number of important ways. First, failure to publish makes it hard to establish the repeatability of specific improvement initiatives—a crucial measure of their efficacy. Second, it minimizes public scrutiny of improvement work, hence limiting accountability. Third, it deprives those who do improvement work of the opportunity and the incentive to clarify their thinking that writing up their work can provide. Fourth, it slows the spread of established improvements. Fifth, it removes an important stimulus to innovation, since innovations build on each other. And finally, it is ethically questionable, since it fails to give back important information to the public in return for the risks, burdens, and costs assumed by the people who are recruited to participate in improvement activities.

At the same time, those patients and providers who participate in medical QI need protection from any and all avoidable risks, burdens, and costs associated with improvement. (Some observers have, however, noted the irony in the likelihood that patients cared for in medical

systems that are *not* actively engaged in QI may need protection more than patients cared for in systems that are.) In years past, medical-care improvement was generally an informal, fragmented activity, largely the work of individual practitioners. In recent years, however, as both public and professional pressure for improvement has grown, medical QI has become increasingly planned and organized, involves large numbers of participants, and requires the collection and analysis of data, thus, superficially at least, coming to resemble clinical research.<sup>4</sup> It is perhaps not surprising, therefore, that the mechanisms developed to protect human subjects in clinical research would be seized on in the search for ways to protect participants in medical QI.

That is exactly what happened in Pittsburgh.<sup>5</sup> In that case, a QI initiative was deemed, retrospectively, to have been research, primarily because a report of the initiative was later published, which in turn was taken as *prima facie* evidence of “generalizability.” And since the project involved human subjects (i.e., patients) and had not undergone ethics (Institutional Review Board (IRB)) review before it was undertaken, it was judged to have violated ethical standards, i.e., the so-called Common Rule.

The framers of the federal standards for protection of participants in human-subjects research, which have come to govern virtually all clinical research in the United States, understandably felt they needed to define *research*. Without such a definition, how would anyone know when independent, formal review of a change in medical practice was appropriate and necessary? The result was the definition of research used in the Common Rule: “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”<sup>6</sup> Through this relatively simple definition, generalizability thus became enshrined as the touchstone for recognizing research. Since generalizability is a rather abstract concept, however, those charged with applying the Common Rule have needed specific, concrete identifiers of generalizability. The most obvious and tangible, hence the most telling, identifier is, of course, whether the results are published.

The relative simplicity of the Common Rule definition has been useful in the huge and complex task of keeping human-subjects research orderly and safe. But by relying on such a stripped-down definition, the Common Rule fails to deal with several important real-world ambiguities. That failure contributed importantly to the difficulties in Pittsburgh and continues to contribute more generally to the “improvement-publication paradox.” Two ambiguities, in particular, stand out: timing and intent.

In using the words *systematic* and *designed* in its definition of research, the Common Rule assumes that people always know beforehand that the information they are about to generate will be a contribution to generalizable knowledge. The reality, however, is that the applicability and value—in a word, the generalizability—of much medical information is recognized only after the fact. For example, case reports and case series which, for all their limitations, contribute importantly to the body of medical knowledge<sup>7</sup> are based on clinical data that are collected in an ad hoc fashion, simply as part of the process of providing care and before any systematic plan or design is developed to make the observations generalizable. When those data are subsequently assembled, organized, analyzed, and published, is the generalizable knowledge that results simply a matter of learning from experience, or is it really “research”? And since the clinicians involved in publishing case reports and case series have no reason to request formal

a priori IRB review of their data-collection procedures and generally do not do so, can they be said to have violated the Common Rule? The rule is silent on such ambiguities of timing. (The more recent Health Insurance Portability and Accountability Act (HIPAA) legislation is specifically intended to mitigate the potential harm that can result from the use of clinical data for purposes other than direct patient care, but the restrictions of that legislation apply broadly, not just to research.)

The Common Rule definition of research also reflects the assumption that generalizable knowledge results only from activities that are “systematic” and that are “designed” mainly to develop such knowledge. That is, it assumes both that the primary intent of researchers is to benefit people (including future generations) other than participants in the immediate, local research situation and that researchers are conscious of that intent. (The researchers themselves also benefit from their discoveries, although that benefit is unlikely to be their primary intent in doing the work.) Clinical research clearly bears the stamp of that intent. For example, most clinical research requires participants to take the chance that they will receive treatments that are not optimal (or may even be harmful)—hence, of course, the requirement for informed consent. This stands in contrast with clinical practice, in which providers are obligated to choose the best known management interventions. Similarly, researchers are under no obligation to see to it that an intervention found as a result of their research to be effective will be implemented or continued for those who participate in the study. In clinical practice, providers are, of course, expected to continue effective interventions as long as patients need them. Finally, the data generated in clinical studies may not be made available for months or even years. The data generated in clinical practice are fed back to providers and patients almost immediately. Direct benefit to the participants in research, while not totally ignored, is a secondary consideration.

Medical QI, aside from being a core element of medical professionalism, shares virtually all of the characteristics of clinical practice. Its primary intent is to provide all patients with the best possible care, here and now, rather than to discover new scientific truths, for others and for the future. It is obligated to continue that optimal level of care as long as necessary. And it is expected to make relevant data available locally to patients and providers immediately and continuously.<sup>8</sup> When information coming from a QI project is subsequently recognized as being of general importance and is then published, in the absence of a priori IRB review, have the authors of that published report violated the Common Rule?

Although the Common Rule itself does not answer the questions of timing and intent, the Belmont report, from which the Common Rule was developed, does. In its words:

Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is a practice and need not be reviewed as research.<sup>9</sup>

According to this reasoning, most medical QI need not be considered research, since it is clearly a procedure applied in practice, and is designed primarily to enhance the well-being of particular individuals and groups, rather than to produce generalizable knowledge. Thus, while a narrow interpretation may, as in the Pittsburgh case, conclude that unless it has under-

gone a priori ethics review, a QI project that is subsequently published violates the Common Rule, such a judgment is inconsistent with both the letter and the spirit of the document from which the Common Rule draws its moral authority. At the same time, it is reasonable to conclude that QI projects can and should be seen as having a research component if the initial plans explicitly call for a substantial effort to produce generalizable knowledge in addition to providing direct and continuing benefit to participants.

Although the complications resulting from publication of QI work have been difficult for all concerned, they have served a useful purpose in bringing to the surface a number of problems with the Common Rule itself, as well as the perverse consequences the rule can create. Apart from an obvious technical flaw (the tautology created by including the word *research* in its definition of research), two substantive problems in the rule are of particular concern. First, and perhaps most important, is the improper assumption of transitivity—a flaw in logic. That is, although the Common Rule appropriately assumes that all research strives to be generalizable (hence publishable), it also appears to assume that all investigations that are published (hence, judged to be generalizable) are research. This interpretation of the rule contributed substantially to the Pittsburgh case. However, roughly two-thirds of the original studies published in clinical journals, which are therefore important sources of generalizable information, are observational in nature, many of them using clinical, administrative, or epidemiologic data that were recognized only after the fact as being of potential interest and value.<sup>10</sup> Moreover, published reviews, commentary, and, as noted, case reports and case series are generally not considered “research,” or at least not “original research,” and are rarely, if ever, subjected to a priori ethics review. The judgment that publication, hence generalizability, defines research (the assumption of transitivity) is simply not warranted.

Second, because its definition of research concerns itself solely with generalizable (hence publishable) knowledge, the Common Rule can be interpreted to mean that knowledge that is not published is less important than knowledge that is published. By implication, therefore, the Common Rule appears to assume that patients and providers who participate in activities that do not lead to publishable knowledge do not require the same protections required when the knowledge is to be published. In fact, although medical QI directly involves human participants, includes trials of many new processes and procedures, and often produces generalizable knowledge, much of that knowledge is gained through experiential learning, both formal and informal, rather than rigorous scientific discovery,<sup>11</sup> and most of it is, unfortunately, never published. The implication that forms of discovery other than “research” are somehow less meaningful and of less ethical concern, on the grounds that they do not produce generalizable (publishable) results, does not seem defensible.

An unintended, and potentially perverse, consequence of the Common Rule’s first problem (that is, the assumption that anything that is published may be considered research) is that people might be tempted to submit virtually all QI projects to their local IRBs for formal up-front review in an effort to protect themselves from the negative consequences of failing to obtain such review, in the event they ultimately decide to publish their work. The majority of IRBs are, however, already overburdened, understaffed, and inadequately funded; full IRB review is often slow and cumbersome; and the ethical judgments of IRBs are frequently inconsistent.<sup>12</sup> Moreover, the rationale for and mandate of IRBs is the protection of human

subjects in clinical research, rather than in QI in its current, broader sense; consequently, few IRBs are familiar with the problems, methods, and ethical issues associated with QI work. Flooding IRBs with QI proposals would very likely interfere with IRBs' ability to carry out their intended research-related function.

Curiously, a similarly obvious, and equally perverse, consequence of the second problem with the Common Rule (that is, blindness to the ethical issues raised by participation in medical activities other than research) is the converse of the first: People may use this interpretation of the Common Rule to "game" the system. That is, researchers may try to avoid the delays and frustrations involved with formal IRB review by claiming that their studies are really "just" QI, arguing that the Common Rule mandates ethical review only for research, not for QI. Anecdotal reports suggest that some researchers are already engaging in such practices.

Yet another and more general negative consequence would be the chilling effect that defining medical QI as research would have on improvement activity itself. That is, many people now involved in medical QI could be discouraged from undertaking such projects in the first place if the additional paperwork, delays, and frustrations of IRB review were always required before they started, particularly since that review is seen to be irrelevant and unnecessary in much QI work. Of equal concern, others who continue to be actively involved in improvement efforts would be careful never to publish their results, fearing that the "generalizability" implicit in publication might come back to haunt them if they had not obtained a priori IRB review for their improvement projects. The improvement community, and medicine generally, would thus be deprived of contributions to useful knowledge; ironically, the Common Rule could therefore be seen as standing in direct opposition to the core professional responsibility of "unceasing movement to new levels of performance."

Fortunately, the emergence of these shortcomings of the Common Rule has also produced a number of useful lessons. The first is a growing recognition of the need to afford participants in QI efforts appropriate protection from potential harm, whatever those efforts are called and whether or not they are systematic investigations that result in generalizable, publishable knowledge. The potential for harm, hence the need for protection, in QI is affected by many factors, including the degree to which the improved practice deviates from established evidence and current standards of practice; the number of people who might be affected by the change; the effect size and efficacy of the intervention being considered; and what is known, or can be reasonably assumed, about associated risks and their severity. Thoughtful, responsible clinicians have always considered these issues when moving beyond known and approved practices. For example, before proceeding with the legitimate and often highly useful practice of using drugs for "off label" indications, they confer—if they have any sense—with independent, expert colleagues, explain the issues to patients, and obtain informed consent. Importantly, these concerns highlight the need to develop new and better mechanisms for ethical review of QI work, particularly the larger, more formal, and more complex QI efforts. What is not clear is who should undertake that task; IRB review does not appear to be the appropriate mechanism.

A second lesson is the importance of considering, consciously and explicitly and right from the outset, the likelihood that any improvement activity might ultimately generate generalizable, hence publishable, knowledge. If and when publishability becomes a serious pos-

sibility, the planners of QI efforts should at least consider the need for some kind of ethical review, formal or informal, by an IRB or by another mechanism. Keeping clear, dated records of the planners' thinking about generalizability and the possibility of publication should help to prevent later misunderstandings about the true nature of the work. Finally, in writing up their results, authors should avoid "dressing up" QI work as research in the hope that it will thereby have greater appeal for the editors and peer reviewers of clinical journals. Using established publication standards for QI can help to increase transparency about the exact history, nature, and purpose of improvement work.<sup>13</sup> Quality improvement should not be considered less legitimate, or less publishable, because it is a process of learning from experience and not, strictly speaking, scientific discovery.

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## The Implications of the HIPAA Privacy Rule for Quality-Improvement Activities

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Health-care professionals and organizations have legitimate reasons for using health information that identifies individuals and/or discloses identifiable health information to others within or outside their organizations. However, because “medical records contain some of the most intimate details about an individual that can be found in a single place,”<sup>1</sup> the public has long been concerned about the privacy of health information. In addition to revealing the nature and frequency of medical examinations and procedures, an individual’s medical record might also include information about the use of legal and illegal substances, the diagnosis of sexually transmitted diseases and mental disorders, or the incidence of abortion and sexual assault, as well as sexual orientation. Medical records might also contain information about a patient’s genetic makeup, as well as health information about one’s spouse(s), nonmarital sexual partners, children, and other family members.

Public-opinion polls conducted in the 1990s revealed that many Americans were concerned about employers, insurers, and others having access to medical and mental health information that might be used for non-health-related purposes. Survey respondents also said they wanted control over the use and disclosure of their identifiable health information and supported federal initiatives to protect the privacy of medical records.<sup>2</sup> Media reports about breaches of medical privacy and the increasing use of health data in electronic form contributed to the public’s unease about who might have access to medical information and for what purposes.<sup>3</sup> Yet at the end of the 20th century, there was no national law or regulation that protected health information privacy. That changed in 2003, when the U.S. Department of Health and Human Services (DHHS) Standards for the Privacy of Individually Identifiable Health Information (the Privacy Rule) went into effect.<sup>4</sup>

The DHHS issued the Privacy Rule pursuant to the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which allows individuals to change jobs without losing their employer-based health insurance for a specific period of time. By making health insurance portable across jobs, HIPAA initiated the development of an electronically based health-care system and heightened public concern about how identifiable health information would be used and disclosed. The Privacy Rule balances individuals’ interest in the privacy and confidentiality of their health information against the need of health-care professionals, health-care organizations, and researchers to have access to identifiable health information without undue burdens imposed on its use and disclosure.<sup>5</sup>

An example of when health-care professionals and organizations may need access to identifiable health information is when they undertake quality-improvement (QI) activities. These activities have been defined as “systematic, data-guided activities designed to bring about immediate positive changes in the delivery of health care in particular settings.”<sup>6</sup> Typical QI activities include developing tracking systems that monitor receipt of timely test results, altering routine nursing procedures to identify whether one method is better at reducing performance time while maintaining patient comfort, and improving the way hospital patients are moved through diagnostic departments. QI activities are intended to produce benefits for patients and are part of normal health-care operations.<sup>7</sup>

This chapter examines how the Privacy Rule affects the activities that health-care professionals, managers, and health-delivery organizations undertake to improve the quality of health-care delivery. The first section discusses who is covered by the Privacy Rule, the type of health information the Privacy Rule protects, and the requirements for using and disclosing such health information. The chapter then examines the Privacy Rule’s distinction between QI and research and shows that federal regulators have provided little guidance on how to determine whether an activity is QI or research. Approaches to making this distinction are examined and suggestions for developing national policy on the matter are offered.

## Key Provisions of the Privacy Rule

The Privacy Rule applies to what it calls “covered entities.” These are health plans, health-care clearinghouses, and health-care providers that electronically transmit health claims, inquiries about eligibility for insurance benefits, and other transactions listed in the Privacy Rule. Health plans include insurance companies and managed-care entities; health-care clearinghouses include billing services; and health-care providers include hospitals, physicians, dentists, and other persons or organizations (e.g., federal, state, and local governments) that furnish, bill, or pay for health care.<sup>8</sup> An individual who conducts research is not a covered entity unless he or she is also a health-care provider who conducts electronic transactions covered by the Privacy Rule. However, a researcher who is not a covered entity may have to comply with the Privacy Rule if he or she is an employee of a covered entity.<sup>9</sup> The Privacy Rule also applies to business associates, i.e., persons or organizations that are not part of the covered entity but that perform activities for the covered entity such as claims processing, data analysis, utilization review, and billing.<sup>10</sup>

The Privacy Rule regulates the way covered entities handle individually identifiable health information called protected health information (PHI), which is defined as health information held or transmitted by a covered entity (or its business associates) in any form or media (electronic, paper, or oral) that identifies or could be used to identify an individual. An individual’s name, address, birth date, or Social Security number—common identifiers used in medical records—make health information PHI when the identifiers relate to the individual’s past, present, or future physical or mental health condition; the health care provided to the individual; and the past, present, or future payment for the individual’s health care.<sup>11</sup>

**Table 1**  
**Core Elements and Required Statements for a Valid Authorization**

Core Elements
<ul style="list-style-type: none"> <li>• PHI to be used or disclosed is identified</li> <li>• Individuals or organizations using or disclosing PHI are identified</li> <li>• Purpose of use or disclosure is described</li> <li>• Date or event when use or disclosure expires</li> <li>• Signature of individual or guardian and date</li> </ul>
Required Statements
<ul style="list-style-type: none"> <li>• The individual has the right to revoke the authorization in writing</li> <li>• Description of how to revoke the authorization</li> <li>• Description of exceptions to revocation or reference to the covered entity's notice that provides relevant information</li> <li>• Whether the covered entity will or will not condition treatment, payment, enrollment, or eligibility for benefits on the individual signing the authorization</li> </ul>

As Pace, Staton, and Holcomb point out,<sup>12</sup> the Privacy Rule is a reverse approach to protecting health information privacy—it prohibits covered entities from using and disclosing PHI except as permitted or required by the rule's provisions. This means that when a covered entity wants to use an individual's PHI or disclose that PHI to someone inside or outside the covered entity, it must first obtain the individual's specific written permission, called an "authorization," that contains several core elements and requirements.<sup>13</sup> There are certain circumstances when the Privacy Rule permits or requires covered entities to use and disclose PHI without authorization<sup>14</sup> and when an Institutional Review Board (IRB) or Privacy Board can waive or alter the authorization requirement.

**Table 2**  
**Requirements for Waiver or Alteration of Authorization Requirement**

<ul style="list-style-type: none"> <li>• An adequate plan is in place to protect identifiers from improper use and disclosure and to destroy the identifiers at the earliest opportunity, consistent with the research, unless there is a health or research justification for retaining the identifiers or if retention is otherwise required by law</li> <li>• The researcher provides adequate written assurance that the PHI will not be reused or disclosed to any other person or entity except when required by law, for authorized oversight of the research study, or for other research the Privacy Rule permits for use or disclosure</li> <li>• The research could not practicably be conducted without the requested waiver or alteration</li> <li>• The research could not practicably be conducted without access to and use of the PHI</li> </ul>
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The Privacy Rule permits, but does not require, covered entities to use and disclose PHI without authorization when the covered entity (1) provides the PHI to the individual; (2) uses and discloses the PHI for its treatment, payment, and health-care operations; (3) gives individuals the opportunity to agree or object to certain uses and disclosures of their PHI specified in the rule; (4) engages in incidental use and disclosure of PHI as specified in the rule; and (5) uses and discloses PHI for purposes related to 12 national priorities, for example, when required by law or for research activities.<sup>15</sup> When a covered entity uses and discloses PHI, it

**Table 3**  
**Minimum Necessary Requirement**

Covered entities must make reasonable efforts to use, disclose, and request only the minimum amount of PHI needed to accomplish the intended purpose of the use, disclosure, or request except when PHI is

- disclosed to or requested by a health-care provider for treatment
- disclosed to the individual about whom the information is requested, or the individual's personal representative
- used or disclosed when an individual's written authorization has been obtained
- disclosed to the DHHS for investigation of complaints or for compliance review or enforcement
- used or disclosed as required by law
- used or disclosed as required for compliance with the HIPAA Transactions Rule or other HIPAA Administration Simplification Rules

must make reasonable efforts to ensure that only the minimum amount of the PHI is used, disclosed, and requested. However, there are several circumstances in which the Privacy Rules' minimum necessary requirement does not apply.<sup>16</sup>

The Privacy Rule permits covered entities to use and disclose PHI for research purposes without obtaining individuals' authorization when (1) an IRB or Privacy Board waives or alters the authorization requirement; (2) the researcher confirms that the use or disclosure of the PHI is solely to prepare for research and certain conditions are followed; (3) the research is conducted with PHI from deceased individuals; or (4) the researcher uses a limited dataset of PHI under a data-use agreement. A limited dataset is health information that excludes 16 elements from an individual's medical record that could be used to directly identify the individual or the individual's relatives, employers, or household members. The Privacy Rule considers a limited dataset to be PHI because it contains elements that might link the health information to a

**Table 4**  
**Identifiers to Remove to Make Records a Limited Dataset and Not Subject to Authorization Requirement**

1. Names
2. Postal address information, other than town or city, state, and zip code
3. Telephone numbers
4. Fax numbers
5. Electronic mail addresses
6. Social Security numbers
7. Medical record numbers
8. Health-plan beneficiary numbers
9. Account numbers
10. Certificate/license numbers
11. Vehicle identifiers and serial numbers, including license-plate numbers
12. Device identifiers and serial numbers
13. Web universal resource locaters (URLs)
14. Internet protocol (IP) address numbers
15. Biometric identifiers, including fingerprints and voiceprints
16. Full-face photographic images or any comparable images

specific individual. Thus, to release a limited dataset, a covered entity must establish a written data-use agreement with the recipient that explains how the PHI will be used and protected.

Unlike a limited dataset, de-identified health information is not PHI, and covered entities may use and disclose it without restriction, which means that they do not have to obtain individuals' authorization. The Privacy Rule permits a covered entity to de-identify health information in two ways: by using statistical methods or by using the "safe-harbor" method.<sup>17</sup> When statistical methods are used, a statistician or other individual with relevant expertise must certify that there is a "very small" risk that the de-identified information could be used to identify the relevant individual. Under the safe-harbor method, 18 elements that could be used to identify an individual or the individual's relatives, employers, or household members must be removed from the medical information. The Privacy Rule permits a covered entity, a researcher who is a covered entity, or a business associate to de-identify health information.

**Table 5**  
**Identifiers That Must Be Removed to Make Records De-identified and Not Subject to the Authorization Requirement**

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1.	Names
2.	All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geographical codes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of Census, <ul style="list-style-type: none"> <li>a. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people</li> <li>b. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000</li> </ul>
3.	All elements of dates (except year) directly related to an individual, including birth date, admission date, discharge date, date of death; all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4.	Telephone numbers
5.	Fax numbers
6.	Electronic mail addresses
7.	Social Security numbers
8.	Medical record numbers
9.	Health-plan beneficiary numbers
10.	Account numbers
11.	Certificate/license numbers
12.	Vehicle identifiers and serial numbers; license-plate numbers
13.	Device identifiers and serial numbers
14.	Web universal resource locators (URLs)
15.	Internet protocol (IP) address numbers
16.	Biometric identifiers, including fingerprints and voiceprints
17.	Full-face photographic images or any comparable images
18.	Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for de-identification

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## The Privacy Rule and QI

An important feature of the Privacy Rule is that it includes QI in the definition of health-care operations. This means that a covered entity may use and disclose an individual's PHI for its own QI activities without first obtaining the individual's authorization. The DHHS included QI in the definition of health-care operations because it recognized that covered entities need to have access to identifiable health information to improve those operations, that QI is a part of normal health-care operations, and that individuals expect health-care organizations to use their identifiable health information to improve the quality of care.<sup>18</sup>

The Privacy Rule also permits a covered entity to disclose PHI to another covered entity for QI purposes without obtaining an individual's authorization in two circumstances: when both covered entities have or had a relationship with the individual whose PHI is requested and the PHI is related to that relationship,<sup>19</sup> or when the covered entities are part of an organized health-care arrangement (OHCA).<sup>20</sup> The Privacy Rule recognizes five types of OHCA, two of which are relevant in the QI context: (1) clinically integrated settings in which more than one provider provides health care to individuals; and (2) organized health-care systems in which the participating covered entities present themselves to the public as part of a joint arrangement and jointly engage in utilization review, quality assessment and improvement activities, or risk-sharing payment activities.<sup>21</sup>

Although the Privacy Rule includes QI in the definition of health-care operations, it says that QI is part of health-care operations "provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities."<sup>22</sup> Elsewhere in the Privacy Rule, the term "generalizable knowledge" is used in the definition of research, which the rule says is "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."<sup>23</sup> When an activity meets this definition of research, the Privacy Rule's authorization requirement is triggered. Moreover, because the Privacy Rule's definition of research is identical to the definition in the DHHS human-research regulations,<sup>24</sup> covered entities whose activities meet the definition of research may also have to comply with the regulations governing research with humans. These requirements include IRB review and approval of the proposed research, informed consent from research participants (or IRB waiver or alteration of the consent requirements), and other reporting and monitoring activities.<sup>25</sup>

By codifying in the Privacy Rule the definition of research used in the human-research regulations, the DHHS maintained consistency across regulations but also contributed to the confusion over drawing the boundary between research and nonresearch activities. How to determine whether an activity is research or "something else" has long been the subject of debate. In the late 1970s, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research commissioned several papers that addressed the boundaries between research and routine medical practice.<sup>26</sup> These papers revealed that it was difficult to reach consensus on drawing such boundaries. More recently, the issue of distinguishing research from something else has been raised in the context of innovative medical technologies (including surgical procedures),<sup>27</sup> public-health practice,<sup>28</sup> and QI.<sup>29</sup>



There are differing views on how to distinguish QI activities from research. In one view, the potential risk of harm to patients should be the criterion for making this determination.<sup>30</sup> For example, Casarett et al. recommend defining QI as research “when (1) the majority of patients involved are not expected to benefit directly from the knowledge to be gained or (2) additional risks or burdens are imposed to make the results generalizable.”<sup>31</sup> The National Bioethics Advisory Commission expressed the view that the boundary between research and QI could be identified by asking whether the activity is new or already established and whether the information has local or external implications:

If the purpose is to assess the success of an established program, and the information gained from the evaluation will be used to improve that program, the activity should not be considered research involving human participants. Evaluation is a program monitoring tool, and the information gained will immediately benefit the program and/or the individuals involved. However, when quality improvement involving human participants is undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective and can be used elsewhere, the activity is human participant research and subject to the oversight system.<sup>32</sup>

On the other hand, Doezema and Hauswald argue that “ethically there is no meaningful difference between collecting data that has local implications and data that has national implications.”<sup>33</sup>

Others contend that QI activities should be reviewed by an IRB and informed consent should be obtained from patients when the activities involve “the allocation of treatment with or without randomization to different cohorts—generally to identify the most cost-effective care but sometimes to identify best practice. . . . This rule should apply whether or not generalizable information is created for public presentation or dissemination.”<sup>34</sup> Yet for Armstrong et al., the important criterion is the intent to publish the findings of the activities. They say that “when a QI-focused project is undertaken with the intent to analyze and publish the data, it is research and should be submitted to an IRB for review and approval before data collection.”<sup>35</sup>

The approach proposed recently by Bailly et al. emphasizes what an activity is designed to do. They recommend that “the category of research be made up of activities *that are designed to learn something enduring about the nature and function of human beings and their environment*” [italics in original].<sup>36</sup> They contend that under this definition, “most QI is not research,” because

QI is designed to bring about the immediate improvement of care in local settings, and most of the urgently needed QI activity involves changes in practice that are clearly within the standard of care—often moving from “dangerously substandard” and “barely acceptable” practices to “better” and “best” practices. As a result, QI activities are generally *based on* knowledge about the enduring “nature and function of human beings and their environment,” rather than designed to create new understandings in this regard.<sup>37</sup>

Although some individuals who submitted written comments on the proposed Privacy Rule asked the DHHS to establish precise definitions for *health-care operations* and *research*,

the agency declined to do so.<sup>38</sup> The DHHS acknowledged the difficulty in distinguishing between projects that are health-care operations and projects that are research but disagreed with commentators on the proposed Privacy Rule that it could “address this issue with more precise definitions of research and health care operations.”<sup>39</sup> However, the agency said that for purposes of defining research in the Privacy Rule, it would follow the approach established by its human-research regulations:

Under the [DHHS human-research regulations], the ethical and regulatory obligations of the researchers stem from the intent of the activity. We follow that approach here. If such a project is a systematic investigation that [sic] designed to develop or contribute to generalizable knowledge, it is considered to be “research,” not “health care operations.”<sup>40</sup>

The DHHS also offered its perspective on what is meant by generalizable knowledge:

We understand knowledge to be generalizable when it can be applied to either a population inside or outside of the population served by the covered entity. Therefore, knowledge may be “generalizable” even if a research study uses only the protected health information held within a covered entity, and the results are generalizable only to the population served by the covered entity. For example, generalizable knowledge could be generated from a study conducted by the HCFA [Health Care Financing Administration], using only Medicare data held by HCFA, even if the knowledge gained from the research study is applicable only to Medicare beneficiaries.<sup>41</sup>

After the Privacy Rule went into effect, the DHHS issued a series of fact sheets about various aspects of it. In the fact sheet “Health Services Research and the HIPAA Privacy Rule,” the DHHS said that the Privacy Rule “*distinguishes between a research study and a study that a covered entity may undertake as part of its health care operations to understand and improve its own service (i.e., a quality improvement study or assessment related to covered functions)*” [italics in original].<sup>42</sup> This distinction, said the agency, is

based on whether the *primary* purpose of the study in question is to obtain generalizable knowledge. If the primary purpose of such a study is to obtain generalizable knowledge, then the activity cannot be considered to be a health care operations activity. Rather, it meets the definition of “research,” and any use or disclosure of PHI for such study must be made in accordance with the Privacy Rule’s provisions on the use and disclosure of PHI for research.<sup>43</sup>

The DHHS’s emphasis on the primary purpose, or intent, of the activity as a criterion meeting the definition of research is consistent with the approach taken by the Centers for Disease Control and Prevention (CDC) in making the distinction between public-health practice and research. In 1999, the CDC issued guidelines to help public-health practitioners, researchers, and IRBs determine whether an activity is public-health practice or research. According to the CDC,

The key word in the [DHHS's human-research regulations'] definition of research for the purpose of classifying public health activities as either research or non-research is "designed." The major difference between research and non-research lies in the primary intent of the activity. The primary intent of research is to generate or contribute to generalizable knowledge. The primary intent of non-research in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service. Knowledge may be gained in any public health endeavor designed to prevent disease or injury or improve a program or service. In some cases, that knowledge may be generalizable, but the primary intention of the endeavor is to benefit clients participating in a public health program or a population by controlling a health problem in the population from which the information is gathered.<sup>44</sup>

Some commentators have criticized federal regulators for focusing on the intent of the activity in making the distinction between research and nonresearch. For instance, James Hodge contends that "if the primary intent changes, what is initially deemed public health practice can become public health research."<sup>45</sup> Moreover, he points out that to avoid having their activity classified as research and thus subject to the DHHS human-research regulations and the Privacy Rule, public-health practitioners have an incentive to say that their activity "is intended to primarily benefit the public's health."<sup>46</sup> Similarly, health-care professionals, managers, and health-delivery organizations have an incentive to characterize their activities as health-care operations to avoid having to adhere to the Privacy Rule's authorization requirement and to the human-subjects protections required by the DHHS human-research regulations.

Hodge lists several reasons why enhanced guidelines are needed to distinguish public-health practice from research.<sup>47</sup> On the basis of Hodge's analysis, with slight modifications, enhanced guidelines to distinguish QI from research should be developed for the following reasons:

- Differing standards for distinguishing between QI and research may lead to different conclusions by those making the distinction. Thus, it may be difficult for health-care professionals, managers, and health-delivery organizations to properly assess whether their activities constitute QI or research.
- When QI activities are misclassified as research, health-care professionals, managers, and health-delivery organizations have to engage in time-consuming adherence to the Privacy Rule's authorization requirement and the DHHS's human-protection requirements, which may thwart QI activities that can improve the delivery of health care.
- When QI activities are misclassified as practice, health-care professionals, managers, and health-delivery organizations might violate the Privacy Rule and other health-information privacy protections or interact with human subjects without complete adherence to ethical and regulatory protections.
- The Privacy Rule and the DHHS human-research regulations impose greater restrictions on researchers in the interests of protecting health-information privacy and human subjects. This creates incentives for health-care professionals, managers, and health-delivery organizations to characterize their activities as health-care operations to avoid having to adhere to the requirements of the Privacy Rule and DHHS human-research regulations.

- In the absence of clear criteria distinguishing QI from research, health-care professionals, managers, and health-delivery organizations may opt to err on the safe side. This means unnecessarily adhering to the Privacy Rule's authorization requirements and the DHHS's human-protection requirements, which may thwart QI activities and unnecessarily burden IRBs and Privacy Boards.
- Because the definition of research in the Privacy Rule is identical to the definition in the DHHS human-research regulations, there is even greater urgency for clarity. Although both regulations carry penalties for noncompliance, the Privacy Rule's sanctions are particularly harsh.

Ideally, health-care professionals, managers, and health-delivery organizations should have confidence that their activities are in compliance with regulatory requirements, especially when violations carry harsh penalties. For instance, the Privacy Rule's sanctions include civil and criminal monetary penalties, as well as imprisonment, if a violation falls under the criminal provisions of the regulation.<sup>48</sup> Yet, for whatever reasons, federal regulatory officials have been unwilling and/or unable to provide clear and coherent guidance on how to determine whether an activity meets the Privacy Rule's definition of research. Indeed, the DHHS's comments about the intent of the activity and generalizable knowledge are not particularly helpful. Moreover, those who believe their activities fall within the boundaries of QI and thus are not subject to the Privacy Rule's authorization requirement will likely be troubled by the agency's assertion that knowledge may be generalizable even when it can be applied to a population inside the covered entity, as opposed to generalizability being defined solely as knowledge applied outside the covered entity. As noted earlier, some commentators have argued that the distinction between using knowledge to guide change at the institutional level and using it for publication or another form of widespread presentation is unrealistic and not ethically meaningful.<sup>49</sup>

At minimum, two separate but interrelated matters need to be addressed. First, at the institutional level, covered entities should decide who will make the determination on whether an activity meets the Privacy Rule's definition of research. The Privacy Rule does not specify who should perform this function. The DHHS human-research regulations are also silent about who should make the research determination for purposes of compliance with those regulations. Many institutions assign this task to their IRB; however, as Hodge and Gostin point out, "at CDC and within many state and local public health agencies, the initial determination of whether an activity is or is not research is typically made outside of the IRB."<sup>50</sup> For purposes of QI activities, Baily et al. recommend that organizations use a "sorting person" who is trained and authorized to determine which activities are QI, which are research, and which fall into a hybrid category that involves both QI and human-subjects research (QI/HuSR).<sup>51</sup>

Second, there is a need for clear, understandable, and reasonable criteria on which to distinguish QI from research. Hodge drafted a checklist to help health professionals and organizations make the distinction between public-health practice and research that derives from the enhanced guidelines he proposed.<sup>52</sup> Baily et al. propose that a "sorting rule" be developed to guide decisionmaking about the distinction between activities that are solely QI and those that are QI/HuSR; such a rule could also be used to distinguish QI from other types of research:

The rule should use easily observed aspects of an activity to determine whether it belongs to the [QI/HuSR] category—avoiding, for example, reliance solely on the intent of the person initiating the activity and focusing on concrete elements in the activity’s design or context. The rule should also be as consistent as possible with the use of the word “research” in both common language and the regulatory definition, while openly acknowledging that some arbitrariness is inevitable in interpreting the word to devise a practical rule for regulatory purposes. Finally, the rule’s arbitrary lines should be drawn so as to best serve the end goal of protecting human participants—from both the harm that might be caused by the activity *and* the harm caused by quality and safety deficits in the health care system.<sup>53</sup>

It is not clear who should develop such a sorting rule or how it would be crafted. Key stakeholders, including the DHHS, would need to be involved in this policymaking enterprise. One approach could be an incremental process in which stakeholders develop a draft sorting rule that could be pilot-tested in diverse institutions for a specified period of time. The institutions could then provide feedback about the implementation of the draft rule in professional settings and relevant publications, with the goal of eventually developing a sorting rule that regulatory officials will accept for purposes of compliance with the Privacy Rule and the DHHS human-research regulations. Another approach would be for the DHHS to solicit public comments for a regulation or guidance document that defines research more clearly. Neither of these approaches will satisfy all stakeholders, and both are unlikely to provide a quick turnaround time. However, the incremental process might be an attractive alternative to the regulation/guidance approach, because stakeholders could develop a sorting rule to test in real-world settings and revise and test again as necessary before implementing it on a national basis.

## Conclusion

When health-care professionals, managers, and health-delivery organizations that are covered by the Privacy Rule engage in QI activities, they do not have to obtain individuals’ authorization to use and disclose PHI. The DHHS recognized that individuals’ privacy interests are of less concern when covered entities use and disclose PHI for health-care operations than when they use and disclose PHI for research purposes. Yet drawing the distinction between QI and research is not an easy task, and there is no national consensus about the criteria to use in making this distinction. Moreover, federal regulators have failed to provide clear and coherent guidance.

Numerous reports and studies have documented the need to improve the quality of care provided by the American health-care system,<sup>54</sup> and QI activities are on the rise in a wide range of health-care settings. Covered entities need to be confident that when they use and disclose PHI, they are not violating the Privacy Rule. Adherence to the Privacy Rule not only protects covered entities from severe sanctions, it also ensures that patients’ privacy interests the rule was designed to protect are preserved. If the Privacy Rule’s goal of balancing individuals’ health-information privacy against the need for more effective delivery of health care is to be met, clearer distinctions between QI and research are urgently needed.

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## **OHCAs and Collaborative Quality-Improvement Projects: Practical and Ethical Issues**

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*Kevin Lawlor*

An organized health-care arrangement (OHCA) is a mechanism under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule<sup>1</sup> that allows covered entities<sup>2</sup> to share protected health information<sup>3</sup> for purposes such as collaborative quality-improvement (QI) projects. They are allowed to share this information based on their relationship with other covered entities, not on the relationship of a covered entity with an individual. The purpose of OHCAs is to provide covered entities with the means to share protected health information to improve the overall processes of health-care delivery. However, in providing this flexibility, OHCAs may allow covered entities to use the information in ways that, while legally proper and vital for the improvement of the health-care delivery system, cannot be meaningfully understood by individuals, especially as the system grows more complex and interconnected. Ironically, while the Privacy Rule generally increases the protection of medical information, OHCAs may lead to an erosion of individuals' privacy expectations by allowing medical information to be used and disclosed more broadly than it has been in the past.

This chapter reviews OHCAs, how they fit within the overall framework of the Privacy Rule, and their practical and ethical issues. Its intent is to provide background material and raise issues for a broader discussion of the ethics of QI.

### **Options Under the Privacy Rule for Collaborative QI Projects**

The Privacy Rule provides five options for sharing protected health information among covered entities for collaborative QI projects:<sup>4</sup> authorization, affiliated covered entities, common relationships, limited datasets, and OHCAs.

#### **Authorization**

An authorization is specific written permission from an individual to use or disclose his or her information for a particular purpose and to a particular entity.<sup>5</sup> The requirements for an authorization to be valid are detailed, making HIPAA-compliant authorization forms complex. Additionally, the operational burden of distributing and collecting authorization forms makes them generally infeasible for sharing large datasets for QI projects that involve retrospective record review.

### **Affiliated Covered Entities**

An affiliated covered entity consists of two distinct legal entities under common ownership or control that have chosen to designate themselves as a single covered entity.<sup>6</sup> However, as a single covered entity, the component entities may only “use or disclose the protected health information of individuals who receive the [affiliated] covered entity’s health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.”<sup>7</sup> This means that an affiliated covered entity must determine whether there is a nexus between both its component entities and an individual before the entities may share protected health information about that individual. On a practical level, this is a significant issue for sharing large datasets, as the covered entities would have to establish the nexus for each individual whose information is in the dataset.

### **Common Relationships**

The Privacy Rule allows one covered entity to share protected health information with another covered entity “if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship,” and the information will be used only for purposes such as QI.<sup>8</sup> The common relationship is useful but can be very limiting when examining processes of care, as a frequent key question concerns which patients did not receive care via a particular process.

### **Limited Datasets**

A limited dataset is one that has been facially de-identified (i.e., it includes no names or other direct identifiers). The Privacy Rule allows one covered entity to share a limited dataset with another covered entity if the limited dataset is shared pursuant to a data-use agreement.<sup>9</sup> Requirements of such agreements include defining how the information will be used and/or disclosed. Limited datasets allow covered entities to focus on processes of care but have fairly extensive administrative requirements that make their use somewhat burdensome. Additionally, without direct identifiers, it is not possible to link records about a single individual from multiple covered entities.

### **OHCA**

As noted above, an OHCA is an arrangement in which two separate covered entities jointly manage their operations.<sup>10</sup> The Privacy Rule requires “that individuals who obtain services from [an OHCA] have an expectation that these arrangements are integrated and that they jointly manage their operations.” There are five types of OHCA under the Privacy Rule. However, three of them deal with insurance arrangements and are not discussed here. The two that are applicable to care delivery are

1. Clinically integrated care settings in which individuals typically receive health care from more than one health-care provider;

2. Organized systems of health care in which more than one covered entity participates, and in which the participating covered entities
  - i. Hold themselves out to the public as participating in a joint arrangement and
  - ii. Participate in joint activities that include at least one of the following:
    - A. Utilization review, in which health-care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;
    - B. Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or
    - C. Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.<sup>11</sup>

The first type of OHCA is generally thought of as a typical hospital setting, where independent physicians practice at the hospital. Because it requires a “clinically integrated care setting,” its applicability to other situations is limited. The second type of OHCA offers more flexibility, but it can be more difficult to establish, since covered entities must establish how they “hold themselves out to the public as participating in a joint arrangement.”

In general, OHCA is significant for collaborative QI projects because they allow covered entities to share information based upon their relationships rather than on the relationship between the covered entity and the individual.<sup>12</sup> However, OHCA lacks a key constraint that limited datasets have: Once protected health information is shared under an OHCA, the covered entity that received the information is not limited to using it for the purpose for which it was received. The receiving entity may use the information for any purpose permitted by the Privacy Rule.

Finally, it is important to keep in mind that with all the options, covered entities are obligated to use the “minimum necessary” amount of protected health information to accomplish the intended task. While this limitation is significant, it still allows covered entities to share large amounts of information for QI projects, for which this type of sharing is often necessary.

## Policy Rationale

The policy rationale for the options described above is at its core simply a balancing of individuals’ privacy expectations and the need of entities within the health-care system to share protected health information for important purposes beyond direct treatment and payment activities. This balance is fundamental to the framework of the Privacy Rule, which is based on the Department of Health and Human Services (DHHS) 1997 recommendations for compre-

hensive federal privacy legislation. The preamble to the 1999 proposed Privacy Rule describes this framework as one that will

- Allow for the smooth flow of identifiable health information for treatment, payment, and related operations, and for specified additional purposes related to health care that are in the public interest.
- Prohibit the flow of identifiable information for any additional purposes, unless specifically and voluntarily authorized by the subject of the information.
- Put in place a set of fair information practices that allow individuals to know who is using their health information and how it is being used.
- Establish fair information practices that allow individuals to obtain access to their records and request amendment of inaccurate information.
- Require persons who hold identifiable health information to safeguard that information from inappropriate use or disclosure.
- Hold those who use individually identifiable health information accountable for their handling of this information and provide legal recourse to persons harmed by misuse.<sup>13</sup>

Moreover, the DHHS explicitly recognizes the tension between privacy and the need to share information in the preamble to the final Privacy Rule. In discussing the complexity of the Privacy Rule, the DHHS states that “the need to balance these competing interests—the necessity of protecting privacy and the public interest in using identifiable health information for vital public and private purposes—in a way that is also workable for the varied stakeholders causes much of the complexity in the rule.”<sup>14</sup> Likewise, when discussing the purpose of the Privacy Rule, the DHHS notes that “the rule seeks to balance the needs of the individual with the needs of the society.”<sup>15</sup>

However, the DHHS did not reach the Privacy Rule’s current balance until it had undertaken two substantial revisions: the changes from the 1999 proposed rule to the 2000 final rule (which added OHCA’s) and the changes from the 2000 final rule to the 2001 revised final rule (which added the common-relationship and limited-dataset provisions). The rationale for the various options is discussed in the preamble to the 2001 revised final rule, which states that “with respect to disclosures for the health care operations of another covered entity [under the common-relationship option], the Department continues to believe that the condition that both entities have a relationship with the individual is appropriate to balance an individual’s privacy expectations with a covered entity’s need for the information.”<sup>16</sup> The DHHS goes on to add that

In response to commentators who were concerned that [the requirement that covered entities have a common relationship to the individual] would impede certain health care operations activities where the covered entity may not have a relationship with the individual, the Department notes that the new limited data set provisions in §164.514(e) are intended to provide a mechanism for disclosures of protected health information for quality and other health at care operations where the covered entity requesting the information does not have a relationship with the individual. Under those provisions, the final modifications permit



a covered entity to disclose protected health information, with direct identifiers removed, for any health care operations activities of the entity requesting the information, subject to a data use agreement. Additionally, as clarified by §164.506(c)(5), covered entities that participate in an OHCA may share protected health information for the health care operations of the OHCA, without the condition that each covered entity have a relationship with the individual who is the subject of the information. The Department believes that such provisions provide adequate avenues for covered entities to obtain the information they need for health care operations activities, without eliminating appropriate privacy protections and conditions on such disclosures.<sup>17</sup>

This policy rationale demonstrates that individuals' expectations of privacy are limited, but also that the further the use of protected health information is removed from individuals' actual knowledge or permission, the greater the need is for other checks to ensure that the information is not used inappropriately. This is particularly an issue with OHCA because of their flexibility and the significant discretion they permit in implementation.

## Practical and Ethical Issues

The Privacy Rule does not detail how to establish or administer an OHCA, and the Office of Civil Rights (OCR)—the agency within the DHHS that enforces the Privacy Rule—has taken the position that covered entities do not need to take any affirmative, formal action, such as entering into a contract, to establish an OHCA. Rather, as OCR sees it, an OHCA exists simply by the de facto nature of the relationships of the covered entities. Covered entities have consequently taken a range of actions to establish or recognize an OHCA. Some have entered into formal contracts, while others have simply acknowledged the existence of the OHCA in a written document.

Regardless of how OHCA are formed, the following operational issues arise from their existence:

- Who is included in the OHCA?
- Do the members of the OHCA share a common notice of privacy practices?
- What are the activities of the covered entities that meet the requirements of the definition of the OHCA?
- Why is it reasonable to think that individuals should expect that the operations of the members of the OHCA are integrated and jointly managed?
- What are the joint health-care operations of the OHCA?

Covered entities will almost always address the first two issues explicitly, as they must in order to conduct their operations. However, it is less clear whether addressing the last three issues in detail is practical or even useful to a covered entity. While explicitly addressing them allows covered entities to clearly establish that they are in compliance with the Privacy Rule,

doing so could be inordinately difficult. For example, describing all the health-care operations of an OHCA for a large, complex organization and keeping such a description up-to-date would be extremely time-consuming and resource-intensive—if it were feasible at all.

These practical issues lead directly to several ethical issues:

- Is minimal compliance with the Privacy Rule's standards for OHCA's sufficient to adequately protect the reasonable privacy expectations of individuals?
- Do individuals understand the extent to which information is shared within the health-care system if covered entities in an OHCA do not explicitly describe the health-care operations of the OHCA in their notice of privacy practices or elsewhere?
- What ethical obligations do covered entities have to clearly define the health-care operations that they claim make them an OHCA?
- What sort of internal controls, beyond the requirements of the Privacy Rule, should covered entities have on the sharing of protected health information within an OHCA? Should there be constraints on the reuse of protected health information disclosed under an OHCA beyond those required by the Privacy Rule?

## Summary

Of all the options under the Privacy Rule for sharing protected health information for collaborative QI projects, OHCA's provide the greatest flexibility. This flexibility is good insofar as it recognizes the nature of the modern health-care system as a series of interconnected processes that may span different entities. However, if not implemented wisely, such flexibility may undermine the intent of the Privacy Rule by setting a lower set of privacy expectations than have existed in the past. Nevertheless, it may be unrealistic to expect individuals to have an even generally accurate understanding of how health-care organizations share and use information to deliver and improve health care, given the highly complex nature of modern health-care delivery—at least without severely burdening efforts to improve the system. Lower privacy expectations may be the price we must pay for a more efficient health-care delivery system.

## Acknowledgments

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## Notes

1. The HIPAA Privacy Rule can be found in the Code of Federal Regulations (CFR) at 45 CFR Parts 160 and 164.
2. A covered entity is an entity that must comply with the HIPAA Privacy Rule. Health plans, health-care clearinghouses, and health-care providers that submit claims electronically are covered entities. See definition in 160.103.
3. Protected health information is information about an individual's health status, provision of health care, or payment for health care that does or reasonably could identify the individual. See definition in 164.501. The Privacy Rule provides a safe harbor as to what constitutes de-identified information in 164.514(b)(2).
4. Under the Privacy Rule, QI is considered a health-care operation. The complete list of activities that are included in health-care operations is lengthy and can be found at 164.501. Like QI in general, health-care operations do not include research.
5. 164.508.
6. 164.504(d).
7. 164.504(g)(2).
8. 164.506(c)(4)
9. 164.514(e)
10. Fed. Reg. 82461, 82494.
11. See the definition of organized health-care arrangement in 164.501.
12. OHCA also allow covered entities that are part of the OHCA to use a common Notice of Privacy Practices. This is a significant operational issue, especially within hospitals where each physician is typically a separate covered entity.
13. Fed. Reg. 59917, 59923.
14. Fed. Reg. 82461, 82472.
15. Ibid., 82464.
16. Fed. Reg. 53181, 53217.
17. Fed. Reg. 53181, 53217.



## Accountability for the Conduct of Quality-Improvement Projects<sup>1</sup>

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*Melissa M. Bottrell*

### Introduction

In landmark reports on U.S. health care,<sup>2</sup> the Institute of Medicine (IOM) and other distinguished groups have called for major commitments to improvement in health-care quality. Increased application of quality-improvement (QI) techniques to health-care settings will be essential to reducing variations in the quality of care provided by hospitals, clinics, and other entities. These groups have also called for enhancements to the health-care accountability system to encourage the achievement of quality and safety outcomes for patients and the health-care system.

Accordingly, the volume and scope of QI initiatives is likely to increase. At the same time, facility QI efforts are becoming more methodologically complex, causing practitioners to question whether their QI projects might be construed as research and might therefore require review by an institutional review board (IRB). A variety of authors have considered whether and what types of QI efforts might be considered research that requires IRB review.<sup>3</sup> Their analyses suggest the following:

- Some QI projects may have research-like aspects that differ from the standard practice of health-care delivery;
- The research-like aspects of such projects may put patients at risk of physical, emotional, and/or psychosocial harms;
- The research-like aspects and potential for patient harm put practitioners and health facilities at risk for legal and regulatory liabilities in terms of clinical malpractice; and
- Organizations that conduct research are at risk of having their research enterprises curtailed or stopped if they violate human-subjects-protection regulations.

These authors and others have called for oversight systems and accountability approaches for QI projects. Koschnitzke, McCracken, and Pranulis suggest that proposals for quality-assurance programs undergo “periodic appraisal by an institutionally responsible, disinterested review panel.”<sup>4</sup> Casarett, Karlawish, and Sugarman argue that a QI initiative should be reviewed and regulated as research if the majority of patients involved in the project are not expected to benefit directly from the knowledge to be gained or if additional risks or burdens are imposed on patients in order to make the results generalizable.<sup>5</sup> Bellin and Dubler state that prospective QI evaluations that allocate treatments differently among cohorts should be subject

to a review external to the QI process and should trigger informed-consent considerations.<sup>6</sup> They suggest that IRBs and standing facility quality-management committees should create collaborative processes to jointly agree on what QI project designs require IRB review and what designs do not. Nerenz, Stoltz, and Jordan distinguish between QI research projects and QI but state that “some QI projects that are not research may still put patients at risk and may require review by some entity or process other than an IRB.”<sup>7</sup> They identify five levels of review that they would associate with five levels of potential risk. Diamond et al. suggest that QI projects that identify individual subjects require informed consent from patient participants.<sup>8</sup> They also suggest that all QI projects should be supervised by new institutional or regional QI review boards that would operate like IRBs; the boards could be independent, organized as part of IRBs, or connected to institutional ethics committees. Lo and Groman suggest that patients be informed within the required notice of privacy practices that their health information might be used for QI purposes.<sup>9</sup> They claim that most projects do not require review and suggest criteria upon which to base decisions about whether review is warranted or specific individual patient permission should be obtained. The National Ethics Committee of the Veterans Health Administration has suggested that organizations use systematic approaches to promote ethical conduct of QI.<sup>10</sup> They note that the level of scrutiny should correspond to the level of potential ethical concern. For example, projects with minimal burdens or risk beyond those inherent in the clinical encounter may simply require brief review discussions with quality management staff. Other projects may require more formal review by a group such as an ethics committee or multisite review committee.

The health-care system has a variety of mechanisms, regulations, and interrelated systems through which it tries to achieve high-quality, safe health-care outcomes and processes. The standards upon which the ethical practice of QI should rest are discussed in “The Ethics of Using QI Methods to Improve Health Care Quality and Safety.”<sup>11</sup> This chapter does not discuss these standards per se; rather, its purpose is to examine the link between the accountability system for quality and safety and an accountability system for the ethical practice of QI activities. In particular, it discusses specific pressure points in the current quality and safety accountability system that could be modified to encourage the practice of QI according to the ethical standards laid out elsewhere in the project. It also discusses some currently proposed practical accountability approaches. No single accountability approach is recommended; what works best and is most appropriate will differ, depending on the resources, organizational styles, and cultures of different health-care facilities. However, some important benefits that could be realized from changes are noted, along with impediments to actual implementation of those changes.

## **The Current Health-Care Quality and Safety Accountability System**

Accountability consists of three facets: the accountable parties, the content for which the parties are held accountable, and the procedures by which they are assessed and held accountable.<sup>12</sup> Numerous organizations and policies throughout the health-care system intertwine to create the health-care quality and safety accountability system. Formal accountability orga-



nizations include state licensing bodies, private-sector accrediting bodies, the Centers for Medicare & Medicaid Services (CMS), and individual certification and credentialing organizations. Additionally, under certain circumstances, health-care organizations are subject to the accountability requirements in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Regulations<sup>13</sup> and the Common Rule.<sup>14</sup> Moreover, these multiple parties hold each other accountable over different content areas. As such, the system involves what has been called a “reciprocating matrix” of accountability.<sup>15</sup> For example, a hospital may evaluate the activities of its physicians, but it in turn is accountable to government regulators, contracting health plans, and the public. Further, depending on the accountability relationship, the content over which parties are held accountable varies, as do the procedures by which they are held accountable. Some accountability relationships emphasize quality outcomes, while others add an emphasis on quality processes. Unfortunately, few of the organizations that embody these approaches require the use of QI techniques to achieve quality outcomes despite the value such organizational learning may bring. And none—because the criteria have not yet been clearly defined—require that QI initiatives be practiced according to ethical criteria.

### **Pressure Points in the Accountability System for Ethical QI Practice**

Generally, the health-care system uses three accountability approaches to measure, identify, and demonstrate quality and safety: the professional approach, the public-sector approach, and the market-driven approach.<sup>16</sup> To these should be added a fourth, an organizational-management approach that recognizes the locales in which most QI activities are practiced. Specific aspects of these approaches offer points at which the accountability system could be modified to ensure the ethical practice of QI.

#### **Professional Approach**

The professional approach to accountability in the health-care system relies on the actions of private-sector accreditation groups, trade associations, health plans, and other providers to assure quality. In this approach, the profession assumes leadership for policing itself and demonstrating quality to outside parties.

Professional codes of ethics set standards for how professionals—from physicians and nurses to health-care managers—should act ethically in the performance of their duties. Many professional codes require participation in quality efforts—for example, the American Nurses Association Code of Ethics states that nurses should “participate in establishing, maintaining, and improving health care environments and conditions of employment conducive to the provision of quality health care and consistent with the values of the profession through individual and collective action.”<sup>17</sup> Such codes and relevant interpretive statements could be further modified to explicitly require that professionals follow the standards for the ethical practice of QI. Unfortunately, professional self-policing via such standards is secondary to other accountability systems such as certification and malpractice systems. Therefore, modifications to codes of ethics should probably be undertaken as part of a series of steps to build a comprehensive accountability system.

Certification and credentialing organizations such as the Accreditation Council for Graduate Medical Education (ACGME), the American Board of Medical Specialties, and the American Nurses Credentialing Center can add knowledge of the ethical standards for QI to the knowledge required for certification. These organizations already review whether programs to certify and credential health-care professionals include training in the value of QI. For example, the ACGME requires that medical residents gain competency in six broad areas, including “practice-based learning and improvement that involves investigation and evaluation of their own patient care, appraisal and assimilation of scientific evidence, and improvements in patient care.”<sup>18</sup> The ACGME also requires competency in “professionalism, as manifested through a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to a diverse patient population.” The ACGME could use these competencies to highlight the importance of not only the practice of QI, but the practice of QI according to ethical standards as required by professionalism. Such an emphasis could help to provide clinicians with both a QI knowledge base and an understanding of the importance of the ethical practice of QI.

The usefulness of accountability mechanisms targeted to individual professionals could be further extended through addition of an enforcement mechanism. As Davidoff has suggested, journal editors could require that articles that discuss QI initiatives report how those initiatives conform to ethicality standards.<sup>19</sup>

At the organizational level, private-sector accrediting bodies set standards for health-care organizations, assess compliance with those standards, and in some cases focus on the operation and effectiveness of internal QI systems. Some state and federal governments rely on or recognize private accreditation to ensure compliance with licensure or regulatory requirements. To encourage accountability for the ethical practice of QI, the standards of major organizations such as the National Committee for Quality Assurance (NCQA), which accredits managed-care plans, and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which accredits most types of health-care organizations, could be modified to add ethics requirements to their review of the QI that is actually performed.<sup>20</sup>

JCAHO has a clear commitment to hold organizations accountable for actually performing QI initiatives. At the same time, JCAHO has no specific requirements that QI—at least QI that is not considered research—be practiced according to ethical standards beyond those required of clinical practice. This is unfortunate because, as has been discussed elsewhere,<sup>21</sup> it may not adequately recognize some potential harms to patients from QI project participation. Adequate guidance regarding standards for the ethical practice of QI could correct this gap in regulation.

In addition to including standards for ethical QI, private-sector accreditation processes could potentially be strengthened through the development of outcome and process indicators for ethical QI. Initially, indicators might include the rate of breaches of privacy/confidentiality in QI projects, patient satisfaction with participation in such projects, practitioner views of having an ethical QI culture, or the number of projects reviewed by internal management procedures to ensure ethical practice. (See Organization Management Approach, below.) At their most extreme, such measures could even be considered for addition to the regularly collected JCAHO ORYX measures or the NCQA Health Plan Employer Data and Information Set

(HEDIS) measures. Alternatively, items related to the ethical practice of QI could be used in conjunction with tools such as Wagner, De Bakker, and Groenewegen's measuring instrument to evaluate how well an organization's quality systems are integrated into the organizational culture.<sup>22</sup> Information obtained from developing outcome measures or comprehensive tools to evaluate quality systems could, in conjunction with more conceptual accountability systems such as modified codes of ethics, strengthen "external" regulation of QI.<sup>23</sup> Moreover, depending on the measures chosen, little additional work might be required on the part of health-care facilities that are conducting QI projects.<sup>24</sup>

### **Public-Sector Approach**

The public-sector approach to quality and safety accountability relies on regulatory oversight actions of government at the federal, state, and local levels. For example, the CMS certifies that organizations must meet federally specified conditions of participation (COPs) or other standards to receive Medicare or Medicaid reimbursement. CMS promulgates COPs for hospitals, nursing facilities, hospices, and other facilities that receive federal funding. States, typically through their health departments, regulate health-care delivery through licensure of health-care organizations. Similar to changes in standards used by private-sector accrediting processes, public-sector licensure—particularly CMS COPs—could be altered to support the ethical practice of QI.

Such an approach would encourage the ethical practice of QI in the most broadly distributed manner across all types of health-care organizations nationally. Realistically, changing the COPs for each type of organization could be arduous and could require significant political capital that may not be available in the field. Additionally, the state licensure and survey process is fraught with problems, including inadequately educated survey staff and inadequate funding,<sup>25</sup> suggesting that even if the COPs were modified, the survey process would not be prepared to actually review and appropriately enforce them.

If indicators for the ethical practice of QI were developed, the public-sector role could potentially be further amended to include appropriate collection and publication of those indicators.<sup>26</sup> Such publication would likely encounter management concerns similar to those noted for publication of other indicators, but it would be another opportunity to introduce changes to the accountability system for health-care quality and safety that would help to encourage the ethical practice of QI.

The HIPAA Privacy Rule and the Common Rule are examples of mechanisms used by the public sector to ensure accountability around the practice of QI and research. Importantly, both regulations carry strong enforcement mechanisms that are not as readily available in most professional accountability systems.

Federal and state statutory privacy laws, the most widely applicable of which is the HIPAA Privacy Rule, regulate protection of identifiable health information. The Privacy Rule requires that "covered entities"—persons and organizations that acquire, use, disclose, or store health information—protect the individually identifiable health information they create or receive.<sup>27</sup> Covered entities must establish and adhere to privacy protections, including providing patients with information about privacy rights and how identifiable information is disclosed, implementing internal privacy policies and procedures, establishing safeguards to protect data pri-

vacy, training employees to understand privacy laws, and assisting health consumers to exercise their rights under the Privacy Rule. The Privacy Rule states that covered entities may use protected health information (PHI) to perform activities defined as health-care operations—including QI—and research within procedures defined in the law. Different standards apply to disclosure of identifiable health information for QI and for research purposes.

The broad applicability of the Privacy Rule across the health-care system could protect patients from privacy breaches when their data are used for QI initiatives. Some authors have argued that privacy risks may be a key area for potential harm to patients from QI projects.<sup>28</sup> At the same time, the mechanisms within the HIPAA Privacy Rule, such as protection of data from unauthorized review, require that only the “minimum necessary” data be used, and the potential for review by a HIPAA privacy board may ease concerns about data-privacy breaches in QI projects.

It has also been suggested that a HIPAA privacy board could adequately review QI projects and even research projects for which the only significant risk to patients was that of a breach of privacy and/or confidentiality.<sup>29</sup> Privacy boards are meant to be more flexible than IRBs, so the use of such boards could reduce concerns that IRBs would be overburdened if more QI projects were subjected to IRB review.

This suggestion has limitations, however. For example, a privacy board may have skills suitable for review of projects using only existing data for which the only conceivable risk would be a privacy breach. But it may not be skilled at evaluating other risks to subjects or at suggesting how such risks could be reduced. Further, without changes to the Common Rule<sup>30</sup> definition that any project that creates “generalizable” information is research, many large-scale QI analyses, even those that only use previously collected data—such as those conducted by large organizations like the Veterans Health Administration and large managed-care plans—could be considered research and would thus require IRB review. If such review did not take place, the organization could face regulatory intervention from the Office of Human Research Protections (OHRP). Moreover, some QI practitioners argue that projects should only collect data (both prospective and retrospective) rather than intervene to change suboptimal systems to meet their definition of QI.<sup>31</sup> Yet initiatives that do not address systems change fail to meet the ethical responsibilities of health-care professionals and institutions to improve quality.<sup>32</sup> Thus, privacy boards may be only one potentially valuable piece in any accountability system to ensure the ethical practice of QI.

Interpretations and adjunct considerations to the Common Rule have been widely discussed as a means to ensure the ethical practice of QI. Most analysis to date has focused on trying to identify characteristics that could be used to define and distinguish research from QI,<sup>33</sup> from public health,<sup>34</sup> from quality measurement and evaluation,<sup>35</sup> and from treatment<sup>36</sup> in order to determine when projects require IRB review. Yet such analyses continue to confront the problem inherent in the Common Rule definition of research as an activity that is “designed to develop generalizable knowledge.” Some authors have examined characteristics of the projects—such as whether the project design includes additional risks or burdens for patients beyond standard therapy, the intention of the investigator, and whether the project design includes randomization or control groups—in order to distinguish when IRB review

might be required.<sup>37</sup> But these divergent approaches still leave many projects in an “ambiguous” zone, would likely move more projects into IRB review systems,<sup>38</sup> and could have the perverse effect of curtailing QI initiatives.

In the United States, OHRP efforts to clamp down on abuses of human-research subject protections overshadow most discussions of development of an accountability system for QI.<sup>39</sup> Two potential modifications to the Common Rule that could ease the movement toward requiring the majority of QI initiatives to be reviewed by IRBs are worth considering.

One approach would involve changing the definition of research in the Common Rule to something other than an activity “designed to develop generalizable knowledge.” This approach is fraught with significant problems, not the least of which would be the tremendous political will that would have to be mustered to make such a change.

An alternative approach would be to add a review exemption for QI projects such as currently exists for reviews of federally managed programs and educational initiatives. This would require a set of operating guidelines and procedures to define the procedural requirements for certain levels of activity. This approach would also likely require a powerful parallel organization, both to develop the political will to make the change and to assure the public that simple exemption would result in improvements to both the IRB system and QI initiatives. While such organizations exist in other fields—for example, the Centers for Disease Control and Prevention (CDC) and state and local health departments play an important role in regulating public-health initiatives that are not reviewed by IRBs—it is not clear that a similar powerful actor exists in the QI field.<sup>40</sup>

### **Market-Driven Approach**

The market-driven approach relies on use of quality data by health-care purchasers and consumers to choose plans and providers. This approach assumes that quality is a market force on a par (or nearly so) with cost. In a functional health-care market, consumers with adequate information should be able to purchase high-quality, safe health care. Consumer pressure is frequently the focus of efforts to strengthen the accountability system for health-care quality and safety.<sup>41</sup> Quality information is available to consumers in a variety of forms, including health-care report cards and data available through employers on plan purchasing; additional types of information to assist health-care consumers will no doubt become increasingly available in the future. Yet even when they are provided with applicable quality data, consumers continue to rely on personal recommendations of their physicians, family, and friends.<sup>42</sup> Increased emphasis by organizations on informing patients about planned QI projects and project outcomes could enhance the ability of the market-driven approach to further support the ethical practice of QI. Such informing could happen both in the practice of increased use of informed consent for specific QI projects<sup>43</sup> and, more broadly, through increased use of notice information such as through required HIPAA privacy information, facility and health-care organizational information brochures, newsletters, and other publications.<sup>44</sup> Institutions could offer patients information about projects, how those projects are designed to improve the system, and where to obtain further information. Additionally, patient-satisfaction or member-satisfaction surveys<sup>45</sup> could be amended to include questions that ask consumers whether they knew they may have participated in or could in the future participate in a QI project or if they were concerned



about that participation. Certainly, developing the items would require careful pretesting and targeting, but this would be another potential mechanism for using a market-driven approach to further develop the accountability system for the ethical practice of QI.

A drawback to the market-driven approach is that patients rarely have adequate control over their purchasing decisions—for example, many consumers, even those who have employer-sponsored health insurance, are limited in the number of plans from which they can choose. To further enhance consumer power, health-care purchasing groups could encourage QI and its ethical practice through their performance contracting. Purchasing groups can base performance contracts solely on price, or they could add requirements that organizations meet outcome and process standards for the ethical practice of QI. (See the previous discussion of the professional approach.) Incentives would likely be required to encourage group purchasers to target achievement of ethical QI practice in their contracting. Incentives would also be required to encourage group purchasers to assist consumers in understanding the need for QI efforts.

### **Organizational-Management Approach**

The mechanisms that may be most directly and effectively targeted to encouraging the ethical practice of QI are contained in the organizational-management approach to accountability. This approach relies on a facility's internal organizational-management systems and practices to build the data and systems for health-care quality, safety, and the ethical practice of QI. Like the overall health-care system, health-care organizations have webs of accountability. In general, the responsibility for health-care quality and safety at the organizational level is deeded to a variety of groups, including facility leaders and managers, professional clinicians, and quality-management professionals. Those groups are responsible for developing the policy and process structures that help to ensure quality and for developing a “culture of quality” in their organizations.<sup>46</sup> Processes, policies, and organizational culture could all be modified to support the ethical practice of QI.

Facility leaders and managers focus on and use the multiple loci for accountability for health-care quality and safety within their organizations; these loci could be modified to also support the ethical practice of QI. For example, their activities could include requiring participation in QI efforts in personnel descriptions and reviewing the participation in QI as another aspect of personnel merit systems.<sup>47</sup> Standard practices that help to move the health-care system toward a culture of quality could also be modified to ensure that when QI is performed, it is done ethically. Likewise, managers are responsible for overseeing QI practices to ensure that quality management professionals are contributing to a system that encourages a culture of quality. Management could also review whether quality management suggestions result in ethically designed QI efforts as well. In essence, organizational leaders' role is to create a culture of QI in their organizations through policies and practices that ensure that when QI is done, it is done right.

Professional clinicians, including physicians, nurses, social workers, and other professionals, should care about the quality of their care practice as a function of their professional roles and professional ethics. They should use their expertise to identify QI opportunities, participate in creating the culture of QI, and make sure that the initiated QI efforts meet standards



for best practice. (See Chapters One and Two in this volume.) In other words, the clinician's role is to oversee medical outcomes on behalf of patients as a group and to provide good care based on best knowledge. Part of that responsibility includes recognizing and voicing opinions about when QI efforts have the potential to harm patients and when patient participation based on notice or even informed consent could help to ensure patient protections.

If an accountability system for the ethical practice of QI is to be developed, each of these groups must come to believe that practicing QI according to ethical principles and standards is part of their responsibility. To support that idea, certain aspects of the professional approach should be brought to bear. For example, changing JCAHO standards or CMS COPs to include criteria for the ethical practice of QI would certainly make this responsibility clear to managers and facility staff. Gathering information from staff at lower levels of organizations could also be beneficial, since those staff often are more aware of what is really "going on" in their organizations and may be more likely to identify problems with the practice of QI that may be missed by either higher management levels or accreditation processes. Even without amendments to the accreditation processes, however, facility managers must recognize the importance of ensuring protections for patients, irrespective of whether change initiatives are defined as research or QI.

Inculcating this sense of responsibility will be challenging for all parties. In a study comparing the views of quality officers, IRB chairs, and journal editors on whether and when QI activities require IRB review and/or informed consent, quality managers were typically less likely to believe that IRB review and/or informed consent was required.<sup>48</sup> Facility management also may have incentives not to recognize the potential for harm to patients from projects designed to contain costs but which are often called "quality initiatives."<sup>49</sup> Unlike clinicians, who have historically been responsible for quality initiatives, facility managers may have limited personal liability and may in fact be adversely affected personally by negative organizational financial performance.<sup>50</sup> Still, more and more facility boards of trustees are being held liable for the quality of care provided in their facilities, regardless of whether or not practicing clinicians are employees.<sup>51</sup>

Organizations do have a variety of policy tools to help inculcate responsibility for the ethical practice of QI into organizational culture. An organization's bylaws could specify the medical staff's responsibility for practicing QI according to ethical standards and reporting the practice of such standards to the board. The bylaws could also clearly state responsibilities for assessing and improving quality<sup>52</sup> and assuring that quality initiatives meet ethical criteria. Organizational leaders could develop auditable plans that identify the standards under which QI will be conducted and the mechanisms for review. (See Chapter Eleven in this volume). If QI efforts are conducted without following the relevant ethical standards, incident reports could be used to track problems or report the problems to the Board of Trustees or accrediting bodies.

Criteria for what could be considered ethical QI such as those offered by "The Ethics of Using QI Methods to Improve Health Care Quality and Safety" and guidelines for the types of projects that might potentially harm patients could reasonably be used to develop a set of structures internal to organizational management processes. This is not to say that all QI projects should have some kind of review; as many authors have suggested, some types of

QI projects pose little or no threat to participants and have little expected value outside of the local context. Such projects should probably be allowed to continue without any intervention or review.<sup>53</sup>

For projects that might require review, a variety of options intermediate to IRB review could be considered. For example, a facility might require, at a minimum, that QI project managers inform a level of management outside of their direct control that a QI project is being undertaken. A small-cycle project on a particular hospital unit could notify the department chief that the project is taking place. Or a facility might require that all QI initiatives be discussed with the director of quality management. Such discussions, with adequate standards for ethical QI practice in hand, could provide internal oversight to ensure that initiated QI projects receive a minimal level of scrutiny that would not hamper QI efforts but would ensure that projects meet adequate ethical standards and safeguards. Such an internal review could be valuable for projects that require significant management effort and could help ensure that patients are protected and that resources are not wasted.

Nerenz, Stoltz, and Jordan<sup>54</sup> suggest a five-level review process for projects that are not required to undergo IRB review:

- *Level 1.* QI projects or management initiatives with no plausible direct effect on patient care would require no review. This level would include many administrative projects that have no intended or plausible effect on clinical care.
- *Level 2.* QI projects with no plausible risk to patients and for which the only plausible effect would be a positive change in patient care would require no review. Such projects might include those designed to reduce medical errors, reduce adverse drug interactions, or reduce delays in receiving test results.
- *Levels 3–5.* QI projects with minor risk and a presumed benefit (Level 3), projects with no clear promise of benefit greater than risk (Level 4), and projects with a clear possibility of harm to patients (Level 5) should be reviewed by a patient safety or clinical policy committee. The intensity of review would depend on an analysis of the risk and benefit and other appropriate criteria.

Having a clearly defined structure and approach for identifying when QI projects should have some type of structured review and what form that structured review should take could be a significant step toward ensuring that QI project participants are protected from potential harms.

A related but different approach suggested by DeVita and colleagues at the University of Pennsylvania Medical Center (UPMC) Presbyterian Hospital in Pittsburgh would involve registering QI efforts electronically with the quality-management department.<sup>55</sup> The quality-management department could design a web-based interface that would allow a project initiator to quickly provide information about the project's purpose, a description of the procedure to be undertaken, and contact information. In the registration process, the facility could require project initiators to answer a series of questions about their project that help to identify characteristics suggesting that the project should receive a heightened form of review, including IRB review. In the proposed design, such questions include whether the research is being

sponsored or funded by an external agency (for which a “Yes” answer would require IRB review) and whether patients are exposed to additional risks or burdens beyond standard clinical practice in order to make the results of the study generalizable (for which a “Yes” answer would require IRB review). When projects requiring IRB review are registered, the IRB would be electronically notified that a project may need its review. Key managers could use the registration database to identify whether similar or related projects had been initiated previously. Such a system would increase the quality-management office’s ability to monitor and follow up on the practices and impact of QI efforts and would broaden facility awareness of the standards for the ethical practice of QI.

Unfortunately, even these minimal levels of management oversight could possibly stifle small-scale efforts on individual units or by private solo practitioners or clinical groups.<sup>56</sup> For very small scale interventions that have little or no potential for patient harm, it may be reasonable to require no management review, particularly if the organization also uses disincentives to discourage unethical QI practice. For example, the UPMC Presbyterian Hospital<sup>57</sup> and Intermountain Healthcare<sup>58</sup> require all individuals who wish to publish the results of QI initiatives to have their projects reviewed, at minimum, retrospectively by the institution’s privacy board or quality-management committee and, if certain criteria are met, by the IRB. The combination of well-publicized standards for ethical practice of QI (particularly if they are written into organizational policies), requirements that practitioners follow organizational policies (particularly if those requirements are included in personnel descriptions), and restrictions on incentives that lead to external and internal recognition could provide a powerful set of structures to ensure accountability for the practice of ethical QI. A drawback of this multifaceted approach could be that managers might use the system to keep projects that produced harm from being publicized. But well-structured standards combined with this multifaceted approach could significantly reduce the likelihood of harm to patients.

Certain caveats do apply. Requiring only internal management review may not adequately ensure that individuals with knowledge about the principles of QI are involved or that the review will result in recognition of the potential for harms to patients. Additionally, management may face significant conflicts of interest, particularly when initiatives are being undertaken for purposes of cost control. Therefore, any internal management system will require both clear standards for determining the levels of review that should be required for particular types of interventions and the inclusion of individuals with adequate knowledge of ethical standards for QI practice.

It is important to note that the systems discussed above may not sufficiently address circumstances under which QI projects may be sufficiently large, may warrant significant resource use, or may have significant potential to harm patients or practitioners to require specialized, intensive review. For such projects, groups with knowledge and expertise beyond that typically available in management structures may need to be developed. Such groups might be called Quality-Improvement Review Committees. At a minimum, individuals performing these reviews must be knowledgeable about QI techniques and ethical standards for QI and must have access to individuals with specific knowledge of the practice area that will undergo improvement. The review committees should include community representation to prevent group-think, to maintain and support transfer of information to the community, and to help

match quality changes to community standards. Reviews should be situated so that when it is beneficial for projects to work across facilities and across organizational boundaries, the review can be coordinated to ensure common standards and requirements and rational use of resources. The review process could even, as has been suggested, be combined with HIPAA privacy boards and/or quality-management groups so that no new mechanism is necessary.<sup>59</sup> Finally, information regarding project descriptions, designs, and outcomes should be maintained by the organization to enable history-taking and independent review, for example, by JCAHO or state survey-takers.

For projects that require significant oversight and that meet the definition of research with human subjects, facilities could develop IRBs that have the specific expertise to review QI projects. This concept of QI-IRBs is discussed extensively in “The Ethics of Using QI Methods to Improve Health Care Quality and Safety.”<sup>60</sup>

## Conclusion

The need for an accountability system for the ethical practice of QI is clear. The need to distinguish research projects from nonresearch projects is being encountered not only within the area of QI, but also in public health. But when improvement initiatives are considered public-health practice and not research, public health has a significant oversight system through state and federal rules, regulations, and codes to protect the public and the individuals involved.<sup>61</sup> This chapter has outlined a range of options for improving health-care quality and safety. The value of any of these mechanisms will depend, in large measure, on the development of a generally accepted set of standards for which practitioners, facilities, and health-care organizations should be held accountable. However, implementation of an effective system will require that a network of mechanisms be brought to bear on the various actors that influence whether QI is practiced according to ethical standards. Starting with management approaches within organizations and enhanced through external support from accrediting bodies, codes of ethics, and so on, better protection of patients can be achieved while ensuring that improvements in the quality of health care multiply. Development of a multifaceted accountability system will be necessary to maintain patient trust and to stave off the potential for the abuses that led to the development of protections for human subjects participating in research. Of course, the best protection for everyone is achieved when the external organizational culture seamlessly expresses ethical standards in every aspect of practice. Structural accountability systems are only one influence on the organizational culture. Identifiable leadership commitments to the ethical practice of QI are also required. But in the absence of such commitments and as the health-care system moves to a broader understanding of what it means to conduct QI under ethical standards, we must develop an accountability system, beginning with opportunities in management and supported by the professional, public-sector, and market-driven approaches.

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## Quality Improvement or Research: Defining and Supervising QI at the University of Texas M. D. Anderson Cancer Center

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### Introduction

Health-care organizations across the country are rapidly developing new ways of providing up-to-date, innovative care through quality improvement (QI). At the national level, there is concurrently an effort to improve patient safety, tie reimbursement incentives directly to quality-of-care outcomes, and contain costs. These objectives can be best addressed through the QI process. Thus, as the value of QI activities becomes more important, seamless, and transparent, questions arise regarding the definition of QI and how this type of work should be supervised, along with ethical considerations for human participants.

In the past, QI activities have been held at arm's length by some in health-care management. QI activities have been viewed as imposed requirements, necessary to meet standards that were mandated by external organizations. During the past several years, however, management has focused on QI because it has come to understand the inherent value of QI activities, including improved patient outcomes and decreased health-care costs. As a result, QI activities are being integrated into health-care operations more rapidly and aggressively. With this integration, QI leaders should recognize that public scrutiny would call into question the benefit of QI initiatives, since not all initiatives will necessarily result in positive outcomes. It is necessary to provide a format for sharing information and for assuring ethical oversight of QI activities.

During much of the 20th century, research that involved human subjects was conducted without the benefit of formalized ethical oversight. As research continued, ethical oversight was mandated because some research studies did not adequately consider the rights of the individuals involved.<sup>1</sup> In parallel with human research, QI initiatives that involve patient care must have ethical oversight to ensure protection of patient rights and patient safety, particularly when cost reduction and efficiency may be primary motives.

In 2000, a nephrologist published a QI project conducted by the End Stage Renal Disease Network which was accepted as QI work by the Centers for Medicare & Medicaid Services (CMS). The Office of Human Research Protection (OHRP), however, ruled that this project was research and required oversight by the Institutional Review Board (IRB). This led to concerns by clinicians that well-meant efforts to conduct patient-related QI projects could be interpreted as a violation of regulations.<sup>2</sup> In 2002, The Hastings Center initiated a project to

address the issue of how to distinguish QI from research and published a report with recommendations for change.<sup>3</sup> In 2005, the University of Texas M. D. Anderson Cancer Center (M. D. Anderson) established a work group consisting of leaders in research and QI to review the report and develop an approach to ensure that improvement initiatives receive the appropriate level of ethical and scientific oversight throughout the organization. This chapter is a summary of the efforts of this work group. It describes our work in defining QI and outlining a process for oversight of clinical QI projects.

The evolving model of care delivery for M. D. Anderson is based on standards of care and research protocols. When patients enter M. D. Anderson, they are assessed for care designed to benefit them, under either a standard treatment or, when applicable, clinical research. It is important to note that the current standards of care integrate clinical judgment and patient preferences. Experimental treatments are offered only to those patients who volunteer to be a part of a research protocol. Just as research studies are reviewed for scientific merit and ethical considerations, it is equally important for QI activities to have clearly defined methods and criteria based on ethical considerations.

As Mary Ann Baily et al. stated, "In QI, however, the changes made in the process of delivering care are expected to be improvements, and given the serious quality and safety problems in health care, patients are often at greater risk if a current practice is allowed to continue than if a QI activity goes forward. Nevertheless, any change may have unexpected negative consequences, and even the data collection and monitoring that makes the change a QI activity may itself impose burdens on the QI participants."<sup>4</sup>

At M. D. Anderson, we recognize these issues and believe that they are important to address, first by providing working definitions of QI and research, and second by describing methods of supervision and ethical oversight for QI projects. Indeed, we have chosen to view the improvement of QI operations as itself a QI project and are therefore using the QI approach to our work.

Our aim is to develop working definitions of the terms *QI* and *research*, with defined methods of supervision for QI activities within our organization by March 2007.

We have four goals:

1. To develop a working definition of QI.
2. To design a QI project-review process that will ensure an appropriate evaluation and avoid unnecessary steps.
3. To define, through a policy, how QI projects will be supervised, including ethical considerations.
4. To provide our guidelines, when applicable, for QI definition and supervision to external organizations.

We have identified the following measures of success:

1. Increased number of QI projects using proper QI methodology and registered on the M. D. Anderson website.

2. Improved survey ratings from faculty and staff regarding their understanding of
  - a. The terms *QI* and *research*, and
  - b. Expected supervision for these activities, based on our policy.
3. An increase in QI publications.

We are at the beginning of a QI project, and we know that we will have further thoughts and subsequent changes in the implementation of this project. We are moving into an area that has not been well developed during the history of QI in health-care delivery. We recognize that “every system is perfectly designed to achieve the results it achieves.”<sup>5</sup> We will continue to review our systems at M. D. Anderson to manage for the results we wish to achieve, as this is the underpinning of QI activities.

## National Drivers Require QI Activities

Many important national initiatives are driving change in care delivery, requiring health-care organizations to improve the quality of care at a faster pace than ever before. Many of these improvements will need to be accomplished through QI activities. It is clear that health-care organizations will not be able to perform to the expectations of the public, government, and outside organizations unless they can make improvements with agility, speed, and accuracy.

### Medical Errors and Patient Safety

The national health-care agenda is pressuring hospitals and clinics to focus on improving care delivery to reduce the number of medical errors and improve patient safety. The Institute of Medicine (IOM) has reported that between 44,000 and 98,000 deaths per year occur as a result of medical errors.<sup>6</sup> In a subsequent report,<sup>7</sup> the IOM called upon health-care organizations to take an active role in improving care by focusing on six major areas: safety, timeliness, effectiveness, efficacy, equity, and patient-centered approach. In response to these reports, U.S. health-care organizations are implementing QI activities to make it safer for patients to receive care. These activities include accurately identifying patients for tests and treatments, improving communication among clinicians, and assuring that medications are administered appropriately. In December 2004, the Institute for Healthcare Improvement (IHI) launched a campaign to have hospitals save 100,000 lives within 18 months and then every year thereafter by making improvements, including preventing ventilator-acquired pneumonia, surgical-site infections, adverse drug events, and central-line infections; deploying rapid response teams to prevent unnecessary deaths; and providing evidence-based care for acute myocardial infarction.<sup>8</sup>

### Reimbursement

In addition to trying to reduce the number of medical errors, the national health-care agenda is moving to monetarily reward physicians and health-care organizations that consistently implement national standards of care. Pay-for-performance requires health-care organizations and physicians to implement QI activities by applying the best current knowledge to care delivery

and reducing inappropriate variation in clinical practice. The results from individual physicians and health-care systems are reported nationally and placed on national websites such as that of CMS. We can anticipate increased expectations and even requirements that QI activities will be tied more directly to reimbursement.

### **Health-Care Costs**

Lowering health-care costs through QI activities is essential to eliminating unwanted costs in health-care operations. Health-care spending continues to grow as a percentage of the Gross Domestic Product (GDP), and it is predicted to reach 20 percent by 2015.<sup>9</sup> Clinicians realize that the resources are finite, and action must be taken to utilize them in more-effective and efficient ways. QI methods get to the core of hospital and clinic operations. For this reason, QI is essential to reducing costs in a manner that assures that quality is maintained.

### **From Projects to Organizationwide Initiatives**

QI projects are moving from a “project level” to an “organizationwide” level. For the past several years, QI projects have usually been developed within a specific clinical area or department, but with growing concerns about organizationwide patient-safety issues, many improvements are now phased in or deployed throughout an entire organization. As a result, hospitals and health-care systems are tracking specific measurements for the entire organization.<sup>10</sup> In addition, many boards of directors of hospitals and health-care systems have defined specific QI goals for their entire system, moving QI to the forefront within the organization.

## **M. D. Anderson Cancer Center**

Having provided a summary of key external factors that are creating changes in QI, we now turn to a more detailed review of current QI efforts at M. D. Anderson.

### **QI and Research**

Human-subjects research is imperative for the advancement of medicine, and QI projects are imperative to ensure that patients are receiving a standard of care that is consistently applied and continually improved by innovative methods.<sup>11</sup> The value that both QI and research bring to the organization is understood. Further, there is an organizational commitment to improving collaboration between QI and research by designing an infrastructure that allows such coordination and defining ways to implement research findings more effectively and efficiently.

There are, however, inherent process differences that we recognize. QI gives us tools with which we can rapidly change processes and treatments in order to provide better care to our patients. QI focuses on real-time applications and rapid change. Research, on the other hand, generates new knowledge to be used by clinicians in the future to treat diseases. QI is a circular and dynamic process, encouraging sequential changes in processes so that improvements can be implemented immediately, whereas research is linear and forward in movement, requiring that consistent uniform steps be implemented to assure minimal disruption of variables that can influence the research project. We need to care for our patients in the safest and most effec-



tive manner possible through QI activities and at the same time develop new ways of treating cancer through research studies. Like two sides of a coin, QI and research are both important in fulfilling our mission.

### **Management of QI**

At M. D. Anderson, QI is an integral part of clinical operations, and the organization could not improve care delivery or move evidence-based health care into practice without it. In addition, QI activities provide tools to implement research findings and meet external requirements such as legislative and accrediting agency standards.

Our current Aim for Excellence QI program is designed to deploy continuous process improvement throughout the organization. The plan is customer-focused, data-driven, collaborative, and interdisciplinary in nature. Because of the complex nature of the organization and our need to accomplish incremental, rapid change, we use a variety of improvement methods, including the Shewart and Deming cycle of plan-do-study-act (PDSA), the six-sigma process, rapid-cycle improvement, causal mapping, lean thinking, and standard industrial-engineering procedures such as mathematical modeling and simulations.

The president of M. D. Anderson is responsible to the University of Texas System Administration and the University of Texas System Board of Regents for the administration and coordination of the organizationwide process-improvement program. The president delegates to the Quality Council the responsibility and authority to manage the program. The Quality Council comprises division heads of Anesthesia and Critical Care, Cancer Medicine, Cancer Prevention, Diagnostic Imaging, Internal Medicine, Pathology and Laboratory Medicine, Pediatrics, Radiation Oncology, and Surgery. Also included are department chairs, the executive vice president and physician-in-chief, chair of the Executive Committee of the Medical Staff, the vice president (VP) of Medical Affairs, the VP of Medical Operations, the medical director of Clinical Operations, the VP of Process Improvement, the VP of Nursing Practice and chief nursing officer, the deputy chief legal officer, the chief compliance officer, and the chief of the Clinical Ethics Service. The Patient Safety Committee, chaired by the VP of Medical Operations, reports actions related to improving patient safety to the Quality Council. Both committees comprise senior leaders with the authority to make decisions, hold project leaders accountable for projects, and provide project teams with the resources needed to succeed.

The Quality Council “charters” up to six teams at any one time to conduct improvement projects. Limiting the number of chartered teams to six ensures focus of energy and resources on the highest-priority issues facing the institution. Each chartered team is staffed by two specialists from the Office of Performance Improvement (OPI) and is assigned an executive sponsor who serves on the Quality Council for the duration of the team’s existence. The executive sponsor assembles a multidisciplinary team of clinicians and staff to carry out the team charter. Each team reports progress to the Quality Council until the project moves to a monitor-only status. To encourage smaller projects at a local level, the OPI maintains a database in which individual work units can register projects. Registered projects are eligible for consultative assistance and process-improvement training by the OPI.

Clinical Effectiveness, Quality Improvement, and Performance Improvement are departments within the organization that lead and support QI projects. The VP of Performance Improvement, the VP of Medical Affairs, the Associate VP of Clinical Operations, the medical director of Clinical Operations, and the VP of Nursing Practice and chief nursing officer work closely to facilitate the achievement of goals of the Quality Council and Patient Safety committees. The primary skilled personnel within these departments are clinical-quality facilitators (e.g., nurses, informaticists), industrial engineers, data managers, educators, human-factors specialists, and statisticians. These specialists partner with faculty and staff in operational units to identify issues, develop solutions, and teach improvement methodologies so that employees can deploy process-improvement skills that units can implement independently in the future. Faculty and staff are supported with expertise in QI methods, rapid root-cause analysis for adverse events, compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards, and implementation of clinical-system tools such as clinical practice guidelines, plans of care, risk assessments, and order sets. Clinical data related to processes and outcomes are given to clinicians to improve their processes.

An early initiative to introduce QI to the organization was directed at operational efficiencies. Create Solutions, a web-based program for training, conducting, collecting, and benchmarking improvements throughout the hospital, was established in 2000. The course includes fundamental theory and practices used in improvement initiatives, including standard quality tools, systems thinking, basic data management, and team effectiveness. Each year, initial educational sessions are tailored to support the wide range of learners conducting improvement projects. There are five video webcasts each year that show different teams' progress in a project using the PDSA methodology.

Teams that are interested in receiving recognition for their work are encouraged to register their QI projects online through the web-based Create Solutions program. The information provided includes the aim statement, evaluation measures, project design, and results. Entries are evaluated for appropriateness with respect to QI methodology and are scored by process-improvement professionals on the basis of correct use of quality tools, results, and breadth of application. Projects are awarded gold, silver, or bronze medals based on the depth, breadth, and application of their outcomes. The database is available for all hospital staff to benchmark ideas and make contacts to conduct similar projects. Teams have access to the Create Solutions website, where they can find more than 50 project tools. To date, approximately 300 teams have used either the training or the website. Each year, we celebrate achievements and recognize individual and team accomplishments through our reward and recognition program. The Quality Council also hosts a luncheon in which selected projects are featured and teams are recognized for their efforts.

Another initiative is the Transformation Specialist, a one-year performance-improvement residency led by industrial engineers. Three senior staff members, nominated by their managers, participate in a one-year program to become competent in system-improvement processes, including six-sigma and lean thinking, as well as data-management skills. The course is tailored to the development of leaders with high-level expertise in process improvement.

The third and most recent initiative is directed toward clinical practice. In fall 2005, the Clinical Safety and Effectiveness (CS&E) Education Program was launched to provide an in-

depth clinical quality-management course to clinicians to enable them to initiate data-driven improvement projects within their own practices and areas of responsibility. The course is modeled after the Advanced Training Program developed by Brent James at Intermountain Healthcare in Salt Lake City, Utah. All CS&E course participants are required to complete an improvement project using the PDSA process and QI tools. Intermountain Healthcare alumni, graduates from M. D. Anderson, and alumni from the CS&E course facilitate the project design and implementation. Participants present their findings to the class, department chairs, and other organizational leaders. Through this course, we are teaching clinicians and leaders proper QI methods to help them make improvements in their clinical areas.

### **Ethical Assessment of QI**

At M. D. Anderson and many other health-care organizations in the United States, ethical assessment and oversight of QI projects are performed informally by individual team leaders for a specific QI project. There is typically an implicit agreement among the QI team leaders and members that a project is valued, needed, and beneficial. In addition, risks to the patients are assessed, safeguarding of patients' protected health information is addressed, resource utilization is justified, and consideration is given to whether the project will likely lead to improved quality of care. Within this informal oversight process, there is an underlying assumption by senior leaders that those engaging in QI projects will

- Protect the best interest of the patient and do no harm;
- Commit themselves to professional integrity and the honest collection and reporting of data;
- Make reasonable judgments about the value of the projects for the relevant work areas and for the organization as a whole;
- Identify appropriate metrics to measure improvement during the projects;
- Collect data that are adequate to measure what is being examined;
- Assure that resources are available to conduct and complete the project;
- Consider whether a process of informed consent is necessary, and if so, move the project to the IRB for review.

These are important aspects of a QI project that must be clearly planned and outlined at the project-design stage. Our goal is to build upon the current process by standardizing the review of QI projects within our organization so that it is clear which will require IRB review and which will not. In particular, we are interested in identifying potential harms to human participants, conflicts of interest, and research activities within QI projects.

If members of a team plan to publish their QI work in recognized journals, the projects have been required to be submitted for IRB approval. There are some important concerns about this process, as outlined by M. Baily et al.<sup>12</sup> Our goal is to develop a process whereby the QI teams interested in publication will not need IRB approval, but instead will have the review completed by a QI assessment board (QI-AB), which will review projects based on specific criteria relevant to the QI process in a timely and efficient manner.

### Organizational Strategy

M. D. Anderson's Institutional Strategy 1.3 (2005–2010) calls for the organization to “increase the quality and safety of clinical care, enhance productivity and efficiency, and contain costs by enhancing our infrastructure and support systems.” To move the organization forward as outlined in this strategy, many QI projects need to be completed. For example, to determine the best ways to schedule a planned surgery in a specific department, a QI project is under way to decrease the wait time for patients to be placed on the surgery schedule and reduce the number of canceled surgeries, which will improve efficiencies and decrease waste. The specific improvement being sought is a consistent process to better identify patients with preexisting medical conditions. This will require improved communication among the people who schedule the surgery and the referring department. A small, but rapid improvement will help to move patients through the clinic faster and will thereby help to achieve the institutional strategic goal. Another example of a QI project is the Heart Success Program. The goal of this project is to consistently implement pharmacologic therapy for heart-failure patients based on the current evidence. In this program, a target goal is defined, standardization of clinical processes and tools is completed, education is provided to the staff, and the project's progress is tracked with frequent data feedback to the team. All of these steps are essential to improving patient outcomes. These QI projects are examples of many that are ongoing within the organization, all designed to help M. D. Anderson achieve its mission.

### The M. D. Anderson Culture

The mission of M. D. Anderson is to eliminate cancer in Texas, the nation, and the world through outstanding programs that integrate patient care, research, and prevention and through education for undergraduate and graduate students, trainees, professionals, employees, and the public. We share our knowledge so that others can learn and apply the best-known treatments for cancer. To fulfill this mission, we must disseminate and publish our work, including articles about QI, methods, and strategies.

Our core values are

1. *Caring*: By our words and actions, we create a caring environment for everyone.
2. *Integrity*: We work together to merit the trust of our colleagues and those we serve.
3. *Discovery*: We embrace creativity and seek new knowledge.

The work of QI incorporates all three core values: caring about our patients and the quality of the work we do; integrity in our striving for excellence by integrating patients' decisions and evidence-based health care; and discovery by continually discovering new and improved ways to care for patients.

### Academic Recognition of QI

In addition to providing QI education to clinicians, we are reviewing ways to integrate and recognize QI work as a part of our formal academic performance reviews. Currently, faculty performance evaluations are geared toward recognizing work by faculty members that is associated with research and publications. In an academic setting, QI activities of faculty members

receive little or no recognition. It is important for this type of work to receive the recognition that is deserved. Therefore, we have named a QI team to develop proposed methods for faculty members who participate in QI activities to receive professional recognition. As part of our QI culture, we expect all departments and work groups to recognize patient safety and improvement issues, to initiate projects, and to continually learn about QI methods.

### **Coordination Between QI and Research**

At M. D. Anderson, there are no clear and distinct boundaries between QI and research, and the federal definition of research is sometimes applied to QI projects. Organizational leaders and IRB chairs use an informal triage process to decide which projects should be considered QI and which should be considered research. Projects that are not likely to be submitted to the IRB include those that do not collect patient data and those that are of no risk to patients or personnel and that are obviously intended to improve a process. Examples of QI projects focusing on clinical practices at M. D. Anderson that have not been submitted to the IRB for review include the collection of data associated with observations of the environment, hand-hygiene practices, medical-record reviews for documentation requirements such as “do-not-use” abbreviations, and timeliness of medical-record completion. These are practice behaviors that we must monitor and quantify by using the QI process to meet required standards.

When a QI project is submitted to the IRB for review, the QI staff view the project as infiltrating the research paradigm and disrupting standard operations. At M. D. Anderson, the IRB assesses research protocols for safety and protection of research participant autonomy but also requires stringent scientific review and approval of the study design. Clinical trials must strictly define sample-size calculations and inclusion and exclusion criteria, classify objectives as primary and secondary, describe human-subject evaluation and methods for subject recruitment during a specified time, specify disease groups and treatment agents, state biosafety mechanisms, develop a clear statistical design, and define resource and space requirements. For a full IRB review, there are multiple pre-reviews before the project reaches the IRB. All human-subjects treatment research protocols are presented to one of the clinical research committees; quality-of life, cancer-prevention, and population-based human-subjects studies are presented to the Psychosocial, Behavioral and Health Service Research Committee. Each protocol is reviewed for scientific merit by two scientific reviewers and, when needed, one reviewer from each applicable department among Nursing, Diagnostic Imaging, Biostatistics, and Pathology. Communication between principal investigators (PIs) and the reviewers is documented, compiled, and made available to committee members. Each protocol is individually presented by the PI, a co-PI, or the PI's department head and is discussed and voted on by the committee after the presenter steps out of the meeting room.<sup>13</sup> For most QI projects, this type of information and review is not needed. When a contingency is placed on the QI project by the IRB, the QI staff do not always understand the question or may see it differently, since the circular and iterative design and implementation of a QI process, as noted previously, is different from the linear and less flexible process of human-subjects research.

Over the past few years, a number of QI projects have been submitted to the IRB. For clearly defined QI projects, the IRB approval process took about three weeks. For QI projects that were not so clearly defined, the IRB approval process took approximately six months. A



QI project involving patient questionnaires that was intended to improve responsiveness and service to patients was never approved because the IRB repeatedly requested more information in the format of the protocol document required for approval of research projects. The project was submitted and resubmitted to the IRB for approval five times, and after two years of discordant communication, it was abandoned.

QI and research professionals can use similar words, but if they are to understand each other, the words must have equivalent meanings that do not depend on which professional is speaking. Because agreement about meaning is often lacking, communication between the two groups of professionals can be unclear. For example, terms such as *human subjects*, *systematic investigation*, *generalizable knowledge*, and *data-driven* bring to mind federal requirements for researchers, but they do not have the same regulatory connotation for QI professionals. When people performing research hear these words from people working in QI, the work is labeled as research.

## Definitions of Research and QI

Both QI and research are valuable to patients and to health-care organizations. Both are undertaken to do the best for patients and to make improvements in the current method of prevention, diagnosis, or treatment. The definitions of QI and research have been debated nationally, yet they remain unclear. Such uncertainty may delay work that should be allowed to proceed immediately to improve patient safety and may deter initiatives that are designed to improve patient care because of fear about the administrative burden of an IRB review.

Baily et al. describe some of the differences between and similarities of QI and research,<sup>14</sup> which we will not restate but will build upon in our discussion below. In the following sections, we provide the definitions we plan to use in our organization and begin to develop the infrastructure needed to provide an ethical review for QI projects.

### Research

Federal regulations provide the definition for research that health-care organizations use: “a systematic investigation, including research development, testing and evaluation, designed to develop and contribute to generalizable knowledge.”<sup>15</sup> It is difficult for health-care organizations to translate and apply this broad definition to health-care delivery and operations.

In determining whether a project is research or not, we will consider whether it is designed to create generalizable knowledge, as stated in the aim of the project. The aim should declare if the project is designed to be consistently reproduced to achieve exact results for organizations outside of M. D. Anderson or if the project is meant to improve a process within the organization and to share its methods and findings with other organizations to apply as they see fit. We would consider the first type of project generalizable for research purposes and the second not generalizable.

According to some, research requires that the null hypothesis be investigated (proved or disproved) based on a state of genuine uncertainty<sup>16</sup> and then investigates whether the new intervention is better than the standard therapy. On the basis of this research principle,



Emanuel, Wendler, and Grady wrote, “If there exists a consensus about what is the better treatment, there is no null hypothesis, and the research is invalid.”<sup>17</sup> A review of the current best knowledge should be examined and considered prior to the initiation of either a QI or research project, but the steps that follow are different. QI is primarily based on the application of best treatment utilizing current knowledge. The knowledge used in QI can be derived from research. QI focuses on the process of applying the knowledge, while research challenges existing knowledge or extends it.

### Quality Improvement

There are several terms in QI that are used interchangeably, including *process improvement*, *performance improvement*, *process management*, and *outcomes management*. This, along with the expanding scope of QI work, has contributed to confusion about QI. No federal regulation defines QI, and in fact, no common definition is used across the United States, further adding to the confusion of QI work. The closest thing to a definition found in a federal document is a definition related to health-care operations that includes QI activities.

Health-care operations consist of any of the following activities of a covered entity to the extent that the activities are related to covered functions: “Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the *primary purpose* of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.”<sup>18</sup>

Table 1 summarizes key characteristics that define QI and research. The characteristics are made up of principles related to the differences between the approaches, tools, participation, oversight, and actions associated with the outcomes.

### Structure of QI Projects

For our working definition of QI, we will use a modification of the definition proposed by Baily et al.<sup>19</sup> Here, QI is defined as methodical, data-guided activities designed to bring about positive changes in the delivery of health care in particular settings at M. D. Anderson through the use of a wide variety of methods.

This definition will provide initial structure for our QI work at M. D. Anderson. In addition, we believe it is important to describe proper QI methodology by establishing criteria necessary for a QI project. Below we describe our initial QI methodology, which we expect to modify once we begin to put it into operation.

The following questions, adapted from Langley,<sup>20</sup> will guide M. D. Anderson’s internal review in determining standards for QI methodology:

1. Is the aim clearly defined? Does the aim contain the end result that will be achieved, the measure for achievement, and the timeline for completion?
2. Does the project align with organizational strategies?

**Table 1**  
**Characteristics that Define QI and Research**

Characteristic	Research	QI
Existing best knowledge	Challenges it	Applies it
Principal aims	To test a hypothesis	To improve a process
Principal goal	Generate new knowledge	Improve efficacy, efficiency, safety of care
Highest ethical principle	Autonomy	Beneficence
Statistical tools	Test for statistical significance	Track direction trends and degree of change
Patient participation	Voluntary	Required in order to receive treatment, part of health-care operations
Informed consent	Required and is specific to each research protocol	Included in consent for treatment upon admission as part of clinical care
Agencies with oversight or influence	OPHR, FDA, NIH, private industry, grant agencies	JCAHO, CMS, IHI, Leapfrog, NQF, AHRQ
Ethical oversight within the organization	Institutional Review Board (IRB)	Quality Improvement Assessment Board (QI-AB)
Sharing of information	Publication is voluntary	Required reporting to regulatory agencies, internal reporting for quality improvement activities, quality improvement publications

NOTE: OPHR = Office of Public Health Research; FDA = Food and Drug Administration; NIH = National Institutes of Health; NQF = National Quality Forum; AHRQ = Agency for Healthcare Research and Quality.

3. Does the project add value to the patient and/or organization?
4. Does the project use data to guide the changes so that the aim can be achieved?
  - a. Does the project track effort over time, especially using such statistical methods as run charts and statistical process control (SPC) charts?
  - b. Does the project provide feedback with data for adjustment in the short improvement cycles?
5. Is the project designed to bring about a positive change?
  - a. Does the project use small samples and short improvement cycles to learn quickly?
  - b. Does the project utilize the plan-do-study-act (PDSA) cycle?
  - c. Does the project incorporate the appropriate type of supervision?
6. Is the project designed to make changes in the delivery of health care?
  - a. Does the project apply existing standards of care based on evidence?
  - b. Does the project integrate legislative or accrediting standards?
  - c. Does the project record the change in processes?
  - d. Does the project define how it will be implemented?
  - e. Does the project illustrate a good mechanism for sustainability?
  - f. Does the project illustrate a good mechanism for dissemination throughout the organization?
7. Is the project designed for a particular setting within M. D. Anderson?
  - a. Does the project use local knowledge, i.e., the knowledge of people actually involved in the process?
  - b. Does the project integrate detailed process knowledge into the work of interpretation, inviting observers to comment on what they notice?

8. Does the project utilize resources efficiently?
  - a. Does the project define the resources that will be utilized to accomplish the aim statement?
  - b. Does the project track efficiencies gained from it?
9. Does the project consider the ethical principles defined at M. D. Anderson, (i.e., beneficence, non-maleficence, justice, and autonomy), and did it obtain an independent review?
10. Did the project achieve the aim?

The project outline in Table 2 provides the format to be used by QI teams in registering their projects within M. D. Anderson.

## Professional Judgment

In QI, we will consider the role of clinical or professional judgment in providing care. Clinicians continuously make changes in their daily work for patients, colleagues, and themselves. If the modification affects only the clinician and a single patient and is not outside the standard of care, it can be considered clinical or professional judgment. In addition, there may be times when clinicians would like to improve their own performance, e.g., improving a surgical technique or altering the care of a patient because the patient is not responding appropriately. These would be considered clinical or professional judgment. We want to encourage this type of activity, because making improvements requires trying new processes, evaluating the outcomes, and then modifying the changes. The clinician or professional making an intervention will need to consider whether the improvement is affecting other people, creating complexities for others, or utilizing resources; or he or she may want to persuade others to incorporate the change into their work later on. If one of these conditions applies, it will be important for the clinician or professional to consider calling the activity a QI activity and to proceed using the proper QI methodology, supervision, and ethical considerations. If not, the clinician or professional could be questioned by peers and supervisors, especially if the work is impacting other people or resources.

## Guidance: IRB-Related Questions

QI project leaders within our organization have asked whether IRB review is required, particularly for projects that include surveys or randomize patients or completed projects that lead to information that is considered of sufficient interest for written or oral presentations. We have formulated the following guidelines on these issues:

1. *Surveys.* If a survey is designed for QI activities and is not designed to develop or contribute to generalizable knowledge, IRB approval is not required. If a survey is developed to gain information, opinions, or practices to make improvements within our

**Table 2**  
**QI Project Outline Form**

Quality-Improvement Project Outline
Project Name:
Project Aim (evidence-based approach):
Alignment with Organizational Strategy:
Value Added to Patient Care or Organization:
Compliance with Regulatory Standards/Laws/Rules:
List of Customers:
Supervision:
Ethical Review:
Measures:
Data (baseline data, data collection method, statistical analysis):
Reporting and Feedback of Data and Accomplishments:
Plan for Implementation:
Sustainability:
Spread Within the Organization:
Resources:
Team Members:

organization, no IRB approval is necessary. If a survey is developed to gain information, opinions, or practices to make improvements outside of our organization, it will require IRB approval.

2. *Randomization.* If patients are to be randomized for therapy, we will consider this to be research and will require IRB approval.
3. *Abstract or presentation.* If the abstract or presentation is designed for QI activities and is not designed to develop or contribute to generalizable knowledge, and only aggregate data are reported, IRB approval is not required.

## Publication

Some organizations and IRB leaders believe that the term *generalizable knowledge* in the federal definition of research includes the notion of publication. If those involved in a project or study consider publishing their findings, they must seek IRB approval prior to publishing.<sup>21</sup> Many organizations believe this kind of approval meets the requirements of the law. However, there are two problems with this way of thinking. First, the intent of IRB review is to protect the rights of human subjects; if those rights are not addressed until after the project or study is completed, the IRB review and approval circumvents the intent of the law.

Second, QI experts seek to share ideas and to develop more-generalizable, standardized methods of health-care delivery. In fact, health-care organizations across the country must demonstrate, for reimbursement purposes, acceptable compliance with standards of accrediting bodies such as JCAHO by completing QI projects. It is important for this type of work to be published. For QI work, the lack of publication results in a lack of scrutiny, and improvements in methodologies are slowed because ideas are not shared. In addition, it is certainly inefficient, if not unethical, to spend resources to make improvements and then not share this knowledge with others.<sup>22</sup>

In many U.S. hospitals, if a QI team wants to publish the results of a QI project, the team must first have IRB approval to assure human-subjects protection and to assure editors of journals that IRB approval has been obtained. One major limitation to this process is that many QI teams will not take the time to submit a QI project to the IRB; therefore they will not continue to make necessary improvements and will not publish if a QI project is not completed. Submitting a QI project in the format required by an IRB takes a great deal of time, and this defeats the purpose of rapid improvements.

We will encourage QI team members engaged in QI activities to publish their projects and describe what they have done so that others may learn. In the future, we plan to review QI projects, using established ethical criteria, which include the ethical rights of human participants. If there are questions from an outside organization or journal, information will be provided about the independent review conducted at M. D. Anderson.

## Health Insurance Portability and Accountability Act

Health-care QI activities are considered a part of health-care operations as defined in the Code of Federal Regulations (CFR), Selected Documents 164.501.<sup>23</sup> Therefore, we will consider QI activities and the data they generate to be part of health-care operations. The data will need to

meet the same requirements as data handled in the hospital or clinic, as written in our compliance policies.

## Supervision of QI Projects

Research and QI are functions that impact the operations and future existence of a health-care organization. For these reasons alone, supervision of these activities is an imperative leadership responsibility. Research has specific supervision requirements by law, but QI does not.

At present, there is no legal requirement to provide an independent review for human participants in QI projects.<sup>24</sup> However, with continual increases in QI work needed in health-care organizations, requirements to provide more careful supervision of QI activities will soon be set forth. The requirement for review of research projects by an independent body came about because of inhumane treatment of human subjects. Our goal is to lay a foundation within our organization to methodically and consistently review QI activities to assure they meet our standards.

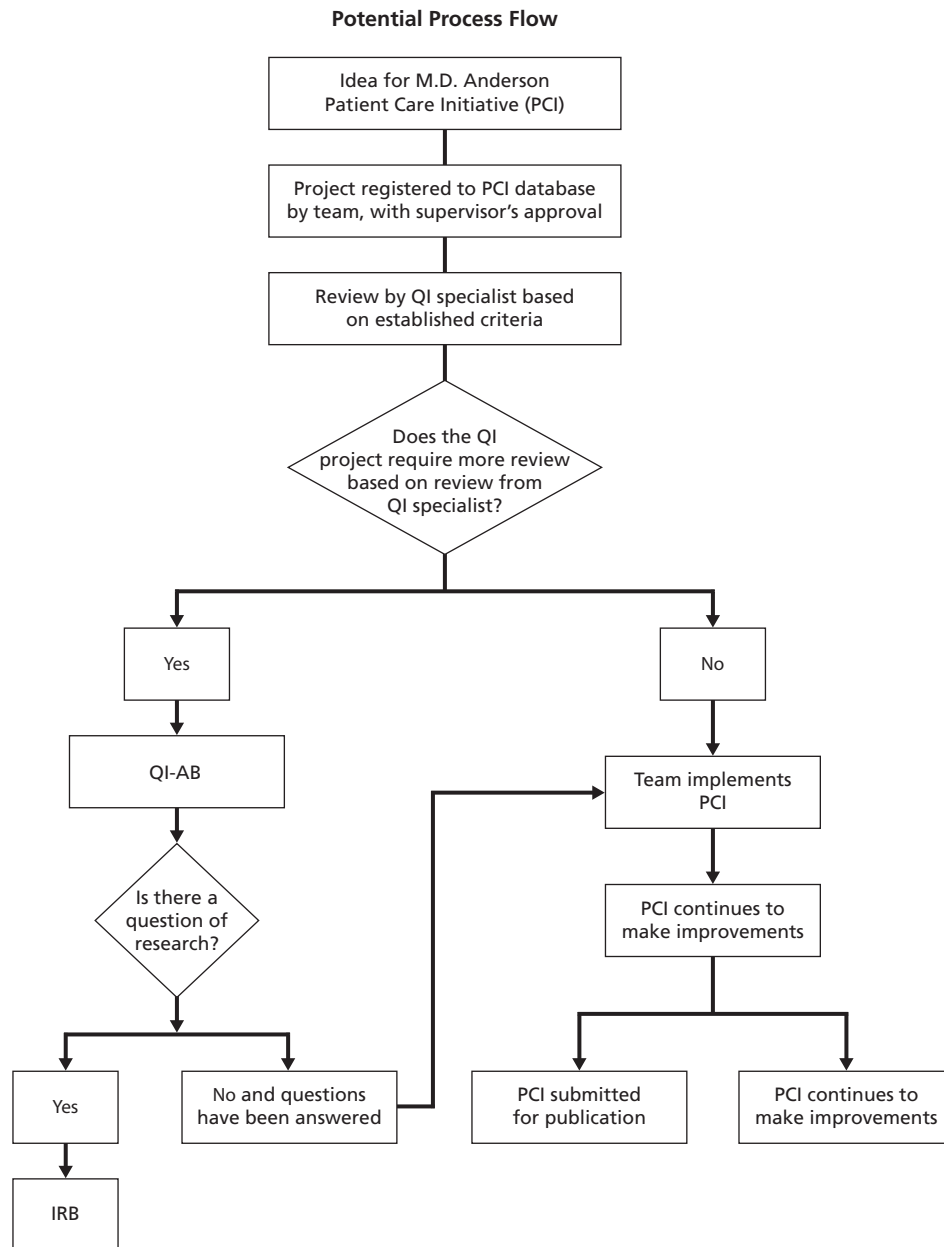
The literature supports different levels of ethical oversight, ranging from no review to some review by a review board within QI, review by a specialized QI IRB, or review by an IRB.<sup>25</sup> Requiring an IRB review of QI initiatives may not be possible because the current IRB system is already overburdened.<sup>26</sup> M. D. Anderson currently has four IRBs that review thousands of new and continuing protocols each year. This large workload contributes to the delay in the review of QI initiatives.

There are benefits to improving QI supervision for the patient, the faculty and staff, and the organization. QI projects usually carry with them the same level of risk that is inherent in delivering standard care. Therefore, by recognizing that level of risk, more QI projects can develop at the same level to improve patient care. The faculty and staff will benefit because they will better understand their role and responsibilities in initiating and completing QI projects and will take the initiative to begin projects when issues are identified. The organization will benefit from the improved review process because there will be a central place for QI activities to surface and be disseminated throughout the organization. In addition, the organization will have a mechanism by which to identify projects that have a potential for patient risk before they are under way. The performance review process that includes recognition of faculty and personnel involved in QI reinforces the importance of QI activities to the organization.

To improve supervision of QI activities requires an organizational infrastructure. We will first develop a QI-AB, which will be integrated into our current organizational structure of clinical operations and will be accountable to the Quality Council. The QI-AB will coordinate closely with the IRB chairs. Its purpose will be to provide a working definition of QI at M. D. Anderson and to provide supervision of QI activities, including ethical considerations for participants. The QI-AB will be responsible for defining criteria for proper QI methodology for our QI projects, describing the elements to be used in ethical oversight of QI activities, defining the data fields to be captured in the database, reviewing data related to QI activities for ongoing monitoring of those activities throughout the organization, and providing reports to the Quality Council and senior leadership. We anticipate that after the criteria for proper QI



methodology and elements of ethical oversight are defined by the QI-AB, many of the QI projects registered in the database and reviewed by the QI specialist will not need further review by the QI-AB. The majority of the QI projects will meet these criteria. The QI-AB will address primarily patient-care initiatives or initiatives that require further review and discussion, a small portion of the QI projects within our organization. For those projects that do not meet the criteria or about which there is a question, we anticipate discussions and further information gathering regarding level of risk, informed consent, beneficence, privacy, data, and other issues that have not yet been defined or put into operations for QI work. The flowchart below describes the current thinking for QI supervision within our organization:



The QI-AB will consist of individuals and representatives such as IRB chairs, QI leaders, ethicists, research experts, faculty, nurses, and QI statisticians. Ad hoc members will be other experts within our organization representing disciplines such as nursing, pharmacy, rehabilitation, palliative care, and environment of care. The IRB is in an independent role within the organization, and to continue to support this role, the IRB chair will act as a nonvoting member of the QI-AB.

Our plan will be to reevaluate the purpose and use of information collected in our current QI project database and determine the information needed for the QI-AB. The QI-AB will request information supporting proper QI methodology, supervision, and ethical considerations, once these have been defined. The supervision of QI activities will begin with the registration of a QI project online into a database, using the template for a QI registration form that is agreed to by the QI-AB and organizational leaders. Once the QI project is registered online, a QI specialist will review the project, using the criteria described in the section on Quality Improvement and ethical criteria to be established by the QI-AB. If the QI specialist has any questions, he or she will forward these to the QI-AB for review. The QI-AB will establish criteria, to include proper QI methodology and ethical considerations, for a QI-AB review. If the QI specialist judges that the project has or might have a research component, the project will go to the IRB for review. The QI-AB review will help safeguard QI activities, including individuals and groups involved in those activities, from potential or perceived conflicts of interest and misunderstandings about the activities.

The database will track QI activities and continuing medical education credits for physicians, advance-practice nurses, and physicians' assistants who participate in QI activities. Employees within the organization will have access to components of the database to identify projects, as well as contact information for others with similar interests.

The process for QI supervision that we will develop will formalize QI activities within the organization, giving them a substantial role in health-care operations. Through these data, we will be able to look at QI activities from an organizational perspective, not just by department. The database will also help to assure that people in our organization have the opportunity to learn from each other. With it, we will be better able to share information between departments, reduce costs, and avoid duplication of effort.

## **Future Directions for Ethical Assessment**

### **QI Ethical Principles**

At M. D. Anderson, we have started from the premise that both QI and research benefit patients, but they branch in different directions. They embody different philosophical approaches, although they sometimes use similar methods, analyses, and measures. Research and QI use ethical principles in different ways. Patient participation in research is strictly voluntary, making autonomy the key ethical consideration for research studies. Before research is conducted, the PI must consider the wishes of the patient and his or her right to make a decision about whether or not to participate in the study. In contrast, QI activities are integrated into health-care operations, so that patients who come for treatment will be involved

in a system that inherently contains QI activities. Therefore, the key ethical consideration for QI activities is beneficence. Because the organization's mission is to improve patients' medical conditions, health-care operations, which includes QI activities, is obligated to maximize benefits to the patients who seek help.

Clearly, QI and research have overlapping ethical considerations, but for both substantive and symbolic reasons, the ethical principles that form the foundation and framework for an ethical assessment of QI activities should be broadly rooted in clinical bioethics. To that end, an ethical framework for assessing QI activities is the concrete application of the four bioethical principles of beneficence, non-maleficence, justice, and autonomy.<sup>27</sup> We recognize that these four principles are the same principles discussed in *The Belmont Report*,<sup>28</sup> which is the foundation for ethical assessment of human research in the United States. We propose to use the bioethical principles as a framework and structure for (1) discussing our future directions for more rigorously, methodically, and ethically assessing our QI program and activities; (2) establishing organizational requirements for conducting efficient and effective QI activities; and (3) establishing a system for QI supervision within the organization.

### **Respect for Autonomy**

Autonomy, or self-determination, provides an underpinning for patients' participation in their own health-care decisions and for the contemporary emphasis on informed consent. The patient makes the choice as to whether or not to engage in the treatment presented to him or her. Many health-care organizations, including M. D. Anderson, make provisions for specific informed consent related to specific diagnostic procedures and treatments but also request patients to provide a more generic, "at-the-front-door" consent prior to treatment. If participation in QI projects that pose no risk or the risk associated with standard care is an obligation of everyone—and we believe it is—patients should be informed during registration and admission. One of our current "front-door" consents for potential research using residual tissue, body fluids, and patient data states:

UTMDACC [University of Texas M. D. Anderson Cancer Center] can also learn about cancer by studying patient information. This information will be gathered from your UTMDACC medical record. Any information that is collected will be maintained by the Institutional Tissue Bank in confidential and secure databases. Before this information can be used for research, the people doing the research must get specific approval from the IRB.

In a parallel fashion, we will include a statement in our admissions consent form informing patients that all patients at M. D. Anderson will likely be involved in QI activities. QI projects with research components will be considered research and will require IRB approval, with the usual informed-consent processes and procedures for human research. A parallel process will be established for employees' involvement in QI projects, including informing them at the time of hiring that QI is viewed as everyone's obligation and describing how its activities are defined at M. D. Anderson and how the review process will differ from that for research.

### **Beneficence and Non-Maleficence**

Quality improvement in general, as part of clinical practice, aims to improve patient care and safety by maximizing patient benefit (beneficence) while minimizing patient harm and risk (non-maleficence). Specific QI projects should reflect these dual objectives in their design, conduct, and impact. In the end, individual QI projects must have a favorable benefit-to-risk ratio for participants (whether they are patients, family members, or employees) and must not compromise optimal care and patient safety. To safeguard participant well-being and best interests, we will develop a QI supervision process for reviewing and monitoring QI projects. Consideration will be given to proposed outcomes such as functional and clinical outcomes, increased patient satisfaction, access to care, and cost-effectiveness. In addition to helping patients, projects will be viewed in relation to the value they bring to the organization and whether they are designed to achieve the intended benefits. The degree or amount of possible risk and harm for participants, based on the principle of non-maleficence, will be one factor used in determining the kind of supervision needed. Other factors include the scope of the project (e.g., number of participants, resources being utilized, degree of impact on the organization) and the methodologies and metric tools to be used in the data-collection process (e.g., run charts and SPC charts).

### **Justice**

The ethical principle of justice includes such concepts as equal access to care, provision of treatment and resources according to need, the fair distribution of health-care benefits and burdens, and good stewardship of an organization's and society's resources. For QI activities, the principle of justice should guide not only the selection and inclusion process related to participants whose activities or data will be observed or collected (i.e., patients, family members, employees), but also QI project leaders and team members who need access to organizational resources (e.g., money, personnel) to initiate and complete their projects. All patients, family members, and employees will be potentially included in QI activities. Patients' participation is required as part of normal health-care operations. Patients expect to receive the best care possible, which can only be achieved through QI activities. It would be unfair and inequitable for patients and family members to receive the benefits of improved treatment and care resulting from QI without participating in efforts aimed at achieving continuous improvement. All patients and family members are potentially the beneficiaries of improved systems of care, and therefore all have an ethical obligation, based on justice, to participate in QI.

For specific projects, regardless of the risk-to-benefit ratio, the QI supervision and approval process will need to assess, from the perspective of justice and nondiscrimination, any delineated inclusion or exclusion criteria (e.g., patient characteristics such as gender or race/ethnicity, disease site, or employee characteristics such as profession or role within the organization). Any inclusion or exclusion criteria will need to be justified and be in accord with M. D. Anderson's mission, vision, and values. Similarly, the QI oversight and approval process, guided by written, concrete, objective criteria, will be used to determine whether specific projects receive available organizational resources.

### Independent Review

An independent QI-AB assessment will provide the oversight necessary to ensure that the proper questions have been asked of those projects requiring a review prior to initiation. The assessment will include considerations for patients and employees involved in QI activities. QI-AB members responsible for reviewing, approving, and monitoring QI projects on the organizational level will need to recuse themselves from oversight duties for projects in which they are involved in order to avoid real or perceived conflicts of interest. We will forward QI projects that involve risk or research questions to the IRB for review.

### Conclusions

At the national level, rapid changes in health care are pushing organizations to (1) improve patient safety, (2) move QI activities from a project level to an organizationwide level, (3) tie reimbursement incentives directly to implementation of best current knowledge, and (4) contain costs. All of these changes require QI activities. Because of these national forces, QI work has received the recognition that it needs and has moved onto a platform of its own, distinct from research. However, with recognition comes responsibility. Two of the main responsibilities of QI are described in detail in this chapter: (1) providing a working definition of QI and (2) clearly supervising the QI process within an organization infrastructure.

At M. D. Anderson, we realize that it is the responsibility of management to provide the infrastructure needed to accomplish the benefits of QI activities. These are fundamental activities that require agreement, support, monitoring with data, and evaluation by the leaders of the organization. In the long term, the infrastructure we are developing will strengthen the operations of the hospital. As Baily et al. write, "In health care facilities today, most clinical care is delivered to patients on a team basis, and the ability of the team to deliver good care depends on the characteristics of the administrative infrastructure and procedures that are in place."<sup>29</sup>

As health-care organizations around the nation move forward with QI activities, it is important that those activities retain local judgment, just as research is allowed local judgment through the IRB process. Local judgment allows for decisions to be made in the community or organization where the knowledge is greatest and decisions can be made quickly.

At the societal level, there are two fundamentally important goals: (1) protection of individuals who may be subjects in research studies and (2) improving quality of care within the health-care arena. These goals appear to be in conflict in the ongoing debate regarding IRB oversight of human-research subjects and health-care organization-based QI activities.

In QI, it is essential that lessons learned and best practices are communicated to other health-care organizations. In the medical world, such communication is optimally accomplished through publication of results in peer-reviewed literature. This process ensures that others who are considering adoption of the approaches or findings know the basic validity of the analysis and the appropriateness of the conclusions in a particular setting.

It is critical that the debate regarding what is QI and what is research does not focus solely on the issue of publication. QI and clinical research are fundamentally different activities of a health-care organization, and although QI must unquestionably be performed in an ethi-

cally valid manner, including undergoing review by those not directly involved in a particular project, the differences in fundamental assumptions (e.g., voluntary versus no-voluntary participation, the process mandated as a component of routine medical practice versus an elective activity of a health-care organization) absolutely must be recognized.

Until these issues are articulated or even codified at the national level, there will be confusion among health-care providers and organizations regarding how to proceed with critically important QI activities. Such confusion may lead to unnecessary delay. Further, in an effort to avoid any suggestion that research is being conducted without IRB review, certain QI initiatives may simply not be undertaken or, if undertaken, they may not be reported to others outside the organization, despite the importance of the outcomes. This outcome would be a national tragedy.

## Recommendations

Through the process of writing this chapter, we have begun to set a course for our organization, and at the same time we have become even more convinced that the work we are describing needs to continue and develop. We look forward to collaborating with other health-care organizations, agencies, and associations to further define this work and to learn from each other. To assist our work and the work that other health-care organizations are doing or will begin, we make the following recommendations:

1. Establish national forums to debate issues surrounding the ethical oversight of QI activities and provide recommendations to appropriate national organizations and agencies.
2. Fund and track demonstration projects by national agencies to support development work in defining and supervising QI initiatives.
3. Develop methods to recognize QI work as academic.
4. Encourage editors of prestigious journals to recognize the QI oversight process established by health-care organizations as valid, to allow for dissemination of QI work.
5. Provide a working definition of QI at a national level, at the same time allowing for local judgment.

We are embarking on a QI project that will provide further clarity and structure within our organization. Research principles have been developed and tested for years. The principles that will be developed for QI also should be allowed to formulate and develop over time to achieve the best health-care system possible.

## Acknowledgments

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## Quality-Improvement Policy at Intermountain Healthcare

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*Brent C. James*

Intermountain Healthcare is an integrated delivery system with 22 hospitals (approximately 2,200 beds), more than 100 outpatient clinics, an employed physician group with more than 450 members, an HMO health plan (more than 400,000 covered lives), and other associated health-care services delivered in Utah, Idaho, and, at a tertiary level, seven surrounding states. In addition to employed physicians, more than 800 independent, non-employed physicians work closely with Intermountain, and more than 1,500 additional physicians hold privileges at one or more of Intermountain's community hospitals or are impaneled through Intermountain's health plan. A charitable, not-for-profit institution founded in 1975, Intermountain has 150,000 inpatient admissions and more than 4 million outpatient encounters annually, supplying more than half of all health services delivered in Utah.

Intermountain has very long experience with electronic clinical-information systems. Dr. Homer Warner, one of the pioneers in the field, began developing electronic medical records (EMR) at Intermountain's LDS Hospital in 1965. By 1979, Intermountain could claim one of the first functional EMRs in the world.<sup>1</sup> Today, Intermountain is considered one of the most "wired" health-care delivery systems in the country.<sup>2</sup>

Intermountain's heavy involvement in electronic patient records led to a parallel deep commitment to protecting the privacy of the patients described in electronic records. The Information Security Committee, reporting to Intermountain's senior management and Board of Trustees, has generated and refined organizational policy to protect patient privacy and confidentiality for almost 15 years. As a result, Intermountain has long experience with detect controls.<sup>3</sup> Detect controls are particularly useful when very high volumes must be overseen and when oversight-associated delays in care delivery could result in patient harm. Today, Intermountain uses more than 15 different modalities to detect ethical violations in patient confidentiality. Some are public, but most operate quietly in the background, outside the knowledge of those being overseen. From that experience, Intermountain has learned three things: First, detect controls can be very effective. Intermountain's Compliance Department investigates more than 60 potential ethical violations per month and takes action about 15 times per month. Most of those actions are warnings, but about two Intermountain employees are terminated from service for ethical violations each month.

Second, ethical violations occur primarily in high-volume, routine-care-delivery areas. In more than 15 years, Intermountain has not experienced a single significant privacy violation associated with quality improvement (QI) or research.

Third, detect controls can form the foundation of an effective management system. Beyond leading to corrective action in specific cases, the patterns of violations evident over time have led to demonstrably more-effective training and oversight, as reflected in violation rates that are literally orders of magnitude below those initially found.

Intermountain began to explore clinical QI in 1986. In 1997, after confirming at a project level the well-described gap between what should be achieved when patients seek care and actual results,<sup>4</sup> Intermountain began to implement data systems to track medical, cost, and service outcomes for key clinical-care-delivery processes. When combined with a clinical management structure, the resulting quality control and improvement system has achieved significant, systemwide improvements in clinical results while reducing care-delivery costs.<sup>5</sup> Performance improvement moved from being an option to being a requirement of good practice.

In that context, The Hastings Center's "The Ethics of Using QI Methods to Improve Health Care Quality and Safety"<sup>6</sup> has proved very useful within Intermountain Healthcare. Because few other care-delivery settings have internal governance structures and information subsystems that closely parallel those found at Intermountain, few systems will find Intermountain's ethical oversight structure a perfect fit. We share our internal implementation structure to demonstrate that The Hastings Center findings can be applied in a reasonable way to manage and improve ethical performance in all aspects of health professionals' interactions with patients.

## Background Assumptions and Principles

At Intermountain, we honor four ethical principles in *all* patient interactions:

1. Autonomy;
2. Beneficence;
3. Non-maleficence; and
4. Justice.<sup>7</sup>

Two main classes of risk are involved:

1. Risks to mental or physical health; and
2. Risks to autonomy (privacy/confidentiality) and associated risks to reputation, including additional financial costs, etc.

We evaluate ethical performance in terms of potential conflicts of interest that might cause a health-care professional to make a patient's health needs anything less than the top priority:

- Specifically, we define "generalizable knowledge" as it is used in the federal regulation governing ethical oversight of research (45CFR46, the Common Rule), in the context of potential conflicts of interest.<sup>8</sup>

- It is impossible to define *research* in terms of publication (or even intent to publish) or the measurement methods used (or whether measured assessment is used at all).<sup>9</sup>
- The Health Insurance Portability and Accountability Act (HIPAA) defines any activity whose primary purpose is care-delivery performance as “health-care operations,” in specific contradistinction to research activities.<sup>10</sup>

We have two main tools to implement ethical oversight:

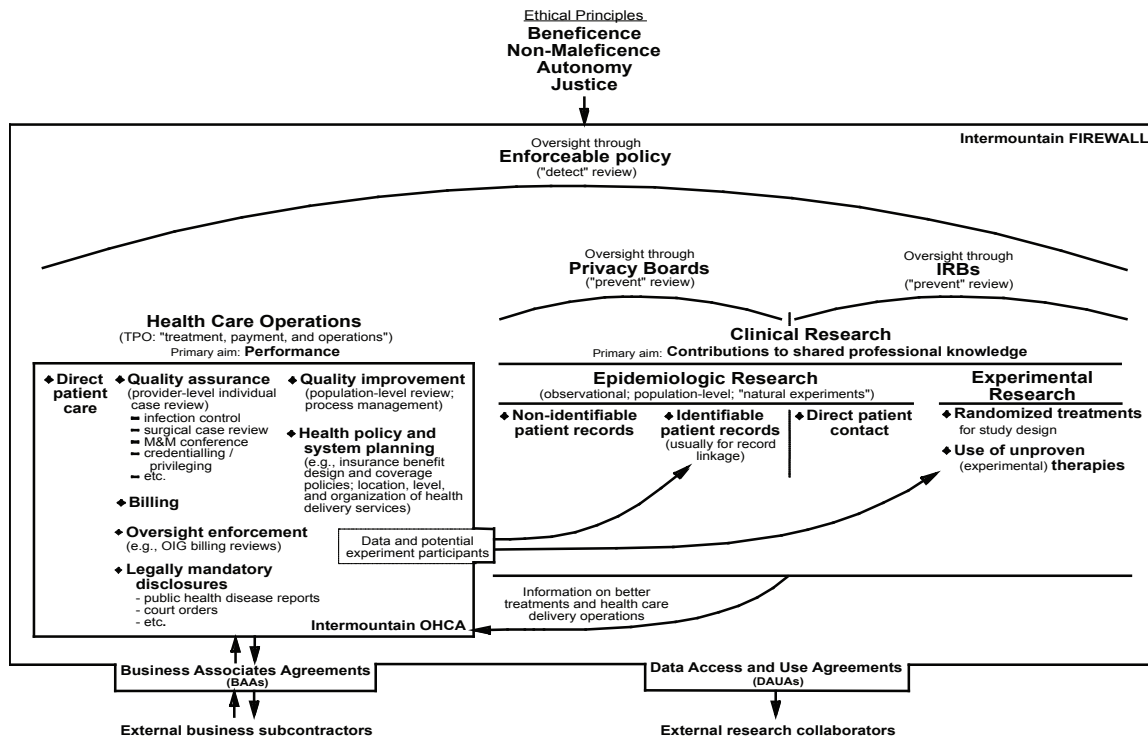
1. *Detect controls* (enforceable policy, retrospective review): set a policy, train all in it, commit all to follow it (e.g., require signed access and confidentiality agreements), monitor for violations, investigate potential violations, take appropriate action based on results of an investigation (Intermountain Sanctions Grid).
2. *Prevent controls* (prospective review): pre-review and approve before activities can proceed; provide subsequent ongoing oversight (i.e., by an Institutional Review Board (IRB) or privacy board).

In general, prevent controls involve much higher costs of operation, in terms of both the time, staffing, and effort required of the organization and the time and effort required of those undergoing review. Therefore, prevent controls are usually reserved for areas with relatively low volume and high risk of potential ethical conflict of interest. Detect controls are usually employed in circumstances of high volume and relatively low risk.

For example, hospitals implement the ethical principle of autonomy through patient informed consent, both on admission to the hospital (to receive health-care services in general) and through specific informed-consent documents completed before major surgical procedures or potentially dangerous medical treatments. Even though risks of inappropriate conflicts of interest can be quite high (for example, a surgeon may stand to receive significant income for performing an operation, which might bias his or her presentation of risks and benefits to a patient), volume alone rules out external ethical review before each procedure is performed (prevent controls). Therefore, hospitals rely on detect controls: The surgeon and hospital staff are required to obtain signed and witnessed informed-consent documents; the consent documents are reviewed through the hospital’s internal quality-assurance procedures; external accrediting agencies (e.g., the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) review the hospital’s oversight practices; and the legal system reviews allegations of violations in individual cases, through malpractice tort actions.

Patient interactions cover a range of activities, loosely described in the figure on the following page. This approach extends the four ethical principles to all patient-related activities, well beyond the areas usually addressed by policies intended to govern research alone.

The term *randomized treatments*, used in the figure to help define experimental research, designates those circumstances where randomization is an inherent part of a study design to compare competing treatments. In some other (rare) circumstances, the act of randomization does not reliably indicate experimental research. Such circumstances include:



- Randomization used for purposes of equity, to allocate a scarce resource; and
- Randomized implementation when introducing a new treatment or service to see if claims for its utility (generated in research settings) hold up in practice. In other words, Intermountain might allow a new procedure or treatment on a pilot basis in some randomly selected subset of the system for a short time to see whether it yields gains as described in the published literature.

We use the definitions provided earlier to distinguish between QI and research. Quality improvement is part of health-care operations. Specifically, in contrast to research, QI

- Describes activities whose primary purpose is better health-care-delivery performance, directly benefiting the individual patients involved;
- Attempts to implement established best practice, as opposed to scientifically determining best practice (defined in terms of Level I (randomized control trial), Level II (observational designs), or Level III (consensus expert opinion) evidence<sup>11</sup>);
- Uses open-loop ("shared baseline") methods that encourage health professionals to diverge from treatment guidelines to meet a specific patient need (in other words, QI activities do not come between a health professional and his or her ethical obligations to a patient);
- Functions at a system level, rather than a patient level (advises and supports clinicians treating patients, rather than directly assigning treatments at the patient level);



- May involve additional measurement and sophisticated analytic methods for purposes of process management and performance assessment; and
- May generate experiential information that is useful to other groups trying to implement best practices.

Intermountain uses prevent controls to oversee the ethical conduct of clinical research activities. Clinical research can place a health professional in an ethical conflict of interest. Specifically, a physician, nurse, or other health professional may consciously or unconsciously place professional demands to produce shared biomedical knowledge above his or her primary ethical commitment to a patient's health-care needs and well-being. As with any other patient interaction, clinical research demands ethical oversight. In an environment with a relatively low volume of research activities and a high risk of ethical failures (as evidenced by several notorious events in the United States and elsewhere in the past), Intermountain uses prevent controls—IRBs and policy boards—to oversee appropriate ethical behavior in clinical research activities.

Intermountain uses detect controls to ensure ethical patient interactions when performing QI projects: Detect controls are appropriate, as (1) we are ethically required to actively encourage performance improvement in all care-delivery settings; (2) there is (and should be) a high volume of performance-improvement activities within the system, making prevent controls very difficult to implement; and (3) the risks of QI activities to patients are low, compared with the well-documented risks of endemic poor-performing care.<sup>12</sup>

Quality-improvement projects should receive prospective oversight (prevent controls) at the point where someone decides to share our care-delivery-improvement experience with the healing professions (that is, the point at which a project shifts into a research setting, raising the risk of potential conflicts of interest):

- This approach closely parallels case-series reports in terms of research risks to patients and models for appropriate ethical oversight.<sup>13</sup>
- Appropriate ethical oversight usually involves an expedited review assessing the release of summary patient information derived from routine health-care operations.

We distinguish administrative oversight from ethical review—specifically, accountability and authority for ethical oversight lie with line administration alone; appropriate administrative officers obtain independent ethical review for specific projects, then act upon IRB recommendations in compliance with Intermountain's internal policies. (This is very important in terms of how Intermountain manages large, multicenter trials and other research collaborations.)

Our ethical commitments to patients are different from our ethical commitments to other groups (such as employees).

## Specific Policies

All Intermountain-associated people (employees, independent health professionals working at Intermountain facilities, etc.) are obligated to meet ethical requirements in all of their patient-related activities, including direct care delivery; other health-care operations, including performance-improvement activities; and research.

QI means measurement activities that

- Focus primarily on local patient-care-delivery performance, rather than the generation of new scientific knowledge;
- Attempt to consistently implement established best practice based on existing Level I (randomized control trial), Level II (observational designs), or Level III (consensus expert opinion) evidence; and
- Involve open-loop systems, in which clinicians are instructed to modify implementation protocols based on patient need (in other words, QI protocol implementation does not create conflicts with a clinician's primary ethical commitment to a patient's personal well-being).

QI does *not* include any activity

- That involves experimental or unproven therapies (not evidence-based best treatment);
- In which patients are randomized among competing treatments (potentially conflicting with a clinician's primary ethical commitment to each patient's well-being) (see note regarding randomization, above);
- That imposes additional testing burdens that represent risk to a patient, while not conveying a countervailing potential benefit to that same patient; or
- That is funded by external grants or awards with primary or secondary goals of knowledge generation, such that those managing the endeavor have potential conflicts of interest that could place patients' interests secondary to some other goal.

Intermountain uses detect controls to oversee all QI activities:

- All Intermountain-associated health professionals are trained (and regularly refreshed) on their ethical commitments regarding all aspects of care delivery, including QI activities (this policy includes an obligation to report any possibly noncompliant activities observed or suspected);
- Intermountain routinely monitors for violations (e.g., experimental research activities masquerading as QI);
- When violations are discovered, the Intermountain Sanctions Grid is applied to correct the situation and administer appropriate punishment, if required;

- Intermountain also uses information gained from the oversight process to routinely improve training and oversight activities (that is, detect controls function as a management system, not just a punishment system).

Intermountain uses prevent controls (i.e., IRBs or privacy boards, as appropriate) to review all research activities before they are initiated and to monitor ongoing research projects.

If a QI effort achieves outstanding performance results and the associated clinical leadership teams want to share their experience through publication, formal external ethical oversight shall be applied *at that point* (most such activities will involve public release of existing nonidentifiable clinical data and so can be overseen through expedited review by a privacy board). This is how we currently handle case-series reports.

## Notes

1. G.J. Kuperman, R.M. Gardner, and T.A. Pryor, *HELP: A Dynamic Hospital Information System* (New York: Springer-Verlag, 1991).
2. J. Towne, A. Solovy, and S. Hoppszalern, "Cover Story: Measuring Value—2006 Most Wired Winners," *Hospitals and Health Networks* (July 2006).
3. Detect controls consist of setting a policy, training all in it, committing all to follow it (e.g., require signed access and confidentiality agreements), monitoring for violations, investigating potential violations, and taking appropriate action based on results of an investigation.
4. Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century*, L.T. Kohn, J.M. Corrigan, and M.S. Donaldson, eds. (Washington, D.C.: National Academies Press, 2001).
5. R. Bohmer and A. Edmundson, *Intermountain Health Care*, Harvard Business School Case Study N9-603-066, October 1, 2002.
6. Mary Ann Baily, Melissa Bottrell, Joanne Lynn, and Bruce Jennings, "The Ethics of Using QI Methods to Improve Health Care Quality and Safety," *Hastings Center Report* 36(4) (2006).
7. This principle includes equal access to health-care services, e.g., it calls for particular attention to underserved populations. In a health-care reality that provides limited resources to meet potentially unlimited demand, within which health care is funded through community mechanisms (through group insurance plans or as government-funded benefits), it extends to appropriate attention to cost-effectiveness and allocation of limited resources to achieve the greatest good.
8. Mary Ann Baily, Melissa Bottrell, Joanne Lynn, and Bruce Jennings, "The Ethics of Using QI Methods to Improve Health Care Quality and Safety," *Hastings Center Report* 36(4) (2006).
9. Ibid.
10. HIPAA §164.501 definitions: Health-care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions: (1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the *primary* purpose of any studies resulting from such activities [emphasis added]; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment; (2) reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities.
11. R.S. Lawrence and A.D. Mickalide, "Preventive Services in Clinical Practice: Designing the Periodic Health Examination," *Journal of the American Medical Association* 257 (1987): 2205–07; E.A. McGlynn, "Introduction and Overview of the Conceptual Framework for a National Quality Measurement and Reporting System," *Medical Care* 41(1) (2003, Supplement): I1–I7.

12. Mary Ann Baily, Melissa Bottrell, Joanne Lynn, and Bruce Jennings, "The Ethics of Using QI Methods to Improve Health Care Quality and Safety," *Hastings Center Report* 36(4) (2006).
13. In a case series, a care team delivers treatments to patients. At some point, the team decides to summarize and share the treatment experience. Research-level ethical oversight happens at that point. It does not retrospectively apply to the care delivery itself.

## About the Authors

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This collection of original papers provides a comprehensive and in-depth discussion of the ethical and regulatory aspects of health care quality improvement (QI). This book combines conceptual analysis with insight gained from clinical and practice examples drawn from leading hospitals and health systems. It addresses such questions as: How does QI differ from clinical research? What duty do physicians, nurses, and health administrators have to facilitate and to engage in sound QI activities? And what is the responsibility of patients to cooperate with them? The book also examines practical goals for QI management and oversight so that patients are protected from harm, privacy is respected, and accountability is ensured.

Contributors to this volume are: George Agich, David Bernard, Rohit Bhalla, Jeffrey Blustein, Melissa Bottrell, Frank Davidoff, Nancy Dubler, Margaret Holm, Brent James, Jacob E. Kurlander, Norma M. Lang, Kevin Lawlor, Maurie Markman, Sharon Martin, Karen J. Maschke, Margaret O'Kane, M. Alma Rodriguez, Mano Selvan, Martin Smith, Richard Theriault, and Matthew K. Wynia.

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