

THE ETHICS OF USING

QI METHODS TO

IMPROVE HEALTH CARE

QUALITY AND SAFETY

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The federal government employees listed above participated in the meeting discussions in an advisory capacity. However, in addition to the preceding disclaimer, it should be further emphasized that the statements in this report should not be construed as endorsement by the Department of Veterans Affairs or any other department of the U.S. government, nor do they represent the policies of any federal departments, agencies, or offices.

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PREFACE

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 of the media and policy debate about cost and access, a quieter but perhaps more significant process of change is under way: the transformation of health care management and delivery—indeed, health professional work itself—through health care quality improvement.

The innovative, interdisciplinary quality improvement (QI) movement has begun to significantly upgrade delivery of health care in the United States. Taking its cue from reform approaches in other industries, and 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, the QI movement has arrived in health care. 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.

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 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 come under the same complex review and regulatory requirements that have been set up to govern biomedical and other types of research. But is this type of regulation necessary, given what QI involves? Is it 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. Thus far, however, relatively few attempts have been made to address QI from an ethical perspective, and the interface between research and quality improvement has not been adequately explored or defined.

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. (See Box 1 for a particularly dramatic example of such a conflict.) The strict ethical rules of oversight, regulation, and patient consent for human subjects research, including the requirement for institutional review board (IRB) approval, have significant 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—that is, 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 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 quality improvement in health care. The project, titled “The Ethics of Improving Health Care Quality and Safety,” was funded by grant #1R13HS13369 from the Agency for Healthcare Research and Quality (AHRQ).

The Hastings Center project assembled a group of experts from a number of interrelated fields and disciplines involved in health care quality improvement, including medicine, nursing, law, social science, health care management, medical editing and publishing, health policy and regulation, health services research, and bioethics. The project’s goals were: (1) to develop an ethical framework that can be applied to ethical issues arising in quality improvement practice, (2) to make practical policy recommendations for quality improvement oversight, and (3) to help promote a constructive dialogue both within and outside the quality improvement community on pertinent ethical issues.

Over a two-year period, the project group met four times for two-day working sessions. Project members and

1. The Pittsburgh ESRD Case

In October 2000, a nephrologist coauthored an article about a project to improve the dialysis care delivered to patients in Medicare's End Stage Renal Disease (ESRD) program.¹ Some time after the article appeared, the university at which he held a faculty appointment notified him that an audit of faculty publications had identified this project as a quality improvement effort that met the definition of human subjects research but had not undergone IRB review. The nephrologist responded that he had participated in the project as the chair of the local ESRD Network's Medical Review Board, that the ESRD Network conducted the project under contract to the Center for Medicare and Medicaid Services (CMS), and that the CMS scientific officer overseeing the project had told him that, as a CMS-directed quality improvement project, it was not subject to oversight by the university's IRB. Later, CMS reaffirmed this opinion in a letter to the university. The university submitted the dispute to the Department of Health and Human Service's Office for Human Research Protections (OHRP) for review.

OHRP responded that the design of the quality improvement project met the definition of human subjects research and that the CMS determination that the project was exempt from IRB review "was not made in collaboration with OHRP." OHRP and CMS have had discussions and exchanged memoranda as to whether this and other quality improvement activities meet the regulatory definition of human subjects research and require IRB review; however, these issues have not yet been resolved. This issue has caused concern among other volunteer physicians in the eighteen ESRD Networks about the implications for ongoing quality improvement projects and the possible impact if their conduct is found to violate the regulations for protecting human research subjects.

1. P.M. Palevsky et al., "Improving Compliance with the Dialysis Prescription as a Strategy to Increase the Delivered Dose of Hemodialysis: An ESRD Network 4 Quality Improvement Project," *Advances in Renal Replacement Therapy* 7, no. 4, supplement 1 (2000): S21-S30.

other invited guests presented and debated the findings of their own research and drafts of commissioned papers focusing on ethical issues in quality improvement. Those papers will be published in an edited volume in 2007. In addition to our deliberations with project participants, we have also made presentations at professional and academic meetings and communicated electronically with a larger group interested in health care system improvement by setting up a moderated e-mail listserv. Following the publication of this report, The Hastings Center will continue to serve as a resource in the process of translating the conclusions and recommendations of the project into practical policies through the listserv, presentations at professional and academic meetings, production of additional written materials, and direct

contacts with persons and organizations interested in the ethics of QI.

This report presents the analysis, findings, and conclusions that emerged from the deliberations of the project participants and staff research conducted for this project. The authors are Mary Ann Baily, Melissa Bottrell, Joanne Lynn, and Bruce Jennings. This report is not a consensus document in the sense that each project participant agrees with it in all details, but we have done our best to present an accurate and faithful reflection of the thinking of the group as a whole, and this analysis certainly would not have been possible without the benefit of their insights and expertise.

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Quality improvement in health care takes many forms, ranging from changes in financing to reforms in professional education to investments in new facilities and equipment. In this report, we are concerned with the form of improvement that occurs through clinical and managerial innovations and adaptations in the delivery of care. These changes have always been an integral part of health care delivery, but in the past they were often introduced informally and idiosyncratically, without careful attention to all of their effects. In recent years, people in health care have begun to use many new formal, explicit methods, some of which were developed in other industries, to make the process of continual adjustment more self-reflective and systematic, and thus increase the likelihood that it produces positive change. In other settings, this approach to improving quality is often referred to as “QI.”

When we use the term “QI” in this report, we mean systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings. While QI uses a wide variety of methods, they all involve deliberate actions to improve care, guided by data reflecting the effects. Depending on the activity, QI can look like a type of practical problem solving, an evidence-based management style, or the application of a theory-driven science of how to bring about system change. Introducing QI methods often means encouraging people in the clinical care setting to use their daily experience to identify promising ways to improve care, implement changes on a small scale, collect data on the effects of those changes, and assess the results. The goal is to find interventions that work well, implement them more broadly, and thereby improve clinical practice. Alternatively, a QI activity might begin with a review of aggregate data at the patient, provider, clinical unit, or organizational level to identify a clinical or management change that can be expected to improve care. The change is made, the effects are monitored, and conclusions are drawn about whether the change should be made permanent. QI can also mean collecting data from multiple organizations, analyzing it to understand what drives positive change, and using the results to design and implement a strategy to achieve a specific improvement across organizations. At its heart, QI is a form of experiential learning and discovery.¹

QI work is data-guided, usually involves human participants, and sometimes uses methods that are also used in medical research. Thus, it is not surprising that the issue of its relationship to federal regulations governing research with humans has arisen. These regulations were put in place to ensure that federally funded research projects

meet accepted ethical standards for protection of human research subjects. The regulations that are relevant to this report are codified at Title 45 CFR 46 as Department of Health and Human Services, Protection of Human Subjects. The core requirements (Subpart A) are that individuals be selected equitably to participate in research; that research subjects give full, voluntary written consent; and that an IRB review proposed research and approve it only if risks to subjects have been minimized and are reasonable in relation to anticipated benefits.² There are additional requirements (Subparts B, C, and D) for research that involves especially vulnerable subjects, such as pregnant women, prisoners, and children. The DHHS regulations do not cover non-federally funded research, but organizations engaged in research are encouraged to provide formal assurances to the government that all their human subject research will comply with the DHHS regulations whatever the funding source. Also, although Subpart A explicitly exempts some categories of human subject re-

Although systematic empirical information on the quality of care is limited—which is itself surprising—what is available is disturbing.

search from the regulations, the DHHS Office for Human Research Protections (OHRP) has issued guidance stating that researchers should not be allowed to decide on their own that their projects are exempt. Many institutions require determination of exempt status to be made by an IRB. In practice, a substantial proportion of both federally funded and nonfederally funded human subject research, especially biomedical research, must be submitted to an IRB. (For a brief summary of the DHHS regulations, see Box 2.)

Discussion of ethical issues raised by QI has tended to center around the legal question, “Is this QI project ‘human subjects research’ as defined by federal regulations and therefore subject to IRB review and the regulatory requirements for informed consent?” The case outlined in Box 1 is but one example of many in an ongoing controversy in the literature, in IRBs, and in organizations doing QI about whether QI is research and therefore covered by the regulations.

Framing the issue in this way may not be the best way to proceed, however. The goal is to ensure that QI activities are carried out in an ethical manner and that their human participants are treated appropriately, however the activities are planned and structured and whatever the ac-

2. Summary of DHHS Policy for the Protection of Human Subjects (Subparts A-D)

Department of Health and Human Services policy sets out a complex set of provisions for the protection of human research subjects. It:

- extends to research funded by the Department of Health and Human Services and to nonfederally funded research conducted at or in conjunction with an institution that agrees through its federal-wide assurance to extend the regulations to all research regardless of funding source. Six categories of research activities are exempt from the regulations (45 CFR 46.101(b)(1)-(6))
- requires prior review and approval of nonexempt research by a duly constituted institutional review board (IRB), and continuing IRB review of ongoing research (45 CFR 46.103)
- permits expedited review (conducted by IRB chairperson or by one or more experienced reviewers) when certain criteria are met (45 CFR 46.110 and Guidance on the Use of Expedited Review Procedures)
- requires seven items to be satisfied for IRB approval of research: risks to subjects are minimized; risks are reasonable in relation to anticipated benefits; subjects are selected equitably; informed consent will be obtained from prospective subjects or their legally authorized representatives; there will be written documentation of informed consent; the trial will receive safety monitoring, when appropriate; provisions are made for subject privacy and confidentiality of data, when appropriate (45 CFR 46.111)
- requires IRBs to ensure that additional safeguards are included in a study when participants will likely be vulnerable to coercion or undue influence (45 CFR 46.111)
- prohibits institutional officials from approving research that has not received IRB approval (45 CFR 46.112)
- permits IRBs to suspend or terminate research approval when a study is not conducted in accordance with IRB requirements or is associated with unexpected serious harm to participants (45 CFR 46.113)
- requires that specific information be provided to research participants to satisfy the general requirements for informed consent (45 CFR 26.116)
- permits IRBs to approve a consent procedure that omits or alters some or all of the elements of informed consent when certain criteria are met (45 CFR 46.116)
- requires additional protections for pregnant women, human fetuses and neonates (45 CFR 46.201), prisoners (45 CFR 46.301), and children (45 CFR 46.401)

tivities are called. Focusing on IRB review and the definition of research may implicitly suggest that IRB review would be adequate and that it is the only way to protect QI participants. This is an overly narrow perspective. In this report, we explore the similarities and differences between research and QI, but rather than focus entirely on “Is QI research?” and “IRB review, yes or no?” we step back to look at the bigger picture. We ask: “What is the place of QI in the operation of the health care system?” “What makes a QI activity ethical?” and “What institutional arrangements should be in place to ensure that specific QI activities meet ethical requirements?” Only after that do we return to the question of how QI activities should relate to IRB review and other procedures for the protection of human subjects in research.

Organization of the Report

Section I explains why quality improvement is important in health care and discusses the role of QI methods in the management of health care delivery. We then consider the underlying ethical question of who has re-

sponsibility for improving the quality of care. We conclude that engaging in quality improvement is not purely discretionary; health professionals, managers, delivery organizations, patients, and government all have an ethical responsibility to cooperate with one another to improve the quality of care. Section II compares and contrasts QI and research in terms of each activity’s goals, methods, role in the health care system, and impact on human participants. We use the principles of research ethics that underlie the current system for protecting human research subjects as a base from which to explore and define the requirements for ethical conduct of QI activities. We then consider the use of IRBs for ethical oversight of the conduct of QI and conclude that, for a variety of reasons, IRBs as currently constituted are not appropriate for this purpose. Section III discusses the institutional arrangements that should be in place to ensure that QI activities meet ethical requirements. Section IV addresses implementation, and Section V briefly summarizes the conclusions and policy recommendations of the report.

I. The Place of Quality Improvement in Health Care

Many Americans have a rosy picture of the quality of their health care system. They believe that it provides a generally high standard of care that is continuously updated as new research findings come out, so that it remains the best in the world. They recognize, of course, that there are some access problems (especially for the uninsured and underinsured) and some below-par facilities and professionals—no health care system is perfect—but overall, the sense is that the quality of care is excellent. Unfortunately, this view is too optimistic. Recent work by individual scholars and by organizations such as the Institute of Medicine (IOM) and the Agency for Healthcare Research and Quality (AHRQ) has provided detailed, compelling evidence of serious problems with the quality of American health care.³

Since quality is a complex, multifaceted concept, assessing just how well the American health care system is doing is not easy. It requires the development of a conceptual framework for understanding quality and the translation of that framework into practical measures that can be applied in specific contexts. The framework developed by the Institute of Medicine in several influential reports 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.”⁴ The core dimensions of quality are identified as safety, effectiveness, patient-centeredness, and timeliness.⁵ Two additional aspects of care that cut across these dimensions are equity and efficiency.⁶ (See Box 3 for definitions of these six quality characteristics.)

The status of efficiency in the quality framework is controversial. In *Crossing the Quality Chasm*, the Institute of Medicine Committee on the Quality of Health Care considers it a dimension of quality, but another IOM committee, charged with translating the IOM’s quality framework into practical measures, does not, arguing that efficiency is “an important goal of the health care system that is related to, but conceptually different from quality of care.”⁷ In this report, we work from the position that increasing efficiency is often a goal of quality improvement activities, since the developers of QI methods have traditionally considered efficiency an appropriate QI concern, and activities involving changes designed to produce the same quality of care with fewer resources constitute an important QI category.⁸

Although systematic empirical information on the quality of care is limited—which is itself surprising, given the size and importance of the health care sector—what is available is disturbing. In a comprehensive review of the literature on quality of care from 1987 to 1998, Schuster and colleagues found substantial evidence of overuse, underuse, and misuse of care in the United States. Serious

quality problems were seen in preventive, acute, and chronic care, in the care provided in different kinds of health care facilities, in care paid for by different kinds of health insurance, in the care received by different age groups, and in rural and urban settings.⁹ The studies they reviewed document unnecessary surgery; inappropriate use of medications; failure to perform standard screening tests; inadequately controlled asthma, diabetes, and hypertension; and significant departures from recommended levels of care for patients with cardiovascular disease. A more recent study examined the care received by a large sample of adults in twelve cities and documented a variety of quality problems, finding that overall, participants re-

3. Quality Framework

Quality is defined in the Institute of Medicine report, *Crossing the Quality Chasm*, 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.¹

The report describes the following characteristics of quality:

Safety: avoiding injuries to patients from the care that is intended to help them

Effectiveness: providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively)

Patient-centeredness: providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions

Timeliness: reducing waits and sometimes harmful delays for both those who receive and those who give care

Equity: providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status

Efficiency: avoiding waste, including waste of equipment, supplies, ideas, and energy

1. Institute of Medicine, *Crossing the Quality Chasm* (Washington, D.C.: National Academy Press, 2001).

ceived only a little over half of recommended care.¹⁰ There is also ample evidence of equity problems: the quality of care varies in ways systematically correlated with ethnicity, geographic location, and socioeconomic status.¹¹

To help remedy the lack of information and make it easier to monitor quality over time, the IOM and AHRQ have developed a comprehensive set of quality measures, and in 2003, AHRQ published the first in a projected series of periodic national quality reports. The report provided a baseline of quality information, including evidence on the tremendous variation in quality of care across geographic areas and across individual care settings.¹² The 2004 and 2005 *National Healthcare Quality Reports* found improvement in some measures, but deterioration on others, and concluded that the gap between the best possible care and actual care remained large.¹³ AHRQ also publishes a companion series, the annual *National Healthcare Disparities Report*. The 2003, 2004, and 2005 reports provided baseline and follow-up information on the pervasive racial, ethnic, and socioeconomic disparities in health care access and quality in the United States.¹⁴ Finally, for an international comparison, in a recent survey, one-third of patients with health problems in the United States reported experiencing medical, medication, or test errors, the highest rate for the six countries included in the survey (the others were Australia, Canada, Germany, New Zealand, and the United Kingdom).¹⁵

The more we learn about current quality, the clearer it is that safe, effective, patient-centered, timely, equitable, and efficient health care will not happen automatically. Rather, it requires and will continue to require systematic and self-conscious management of health care delivery expressly directed at improving care. This means not only the implementation of specific changes, but also the transformation of the culture of health care delivery into a culture that is committed to continuous quality improvement.

QI Activities: Part of Normal Health Care Operations

Efforts to improve quality take place in a health care environment that is continually experiencing change. Some of this change occurs in response to fluctuations in market conditions as, for example, the age distribution of the population evolves, new diseases emerge, or careers in health care are considered more or less attractive. Some of the change occurs in response to scientific progress as, for example, a known disease is better understood, a new drug is developed, or new diagnostic technology becomes available. Managing this constant change is a core responsibility of the people and the organizations that make up the health care system. The specific patterns and processes of care in one clinical setting are the product of thousands of small and large decisions about handling change that

could have been made somewhat differently in that setting, and that have been made differently in other settings.

Within this universe of change-related activity is a subset of *deliberate efforts to make positive changes in the delivery of clinical care*. Many of these “designed changes” come about by “just doing it”; someone decides that a change in clinical practice or organizational arrangements seems like a good idea and the change is made. Such innovation and adaptation is an intrinsic part of clinical and managerial practice. Health care practitioners must tailor a general standard of practice to individual patients, relying on their clinical knowledge, their unique knowledge of each patient, and the characteristics and capabilities of the local context in which care is being delivered. Managers must exercise judgment about how resources in a particular setting should be organized to carry out treatment plans for the patients being served.

When this innovation and adaptation is undertaken in a systematic, data-guided way, it becomes what we are calling QI. The category of QI includes a wide variety of activities and cannot be defined by any one method or procedure.

QI is closely related to clinical practice, and in fact, much of QI is simply good clinical care combined with systematic, experiential learning. Individual practitioners are constantly learning by doing and taking steps to improve their own practice. Physicians may develop personal templates for entering information in medical records and for tracking the lab tests they have ordered; surgeons may work on their surgical techniques to reduce the time patients spend anesthetized; nurses may refine their skin care methods to reduce the incidence of bedsores.

Very quickly, however, the effort of an individual clinician to improve his or her practice becomes an issue for others working in the same environment. 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. In other words, both patients and providers are part of *systems* of care. A key insight of those promoting QI methods is that quality and safety are largely systems issues, and understanding the interdependencies and relationships within systems is at the heart of QI work.¹⁶ In systems, management practices may be as significant to good outcomes as the clinical practices of individual care providers, so learning by doing in management is also important. Many QI activities involve clinicians cooperating with each other and with management and support staff around improvements in scheduling procedures, encounter forms, medication handling, patient flow within and across clinical departments, communication within patient care teams, record-keeping, and other administrative procedures.

QI methods include a variety of tools for motivating and structuring the cooperation, changing the process or system, monitoring what happens, and evaluating the

change. In addition to local “learning by doing,” QI involves deliberate applications in local settings of new knowledge developed elsewhere. The goal of many QI activities is to introduce a new clinical practice based on an advance in medical science or a new administrative practice based on managerial experience or social science research. Moreover, QI activities often use the science of organizational change to design strategies for changing behavior in the local setting—for example, to get adherence to a new practice guideline or a new patient safety protocol.

In sum, QI is a particular form of the clinical and managerial innovation and adaptation that has always been an integral part of health care operations. To the process of change, it adds systematic, self-reflective design, monitoring, data analysis, and assessment of the effects of changes to ensure that they are in fact beneficial, and it feeds this information back into the delivery setting. It uses new knowledge developed in the medical and social sciences to help identify positive changes and design practical strategies to implement them in the local setting. In the process, the QI practitioner implicitly or explicitly uses each attempt to improve care to deepen his or her understanding of the content and process of bringing about positive change in that setting. Ideally, over time, the successful use of QI methods helps to transform the culture of an organization into one in which everyone is committed to continuous quality improvement and has the skills to participate in it. Thus, QI has the potential to make a substantial contribution to solving the quality problems in American health care.

The Ethics of Improving Health Care Quality

Before we can discuss the ethical issues that arise when QI methods are used in health care, we must address the underlying question of who is responsible for improving the quality of care. Health care is of unusual consequence because of the role it plays in relieving suffering, preventing premature death, restoring function, increasing opportunity, providing vital information about an individual’s condition, and giving evidence of a community’s mutual empathy and compassion. As a result, health care access, quality, and cost have always been matters of *societal ethical concern*.¹⁷

Since antiquity and across different cultures, healers have been revered as persons with special knowledge of the mysteries of life and death, and the relationship between patient and physician has held deep moral and religious significance. Physicians, nurses, and other health professionals have been understood to have a special ethical responsibility to serve the interests of their patients, including the responsibility to maintain and continually strive to improve the quality of the care they provide.

Over time, the concept of medicine as a profession has taken hold and science has replaced religion as the basis of

medicine. With scientific progress has come better understanding of bodily processes and more effective treatments for illness. As these treatments have been embodied in new technology, the provision of health care has become a more complex process, involving an array of organizations and specialized professionals working together in complex systems of care.

Nevertheless, even as medical practice has changed, the moral and ethical aspects of medicine have remained central to the understanding of what it means to be a member of a health profession.¹⁸ Since health outcomes are inherently uncertain and vary under different treatment options, health care decisions are complicated. Patients find it difficult to understand their choices, especially when uncertainty and the risk of adverse events are involved, and they must rely on physicians and other health care providers for help. Given the importance of health to well-being, patients are vulnerable to exploitation in this dependent role.

Therefore, society continues to expect physicians to accept a special ethical responsibility to serve each patient’s interest. As other health professionals and health care or-

Improvements in the quality of health care will not happen automatically. Systematic and self-conscious management of health care delivery is needed.

ganizations have played increasingly important roles in care delivery, analogous ethical responsibilities to serve the patient’s interest have been recognized for them.¹⁹

The understanding of these ethical responsibilities has sharpened as health care has evolved from a simple patient-physician interaction to today’s complex interactions between patients and caregiving teams and organizations. It is more evident now than in years past that the ethical imperative to “serve the patient’s interests” does not mean ignoring the interests of every patient except the one present at the moment. Since health care organizations serve groups of patients, clearly they must manage the process of care with policies and procedures that balance the needs of all the patients they serve. Characterizing this as “we treat populations now, not patients” or “the patient’s interest must now be subordinated to the population’s interest” is misleading, however. Physicians have always had multiple patients in their practices, and hospital-based nurses have always managed care for multiple patients simultaneously. They have thus had to consider the interests of all their patients in allocating personal resources of time and energy to their practices. Moreover, it is in an individual patient’s interest to have health care providers follow or-

derly processes that function well for people in different situations. After all, one could be in one of those situations oneself sometime.

It is abundantly clear, therefore, that health professionals and health care organizations have an ethical responsibility to serve the interests of patients, and patients certainly have an interest in the quality of health care. But what is the nature of this interest? What level of quality do patients want? What level are they entitled to? In the case of an ordinary commodity, these questions would usually be answered through a market process. Buyer preferences and budgets would interact with seller production costs to produce the products that buyers wanted and could afford—and there would probably be an array of quality levels.

But given health care's complexity, people cannot easily make informed assessments of quality and develop sensible and stable preferences for their health care. Moreover, even if they could, they would have difficulty getting them implemented, because often they are not paying directly for their care. Since future health status is uncertain, people need insurance to make sure they will be able to afford the care they want if they get sick. In addition, like most societies, the United States recognizes a societal ethical obligation to provide at least some basic health care without regard to ability to pay.²⁰ Third-party payment adds a social dimension to decision-making. When resources are pooled, whether through private insurance or through publicly funded social insurance, collective decisions must be made about how the pooled resources should be spent. These decisions play a key role in determining both the quality and the quantity of care to which patients are entitled.

Within the framework of these collective decisions, health professionals and health care managers have an ethical responsibility to meet socially determined quality expectations, which may take the form of a threshold of minimally acceptable care with a range of permissible quality variation above it. They have an ethical (and often a legal) responsibility to cooperate in activities to improve the performance of the teams and the organizations they belong to in order to meet those expectations. They also have an ethical responsibility to cooperate in societal efforts to improve the overall health care system to accord with those expectations. These obligations follow directly from their underlying professional responsibility to serve the interests of patients.

The responsibility to improve has been stated in terms of meeting current expectations. That is, it is a responsibility to reach at least a threshold standard of quality. What makes it a responsibility for *ongoing* improvement is the understanding that the societal expectation is one of continuous progress in medicine—progress that produces its benefits when it is incorporated into medical practice.

As part of the system of care, patients also have a responsibility to participate in quality improvement.²¹ To

meet the quality expectations of patients, health care professionals and managers must have the cooperation of the patients themselves, because modern health care delivery is a collective enterprise. Providing safe, effective, patient-centered, timely, efficient, equitable, and up-to-date care is a health care organization's mission.²² QI methods allow the organization to pursue its mission in a systematic, data-guided way. To be effective, these methods require at least a minimum level of cooperation from patients, such as permission for the collection and use of data on their health conditions, treatments received, and outcomes. In other words, ongoing activities to maintain and improve the quality of care, including activities using QI methods, are an integral part of the normal operations of the organization. This means that someone seeking care from a health care organization cannot insist on the freedom to opt out completely from efforts to improve the quality of care in that organization without jeopardizing the very benefits he or she seeks. In fact, it is in the best interest of patients to cooperate with QI activities and even to seek out the health care organizations that are the most committed to QI.

As an ethical matter, the responsibility of patients to cooperate in QI activities is justified by the benefits each patient receives because of the cooperation of the others in the collective enterprise. To reap the benefits of such a system without participating in it—to be a “free-rider”—would be unfair.²³ A patient's responsibility to cooperate is, of course, subject to a standard of reasonableness, which presumes that adequate protections against individual harm and violation of rights are in place. For example, patients can reasonably expect to have the confidentiality of their personal health information protected, and to have the opportunity to choose whether to participate in a QI activity that exposes them to more than minimal risk compared to routine medical care. We will address the nature of these protections and what constitutes minimal additional risk over and above that found in routine medical care in greater detail later in this report.

In sum, health professionals, health care organizations, and patients have an ethical responsibility to cooperate in maintaining and improving the quality of health care. In its traditional role of protector of the health and safety of its citizens, government also has ethical responsibilities with respect to the quality of care. In particular, it should help to clarify the content of the ethical and legal responsibilities of health care professionals and organizations toward their patients and to ensure that the responsibilities are met.

II. QI and Research: Similarities and Differences

Although QI is closely related to clinical and managerial practice, it also has much in common with research. QI uses the kind of reasoning that is inherent in the scientific method, it involves systematic investigations of working hypotheses about how a process might be improved, and it frequently employs qualitative and quantitative methods and analytic tools that are also used in research projects. It is these similarities between QI activities and research projects that have touched off the debate about whether QI activities should be subject to the DHHS regulations on human subjects research.

How does QI differ from research? The definition of research in the DHHS regulations highlights the knowledge-seeking aspect of research as the element that separates it from other activities: “Research means a systematic investigation, including research development, testing and evaluation, *designed to develop or contribute to generalizable knowledge.*”²⁴ In this definition, research is designed to develop new knowledge, not to implement knowledge; implementation happens later and separately, if it happens at all. Dissemination of research results, such as through publication in scientific journals, is thus of fundamental importance. Allowing research subjects to assume the burdens and risks of research is justified by the expectation of societal benefits from the new knowledge produced; publication is an important step in conveying the new knowledge to those who can put it into practice and thereby create the social benefits.

Although the definition does not make it explicit, the regulations implicitly reflect a view of research as a *knowledge-seeking enterprise that is independent of routine medical care*. Opinions differ on whether a society has an obligation to engage in research, including research that will ultimately yield important benefits to human health. But even if such an obligation exists, there is a presumption in research ethics that the research enterprise should rely on volunteers.²⁵ Investigators choose to do research, and people should be able to choose whether to be research subjects. This ethical paradigm emerged in response to research that imposed substantial risks on subjects yet offered them no prospect of direct benefit (such as the Nazi experiments and the U.S. Public Health Service Study of Untreated Syphilis, commonly known as the “Tuskegee syphilis study”), and it builds on the observation that the interests of researchers are inherently tangential to, and possibly even at odds with, the interests of the subjects. Since researchers want to produce successful research, they have a strong interest in enrolling subjects in their studies, keeping them in, and getting them to conform to study rules. People who do not know themselves to be involved in research, or who do not have the opportunity to discern the merits of their own involvement, are at risk of being

exploited in the scientist’s search for insight—or more pragmatically, the search for funding, publication, and career advancement. To counter these pressures to use people wrongly to further the ends of other people and justify the research, the subject’s decision to participate in the research must be voluntary and fully informed.

In health-related research, the independent nature of the enterprise is obvious when the research takes place away from a health care delivery setting and the human subjects are healthy. When the research takes place in a clinical setting and involves sick patients who are receiving care, research and therapy may be mixed, complicating matters significantly. Nevertheless, even research on an intervention that holds out the prospect of direct benefit to the subjects is seen to have a different relationship to its setting when compared to QI. Research with human subjects in a clinical setting is usually conceived, funded, and

QI is an ongoing process undertaken as a consequence of health care providers’ responsibility to serve their patients’ interests. This makes it very different from research.

managed as discrete projects, each led by a principal investigator who is responsible for the project’s design and conduct. For research in a clinical setting, the resources often come from outside the organization in which it is carried out (from a federal agency, private foundation, or biotech or pharmaceutical corporation, for example); or, if from inside, from a separate research budget, not from clinical care resources. Most important, there is significant uncertainty about whether the intervention is in fact beneficial, and the activity is designed to produce generalizable knowledge about the intervention, not immediately improved care. This usually means that research has a protocol that is constructed to minimize the effect of specific local variables and is maintained unchanged during the period of the research. It also means that there is relatively little urgency to disseminate the results, and the results may not be made known to the scientific community for many months, even years, after the research is begun. Finally, there is no presumption that the results will be incorporated into the local care delivery process, and frequently little or no attention is paid to the challenges and opportunities for implementation of the findings in any setting at all.

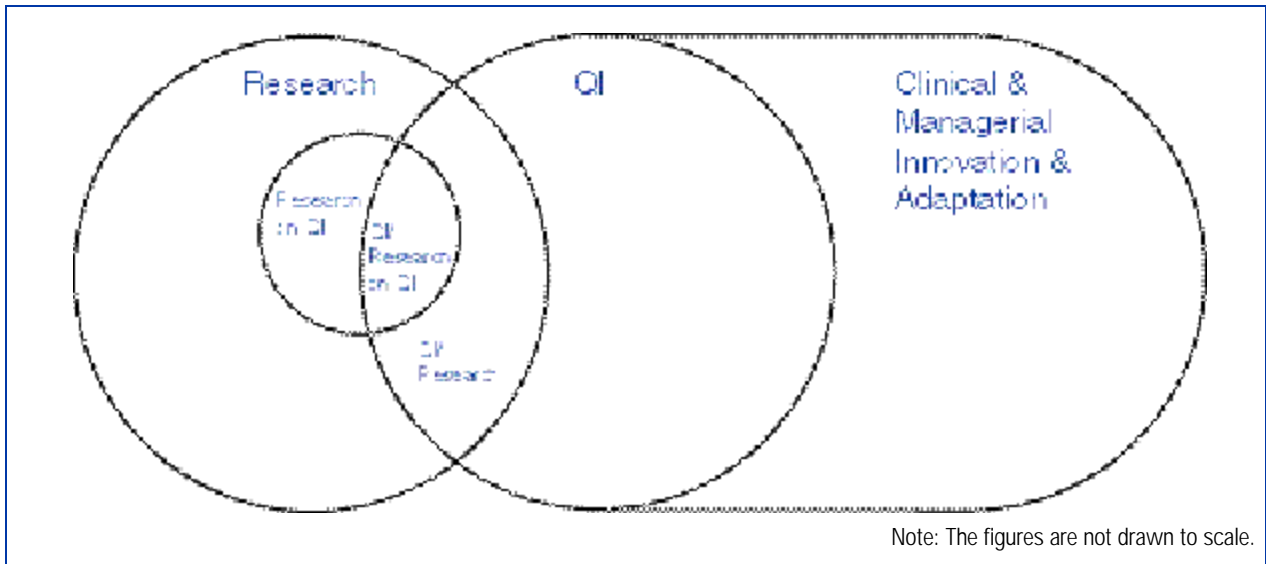


Figure 1.

In contrast, QI is *an integral part of the ongoing management of the system for delivering clinical care*, not an independent, knowledge-seeking enterprise. QI practitioners design QI activities to bring about immediate improvements in care, relying on theory and evidence from research and practical experience to identify changes that are very likely to be beneficial. QI activities take place in a particular localized health care setting, their design is expected to incorporate the specific features of the setting, they are led by people who work in that setting, and they incorporate rapid feedback of results to bring about positive change for the patients in that setting. Instead of a fixed protocol implemented for a time period that may last for years, QI methods often require repeated modifications in the initial protocol as experience accumulates over time and as the desired changes engage the local structures, processes, patterns, habits, and traditions. The term “continuous quality improvement” (CQI), used almost interchangeably with the term QI, highlights the fact that QI is not so much the implementation of discrete projects as it is an ongoing process of continual, self-conscious change, undertaken as a natural consequence of health care providers’ ethical responsibility to serve the interests of their patients. This makes it a very different kind of endeavor from research and generates the *prima facie* case for questioning whether the public’s interests would be best advanced by subjecting QI to exactly the same process of review and evaluation that has been designed for discrete research projects.

QI and research are thus both conceptually and practically distinct and play different roles in health care. Nevertheless, in the process of making change, QI does yield information about what works and the way in which change can come about. When the results of QI activities in various settings are looked at together, patterns may emerge—and even a single QI endeavor may yield valu-

able insights for a QI practitioner in another setting. Moreover, QI activities that have theory-based designs inevitably become examples that in the long run tend to increase or decrease the level of confidence in the theories on which they are based. With careful, systematic reporting, the insights from QI are of use to people in other settings, just as case reports on individual patients are useful (although they too are not research). Given this, QI practitioners should be encouraged to share information about their QI activities with others in the health care system.

Furthermore, although QI and research are conceptually distinct, in practice they are sometimes combined in one activity. In other words, some systematic, data-guided activities designed to bring about immediate local change are also “investigations designed to develop or contribute to generalizable knowledge”; they are *both* QI and research.

At this point, a diagram is useful to illustrate the relationships among the activities under discussion. In Figure 1, the set “Clinical and Managerial Innovation and Adaptation” is shown as a large oval and consists of activities designed to bring about immediate local improvements in clinical and managerial practice. The set “QI” is shown as a subset of that oval; it consists of clinical and managerial innovation and adaptation activities that are designed and carried out in a systematic, data-guided way.

“Research” is the large circle and consists of systematic investigations designed to develop or contribute to generalizable knowledge. The “Research” set includes basic and applied medical research, of course. It also includes other categories of research with a potential impact on health care quality, such as epidemiological research, health services research, management research, and educational research. The activities that are both QI and research are

shown in the diagram as “QI/Research”—the overlapping section of the “QI” set and the “Research” set.

One important research category, “Research on QI,” is explicitly depicted in Figure 1. It consists of systematic investigations designed to produce generalizable knowledge relevant to the design and implementation of QI activities. The application of evidence-based medicine requires the generation of new knowledge on the behavior of systems, and research on QI contributes to this knowledge by helping to answer questions such as “What are the principles of change?” “How do these principles work within different organizational contexts?” and “How can one spread desired change across an organization or between organizations?”

Research on QI can be independent of the QI activities it studies. For example, an investigator could do a retrospective study of QI activities carried out in different organizations with the aim of testing a hypothesis about the effects of organizational characteristics on results. Alternatively, QI and research on QI can be combined in a single activity designed to produce both immediate local change and generalizable knowledge about the process of change. For example, a health care organization with multiple delivery sites could conduct an activity in which the sites are divided into two groups, a different strategy is used in each group to introduce a new practice, and the results of the strategies are compared, with elements included in the activity’s design to facilitate generalization of the results to other organizations. In Figure 1, the set of such hybrid activities is the region of overlap between the sets “Research on QI” and “QI,” and is labeled “QI/Research on QI.”²⁶

Protection of Human Participants in QI and Research

Both research and QI can adversely affect the people who participate in them. Today’s human research subject protection system was inspired by research projects that offered subjects no direct benefit and exposed them to substantial harm. 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 they are 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.

Burdens can take the form of direct physical harms, mental and psychological harms, “hassle” harms such as time consumed in completing surveys or submitting to extra clinical or administrative procedures, or harms related to loss of privacy and confidentiality. Often, there is uncertainty about whether a harm will occur and how severe it will be if it does occur. In the rest of this report, we will use the broad term “risk” to refer to the various kinds

of burdens that may fall on participants as a result of a QI activity.

Researchers have a recognized ethical responsibility to ensure that the human subjects of their research are appropriately protected. The people using QI methods to manage the quality of care also have an ethical responsibility to participants in their QI activities. The need to meet ethical standards creates a potential need for explicit structures and oversight to ensure that research and QI are practiced appropriately. It does not necessarily follow, however, that the standards and oversight should take the same form for both activities.

To address this issue, we must first consider the general principles and values that are at stake. We begin with the principles of research ethics that form the foundation for the current system for protecting human research subjects. The discussion is organized around seven ethical requirements: social or scientific value, scientific validity, fair subject selection, favorable risk/benefit ratio, respect for potential and enrolled subjects, informed consent, and independent review.²⁷ We discuss the justifications given for each requirement in the context of research and then ask whether the same reasoning applies to QI work. (The results of the latter portion of this analysis are summarized in Box 5 near the end of this section.)

*Social or scientific value: Is the research worth doing? Do the potential gains from doing it justify the resources spent and the risks imposed?*²⁸

To be ethical, research must be worth doing, because there is an ethical obligation to use scarce resources responsibly. Also, it would be wrong to expose human subjects to risk without social or scientific benefit. This means that researchers have an ethical obligation to share the knowledge gained from research with others, through publication in peer-reviewed journals or by other means, so that the benefit can actually be achieved.

Obviously, QI should also be worth doing for the same reasons. The potential gains must justify the resources spent on the activity and any risks imposed. The primary gains from QI are the benefits from the local improvements that result. Broader social benefits are also possible when reports of QI activities in different settings generate insights about the nature and process of improvement. To achieve the social benefits, those who conduct QI activities should be willing to share information about them with others in the health care system.

This requirement is thus the same for QI and research. Its application is different, however—and in some ways more difficult—in the QI context. To establish the worth of a research project, one must assess the net benefit to society from the knowledge it might produce. Usually, this amounts to ensuring that the research question is appropriate and the research design adequate. To establish the worth of a QI activity, one must assess the expected net effects of the proposed process of change on present and fu-

ture patients in the local setting, as well as any social benefits that may result from sharing the insights gained. Forming an estimate of the impact of the local change can be a complex professional and management task that requires a detailed understanding of the local system of care delivery.

One must also assess the potential risks to those who participate in the QI activity itself. The chief difficulty here lies in the identification of the appropriate baseline from which to measure the risks to participants attributable to the QI activity. In a freestanding research project, a person is either getting an intervention or not, and the baseline for measuring harm and risk is ordinary life with no intervention. In a clinical treatment research project, the fact that the subject would be receiving clinical care in any case complicates the assessment, but typically, the research has a control group receiving a carefully specified standard treatment that is the appropriate baseline from which to measure the risks to subjects receiving the unproven treatment.

In the QI context, the risks related to extra visits, questionnaires, or procedures needed for data collection and monitoring can be distinguished and attributed to the QI activity. Although these burdens are usually small, they should be weighed in deciding on the merits of proceeding. But how should one assess the net risks to the participant associated with the proposed change itself? Here it is important to note that the care delivery process to which a patient is entitled is not specified in all its details; in fact, it is always changing. Even in a single clinical setting, the attributes of the care patients receive can vary from day to day, depending on the availability of staff, the number of patients scheduled, and other factors. Managers and clinicians have the professional discretion to make changes in care within certain (fuzzy) limits related to the range of variation in existing health care delivery. Over time, they are actually *required* to make changes in order to remain in compliance with evolving minimum standards of care and to avoid malpractice liability. For many of the changes introduced through QI methods, the difference for patients between being in or out of the QI activity may be no greater than the existing variation in the patterns of care across organizations, or within the same organization. Moreover, the methods of QI guide practitioners to use theory, evidence, and practical experience systematically in order to identify and implement changes that are very likely to be beneficial. We are not suggesting that it is impossible to recognize that a specific change has the potential to cause significant harm. Rather, we are noting that patients cannot expect that services will only be presented in one way, or that those services can be specified fully in advance. This fact is relevant in the assessment of the risk attributable to inclusion in a QI activity.

A related issue arises for staff members, the other major group of human participants in QI activities. For them, the appropriate baseline for measuring QI effects is the

risks in the usual work situation. For example, in the unlikely event that a QI activity exposes workers to extra radiation or toxic chemicals, or invades privacy by collecting information employers are not normally entitled to have (as might happen with surveys of the use of alcohol, cigarettes, or illegal drugs outside the workplace), the potential effects on workers should be included in the assessment of QI-associated risk. On the other hand, one should not include the harm to a worker's economic security that might result if a QI activity reveals that the worker is incompetent or the organization can provide quality care with fewer workers. A health care employer has a moral and legal right—and responsibility—to ensure that employees are competent and conscientious, and the operations of the organization are efficient. The collection of information on individual and system performance is a feature of normal working conditions, and the risk that it will produce information that leads to adverse job actions is part of the baseline job risk.

Scientific validity: Is the research methodologically sound—for example, is it properly structured to achieve its goals?

This requirement is also justified by the scarcity of resources and the need to avoid exposing subjects to possible harm without benefit, and it also applies to both research and QI. The interpretation of “scientific validity” and “methodologically sound” must be adjusted to QI, however. Since the primary goal of QI is local improvement, QI's methods and the local knowledge they generate can be quite different from the methods designed to enhance the opportunity to gain generalizable knowledge through research.²⁹ QI methods should be chosen on the basis of knowledge of the context, the requirements for connecting evidence to the context, and the requirements of actually “making something happen” in the local setting while balancing the importance of the improvement sought and the clarity needed in the assessment of changes against the practical costs of monitoring the effects. A randomized controlled trial seeks to eliminate context—key to QI—as a variable and thus would usually be inappropriate for the kinds of questions and changes that QI addresses, while changes that are already known to be worth their costs and readily implemented should in general simply go forward.³⁰

Fair subject selection: Are the subjects of the research selected so that vulnerable individuals are not targeted to bear the risks of the projects while the rich and socially powerful are favored for receiving the benefits?

In the selection of research subjects, there should be similar treatment of equals, and both the burdens and benefits of the research should be distributed in a fair manner. But, to quote Emanuel and colleagues: “This does not mean that individual subjects and members of groups from which they are selected must directly benefit from each clinical research project or that people who are

marginalized, stigmatized, powerless, or poor should never be included.”³¹

This requirement applies to both research and QI. Fair subject selection is particularly relevant to organizations conducting entire programs of QI activities. The choice of objective and the design of the activity will sometimes have implications for the fairness of the distribution of benefits and risks across patients. For example, the distribution of benefits and risks may be affected by choosing to do QI projects on treatment of heart disease rather than treatment of diabetes or asthma, or introducing improvements in some parts of an organization and using the other parts as comparison groups. Such distributional effects should be considered in evaluating the ethical acceptability of QI. In particular, people who are currently disadvantaged in the health care system should not have to bear a disproportionate share of the burden of improving the system, and in fact should be given priority in the distribution of the benefits of QI activities.

Favorable risk-benefit ratio: Is the research designed to minimize the risks and maximize the potential benefits? Are the risks to an individual human subject proportionate to the benefits to the subject and to society?

This requirement applies to both research and QI. It relates to the requirement of social or scientific value, but focuses directly on the participant’s situation, rather than the activity’s overall net benefit. An affirmative effort should be made to design both research and QI activities to minimize the risks and maximize the benefits to the participants and society. For example, an activity may have a risk/benefit relationship within an acceptable range, but if the relationship could be improved with minimal effort/cost, both researchers and QI practitioners are ethically obliged to do so.

Respect for potential and enrolled subjects: Is respect for subjects demonstrated by the following actions?

- protecting the privacy of individuals and maintaining the confidentiality of private information
- maintaining the welfare of the subjects
- informing subjects of newly discovered risks or benefits associated with participation
- permitting withdrawal
- informing subjects of the results

The first three of these requirements apply to both research and QI. Protecting privacy and maintaining confidentiality is important in QI, as is maintaining the welfare of the participants and informing them of newly discovered risks or benefits associated with their participation.

The other two requirements do not apply to QI as stated. The next section on informed consent explains why permitting withdrawal from QI activities does not always apply. It also argues that QI participants should receive general information about QI efforts and should be able to learn more about specific projects if they are interested, but a QI practitioner is not required to provide information automatically about a QI activity’s existence or results to the participants.

Informed consent: Do the subjects receive information about the purpose of the research, its procedures, potential risk, benefits, and alternatives, so that each subject understands the information and can make a voluntary decision whether to enroll and continue to participate?

This requirement differs for QI and research. In principle, research participation is optional for all parties,³² but we have argued that this is not so for QI. Continuous quality improvement is part of the mission of health care

Because QI is an essential part of normal health care, it is necessary—and acceptable—to have consent to receive health care include consent to a reasonable level of cooperation with QI activities.

professionals and health care managers. They owe it to their patients to be constantly trying to improve their practice; QI is an important tool for doing this; and therefore, participating in QI is not completely optional for them. Since quality improvement is a critical ingredient in the creation of the benefits a patient seeks from health care, QI is not completely optional for patients, either.

In practical terms, this means that specific informed consent is not required every time a human participant is included in a QI activity. Because QI is an essential part of normal health care operations, it is necessary—and ethically acceptable—to have consent to receive health care include consent to a reasonable level of cooperation with the ongoing QI activities of the organization providing the care. Through public education, people should already be aware of this before they seek care. When they present themselves for care, they should be reminded of the background expectation and informed in general terms about the QI that occurs in the particular setting and how they can obtain more information about individual projects.³³

By “a reasonable level of cooperation,” we mean that patients may be included without their specific consent in QI activities that involve no more than minimal additional risks to them compared with the normal risks associated with receiving standard medical care. If a QI activity is as-

sociated with more than minimal additional risk, patients must be asked for their specific informed consent before inclusion, and they are free to refuse it. In the latter case, patients must receive full information about the activity and the risks to them personally when they are asked to participate, just as for any clinical consent. If later on they would like information about the activity's results, they should be able to obtain it.³⁴

Organizations should not be required to distribute detailed information proactively about the results of individual QI activities. Most people would find the detail superfluous, and the effort would waste their own resources since they ultimately pay the bill for the health care system. QI practitioners and the organization as a whole should, however, willingly provide information to anyone who asks about any QI activity, to the extent possible while respecting patients' and providers' right to privacy.

The most common examples of QI activities that do not require consent are those activities that use routine personal health information to implement a change in the care process and impose no additional risk on participants beyond that associated with the information use. For example, a group practice might decide to modify scheduling practices to reduce the time patients spend waiting to see their physicians when they come for an appointment. The QI team might begin by reviewing patient visit records to develop data on the types of visits, the average time needed for each type, the pattern of visit types over a typical month, and so on, and then use the data to develop new scheduling practices, implement them, monitor the effect on waiting time, and refine them until the desired result is achieved. If confidentiality is appropriately protected, then using patient information for QI activities without specific consent is ethically acceptable on the same grounds that its use is acceptable in other normal health care operations. Since QI is part of the care process, the people doing QI have the same status as others in the care process. Often this is literally true, since QI teams are often made up of the people who provide direct care; however, the rationale is the same when access to protected health information is granted to someone more removed, such as an epidemiologist abstracting information from medical records for statistical analysis.

The Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) has established standards for the protection of the confidentiality of personal health information in normal health care operations, and has included QI (but not research) within that category.³⁵ Consent to the use of protected health information for QI activities is provided as one item in the list of routine uses the patient agrees to as a condition of treatment. According to HIPAA standards, a QI practitioner's access to protected health information is limited to the information needed for the activity, persons engaged in QI have the same confidentiality obligations as other health care workers, and the same precautions must be in place for the use

of protected health information in both clinical care and QI. (See Box 4.)

When the human participants in a QI activity are staff, consent requirements play out a little differently. Health professionals, management, and other workers have a general ethical obligation to cooperate to improve the quality of care, and a specific contractual obligation to cooperate with their organization's QI program (since it is part of normal health care operations). The obligation is not unlimited, however. Specific consent is required when the QI represents more than minimal risk to the worker, as measured from the baseline of normal working conditions. Therefore, consent would be required for a QI activity that exposed workers to more than minimal additional risk of physical or mental harm compared to their current working conditions (exposure to radiation or toxic chemicals, for instance) or collected information about workers that was outside the category of information employers are normally entitled to have about their employees (such as their use of tobacco, alcohol, or illegal drugs outside of the workplace). Consent is not required, however, for QI that is risky to the worker simply because it might generate evidence of incompetence on the job or lead to a reduction in force for efficiency reasons. The formal contracts with workers and the informal workplace expectations should reflect the understanding that cooperation with minimal risk QI activities is part of the job. As with patient participants, confidentiality of personally identifiable information about workers should be appropriately protected within the organization.

Does any of this analysis change if those leading the QI project publish or otherwise share their process and accomplishments with others? Do participants have to give specific consent to the publication of QI results? QI practitioners should be encouraged to share QI results through publication and other means, since sharing yields benefits to individual patients and to society as a whole. The people who receive care from health care organizations pay as a group for the development of this knowledge, and over a lifetime, people receive care from many different organizations. Although some organizations may consider QI results proprietary information and wish to maintain secrecy for competitive advantage, patients are better off if health care providers cooperate by sharing QI results.

Even though most QI can be carried out ethically without explicit patient consent, published results must be presented in a form that preserves patient confidentiality; otherwise, the team must have the patients' specific consent to publication. Similarly, individual worker information must be nonidentifiable or worker consent to publication must be obtained, unless there are overriding contractual or legal rules relating to the provision of information on worker performance.

The ethical acceptability of the QI activity itself and the ethical acceptability of the form in which the results are disseminated are conceptually distinct, and the deci-

4. Summary of the Privacy Rule of the Health Insurance Portability and Accountability Act 45 CFR 160 and 45 CFR 164, Subparts A and E

■ defines health information as “any information, whether oral or recorded in any form or medium that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual” (45 CFR 160.103)

■ defines protected health information (PHI) as “individually identifiable health information that, subject to exceptions, is (i) transmitted by electronic media; (ii) maintained in any medium described in the definition of electronic media; (iii) transmitted or maintained in any other form or medium” (45 CFR 164.501)

■ extends to a defined set of covered entities that transmit health information electronically in connection with certain defined HIPAA transactions (45 CFR 160.13):¹

- health plans
- health care clearinghouses
- health care providers
- nonemployee business associates of covered entities
- researchers who are health care providers engaging in any of the covered electronic transactions

■ prohibits a covered entity from using or disclosing PHI about an individual without the individual’s specific written permission (“authorization”) unless:

- PHI will be used/disclosed for treatment, payment, and health care operations (45 CFR 164.506(c))

- PHI will be disclosed to business associates provided certain arrangements in place (45 CFR 164.502 (e))

- the disclosure is required by law, authorized by law for public health purposes, or required by the FDA for adverse event reporting (45 CFR 164.512)

- an institutional review board (IRB) or privacy board waives or alters the authorization requirement to use or disclose PHI for research, which is possible when certain conditions are met (45 CFR 164.512(i))

- a researcher satisfies certain conditions to use PHI for review preparatory to research (45 CFR 164.512(i)(1)(ii))

- a researcher satisfies certain conditions for research solely on information of decedents (45 CFR 164.512(ii))

- the PHI has been deidentified in accordance with specific Privacy Rule standards (which makes the data no longer PHI [45 CFR 164.514(a)-(c)])

- the covered entity releases the information in the form of a limited data set that includes the removal of certain identifiers and a data use agreement between the researcher and the covered entity (45 CFR 164.514(e))

■ QI (but not research) is included in health care operations and specifically exempted from the above requirement for project-specific written permission (“authorization”)

1. For additional information see U.S. Department of Health and Human Services, OCR Privacy Brief, Summary of the HIPAA Privacy Rule, at <http://www.hhs.gov/ocr/privacysummary.pdf>.

sion about whether to publish and in what form may reasonably be made after the results are in. Therefore, it is acceptable and may be desirable to separate ethical assessment of the activity itself and ethical review of the form in which the results are disseminated. Thus, organizations might well have different procedures for ensuring ethical implementation of QI and ethical dissemination of the findings.

Independent review: Is there review of the design of the research, its proposed subject population, and its risk-benefit ratio by individuals unaffiliated with the project?

In research, the purpose of ethical review by individuals unaffiliated with the proposed research activities is to ensure that the researcher has understood the requirements for ethical research and applied them properly in developing the proposed activities. Applying requirements

takes judgment calls, and conflicts of interest may distort the researcher’s judgment (consciously or unconsciously), potentially causing harm to participants or taking away their opportunity for voluntary consent. Review can protect against such distortion and help potential research subjects have confidence in the honesty and integrity of the offer to volunteer to participate. In the United States, this ethical review takes the form of review of research protocols and relevant documents by the institution’s IRB.

In the discussion of the first six categories of ethical requirements for human research subject protection, we have concluded that QI activities with human participants should meet similar ethical requirements, but the requirements must be interpreted and applied somewhat differently. (See Box 5.) As with research, some considerations might justify review of QI activities to ensure that the requirements for ethical conduct of QI are met. Review

might be justified, for example, if the QI might pose substantial risks or waste substantial resources, and if review by a nonparticipant could raise those issues and stop the activity. As QI becomes a desirable skill and care systems invest in QI budgets, the leaders of QI might find themselves invested in QI work that has become unresponsive to the real needs of patients and families—a conflict of interest that would echo that which gave rise to research review. Furthermore, the focus on QI is relatively new, and the practices that support it are still in flux. Thus the boundaries between QI and research and between QI and routine treatment are not well understood. Review by a nonparticipant would be useful if a project that should have counted as research is not being managed as such, or if a project that offers no particular opportunity for improvement over usual practice is being touted as QI.

Since these arguments justify some review, at least for some projects, the question is what form it should take. Should QI also receive IRB review, or would some other approach to ethical oversight be more appropriate? In the next section, we will discuss why we have concluded that IRB review is not ethically required and would not even be generally beneficial or effective for QI activities.

IRB Review of QI: Why Not?

Much of the concern expressed about IRB review of QI has focused on the time and effort associated with the preparation of documents for submission to an IRB and the time required for the IRB to complete its review.³⁶ Researchers have been dissatisfied with these aspects of IRB review for some time, and improving IRB efficiency is an acknowledged policy goal.³⁷ This issue is even more important for QI than for research, since the people who initiate QI are already employed in the delivery of care, and the resources used for QI are part of the health care system's cost structure. Even with a more efficient IRB process, many valuable QI projects would be unable to muster the necessary resources and simply would not be done if IRB review were required. For those QI activities that did go forward, the process would impose high transaction costs on improvements that are often small in scale and represent little burden or risk to participants. This would be a poor use of scarce resources and would in itself be a kind of harm to the patients, whose resources are thereby wasted.

There is a more basic problem, however: the current structure of IRB review is inappropriate for QI. To explain why, we will describe the process and discuss its limitations in the QI context. The IRB's role is to ensure that research carried out under an institution's auspices complies with federal regulations and conforms to accepted ethical principles. Usually, the IRB is part of the institution in which the research is done, but it is always independent of the research itself. The IRB meets at intervals to review research protocols, consent forms, and other relevant docu-

ments. The research protocol specifies the goals of the project, the subject population, methodology, and time period for the research. After reviewing the documents, the IRB either approves the research project or requires the principal investigator to make changes to the protocol, the associated consent form, or other documents until all are acceptable. Then the project begins and continues unchanged unless the PI obtains IRB approval for modifications. In addition, the PI is required to report any unanticipated problems involving risks to subjects or others to the IRB. Although the research is carried on under the auspices of the institution and receives continuing IRB review (at least once per year), the PI takes full responsibility for its day-to-day conduct.³⁸

Most QI activities are unlike the activities that IRBs routinely approve and monitor. Instead of a fixed protocol with fixed goal, methodology, population, and time period, QI activities ordinarily entail frequent adjustments in the intervention, the measurement, and even the goal over time as experience accumulates. Even in cases where a QI activity produces insights useful in other settings as well as local change, the activity is not a knowledge-seeking enterprise that is independent of ongoing clinical care. It is designed to produce local change and is closely linked to the normal operations of the institution in which it takes place. QI occurs in the context of the professional obligations of the health professionals involved, and the people who initiate or lead a QI activity are often part of the team that provides care. All parties affected by the QI activity function within a supervisory and management structure that already bears responsibility for clinical care, including its quality and safety. As we have shown above, the ethical requirements for QI are in some ways similar to those for research, but they must be modified to the particular local setting and the QI goal of immediate improvement. In particular, the desirability of the change itself and the risks to participants often depend heavily on the characteristics and reactions of the system in which the QI activity occurs. This means that assessing the activity's potential effects and understanding how risks can be minimized requires intimate knowledge of that system.

Given these characteristics of QI and its role in health care, the procedures used to ensure its ethical conduct must allow QI activities to remain flexible and fully integrated into the ongoing management of care delivery. Since the current IRB review process does not readily allow this, requiring QI to undergo IRB review would create perverse incentives for professionals and organizations trying to improve care. Change is already an intrinsic feature of health care delivery. Solving the quality and safety problems in American health care will require many changes—and these changes are more likely to be genuine improvements if done in a systematic, data-guided way, using QI methods. If the “price” of making change in this way is a cumbersome, costly process of review, however,

managers may opt to make change without using QI methods. Worse, they may simply leave things as they are.

Of course, not all clinical and managerial changes are ethically acceptable. The underlying questions here are: What standards should be applied to determine whether a change is ethical? How should the agents of change in health care be held accountable for their actions? Currently, to the extent that accountability for clinical and managerial change occurs, it is through the system of accountability that has been established for all ongoing clinical care. Admittedly, the clinical accountability system has shortcomings, and concern about these shortcomings fuels the concern for the welfare of QI participants. Nevertheless, desirable procedures for ethical oversight of QI should encourage, not discourage, the collection and evaluation of information on the consequences of any change that could harm someone, and should avoid acting to slow the pace of improvement. These ends cannot be accomplished by exporting QI into the IRB-based research review system.

Instead, in our view, ethical review to protect human participants in QI should be selectively imported into the accountability system for clinical care. By this, we mean that ethical oversight of QI should be fully integrated into the routine management and supervision of health care operations.³⁹ The responsibility for ensuring that this integration occurs and results in ethically conducted QI should belong to the entities that already have responsibility for the quality of care provided by individual professionals and health care organizations.

Protection of human participants in QI belongs in the clinical accountability system because ethical decision-making is an intrinsic part of everyday clinical management. Clinical and managerial decisions in health care often—perhaps always—have ethical dimensions. Sending QI to an IRB for ethical review implies that protection of participants is an ethical question that is separate from the other ethical questions that arise in managing patient care—or even worse, that ethical decision-making in general is something to outsource. When an activity is as closely tied to clinical practice as QI is, the responsibilities for its conduct should remain closely aligned. The special circumstances of widespread conflict of interest and risks of wrongful use of human subjects without consent that generated the strong requirements of separate ethical review do not apply to QI.

Some might challenge the last statement by arguing that change in health care is inherently biased toward making patients worse off for the sake of “the bottom line.” From this perspective, QI is often just a cover for change motivated by concern for profits, not patients. The underlying issue here is that of the relationship of cost containment to quality improvement, and the relationship of both to professional and organizational ethics. To respond to the challenge, one might point out that in today’s health care system, it is often possible to make changes

that improve quality and lower cost at the same time. There is ample evidence of waste in the system, in the sense of care that is unnecessary, harmful, or inefficiently produced and delivered. Reallocating the resources devoted to this care to beneficial uses improves care without increasing cost.⁴⁰

Nevertheless, sometimes a tradeoff between quality and cost is unavoidable. Managers must make changes for budgetary reasons, and the changes may reduce the quality or quantity of care for some people. Is it always unethical to make patients worse off than they are under existing practices—or even to expose them to a small chance of being worse off—without their explicit consent? The answer is no. Patients have an interest in maintaining and improving quality, but they also have a stake in ethical stewardship of the resources devoted to health care. When changes must be made and budgets are tight, sometimes it would be unethical *not* to reduce the quality or quantity of care for some people. For example, suppose a costly new diagnostic test becomes available that allows diagnosis of a deadly disease at a treatable stage. The medical staff members of a nonprofit health plan think the plan should begin using it immediately in patients at risk for the condition.

The procedures used to ensure that QI is conducted ethically must allow QI activities to be flexible and integrated into the management of care delivery. The current IRB review process does not allow that.

How should the plan find the resources to cover the testing and the effective treatment it makes possible? The plan could raise premiums, free up resources by producing the same care more efficiently, reallocate resources by reducing the quality of care slightly for plan members in a domain where the current quality level is well above the acceptable threshold level, or do some combination of the three. Each alternative has ethical implications, all should be on the table, and sometimes, reducing the quality of care in another domain is the solution that best meets ethical requirements. Similar examples could be constructed for a hospital, a group practice, or an individual physician.

One might acknowledge that change must be managed, that decisions about change have ethical implications, and that a decision to trade quality for cost can be ethically acceptable, yet still argue that, given the current state of quality and safety in health care, these decision-making processes cannot be trusted. Many now agree that a transformation in the organizational culture of health care is needed to improve the quality of care. This is exactly where QI methods make their contribution, however.

Optimal oversight of change requires learning how to assess the dangers of specific changes to patients, and QI is a systematic approach to improving decisions about change. By providing evidence on the effects of changes, QI methods are valuable tools in holding health care providers accountable for the care they deliver and can be used to respond effectively to past failures to live up to quality standards. We conclude that to the extent that health care managers have a conflict of interest in managing cost-reducing change in health care, QI methods are not the problem, but an integral part of the solution.

Our discussion has brought us back to the question raised in Section I of this report: should increasing efficiency by providing the same quality of care at lower cost count as an improvement in quality? One way to answer is to say: “No, it is a good thing, but it is cost containment, not quality improvement.” Another way to answer is to say: “Yes, ‘value for money’ is a quality characteristic of health care.” Both positions have conceptual merit, but ac-

cepting “value for money” as a quality characteristic has practical advantages. In considering the ethics of using QI methods to evaluate a designed change, it is best to avoid creating a bright-line distinction between efforts to improve quality and efforts to reduce cost. When assessing quality, people often disagree about what weights to apply to different dimensions of care. If several dimensions change at once, some may consider the result higher quality care and others lower quality care. Thus, when a project reduces cost and also changes quality characteristics, there may be no consensus on whether the change is quality improvement that also lowers cost or cost containment achieved at the expense of quality. Either way, management should know what the consequences of the change are, and QI methods can be used to find out.

Note that the methods used in QI are also useful for the study of changes that everyone agrees are not good for patients but that are made anyway: for example, changes forced by budget deficits, such as cuts in nursing staff or

5. Ethical Requirements for the Protection of Human Participants in QI Activities

Social or scientific value

The gains from a QI activity should justify the resources spent and the risks imposed on participants.

Scientific validity

A QI activity should be methodologically sound—properly structured to achieve its goals.

Fair subject selection

Participants should be selected to achieve a fair distribution of the burdens and benefits of QI.

Favorable risk/benefit ratio

A QI activity should be designed to minimize risks and maximize potential benefits, and to ensure that risks to an individual human participant are proportionate to benefits to the participant and to society.

Respect for participants

A QI activity should be designed to protect the privacy of participants through confidentiality.

Participants in a QI activity should receive information about findings from the activity that are clinically relevant for their own care.

All patients and workers in a care delivery setting should receive basic information about the program of QI activities.

QI results should be freely shared with others in the health care system, with participant confidentiality protected by putting results into nonidentifiable form or obtaining specific consent to sharing.

Informed consent

Patients should give background consent to inclusion in minimal risk QI activities as part of consent to receive treatment.

Patients should be asked for informed consent to be included in a specific QI activity if the activity imposes more than minimal risk.

The risk-harm ratio for patients is measured relative to the risk associated with receiving standard health care.

Workers (employees or nonemployee professionals who provide care within an organization) are expected to participate in minimal risk QI activities as part of their job responsibilities.

Workers should be asked for their informed consent to inclusion in a QI activity that imposes more than minimal risk.

The risk to workers is measured relative to the risk associated with the usual work situation and does not include any risk to economic security that might result if a QI activity reveals that the worker is incompetent or that the organization can provide quality care with fewer workers.

Independent review

Accountability for the ethical conduct of QI should be integrated into the system of accountability for clinical care. Each QI activity should receive the kind of ethical review and supervision that is appropriate to its level of potential risk and project worth.

elimination of evening clinic hours. In fact, it may be especially important to understand the effects of purely cost-driven changes, since their effects may be more far-reaching and more negative than anticipated. When such changes are made in an incremental, data-guided, monitored way, management can understand better what is actually at stake and more easily minimize the negative impact. Obviously, these activities are not quality improvement and should not be referred to as QI, since doing so would foster cynicism about the whole QI enterprise. Nevertheless, the practices that provide ethical review of QI should be designed to encourage rather than discourage the use of data collection and monitoring methods to minimize harm in these situations.

In sum, we argue that ethical review of QI activities for purposes of protection of human subjects should be integrated into the accountability system for managing the quality of care rather than delegated to the IRB-based research review system. Is this a proposal to give QI a “free

pass” compared to research? No. We believe that review can be cheaper, less bureaucratically frustrating, and—most important—at least as likely to ensure ethical conduct of QI if designing and implementing it is seen as a core management function.

This approach will be most effective if it occurs as part of a systematic transformation of the existing clinical accountability system. The transformation should include clarification of the ethical responsibility of clinicians and managers to take the lead in improving the quality of care, ongoing guidance on the requirements for the ethical use of QI methods, and change in professional and internal organizational cultures to make continuous quality improvement routine. Established external clinical care accountability mechanisms should then be used to make sure that professionals and organizations have proper supervision of the conduct of QI, including the extent to which ethical requirements are met and whether human participants are adequately protected.

III. Institutional Arrangements Needed to Ensure Ethical Conduct of QI

To ensure that QI meets ethical requirements, there must be a set of regular procedures, understood obligations, and clear standards to hold health care professionals and organizations accountable.

Many organizations and policies within the health care system intertwine to create the existing system of accountability for the quality and safety of health care.⁴¹ First, of course, is the widely understood social contract, articulated in statements of professional ethics, which calls on practitioners to be allegiant to the needs of their patients. Formal accountability organizations include state licensing bodies, private sector accrediting bodies, the Centers for Medicare and Medicaid Services, and certification and credentialing organizations. Managed care organizations and large employers often impose quality performance requirements on the professionals and organizations with whom they contract. Medical staff in hospitals and group practices undertake responsibility for credentialing their members and awarding staff privileges. Many hospitals now support clinical ethics committees. Under certain circumstances, health care organizations are subject to the accountability requirements included in the HIPAA Privacy Rule and the DHHS regulations for the protection of human research subjects. The malpractice litigation system allows patients to pursue compensation from health care providers for harms caused by negligence in the delivery of care. Within this accountability system, the various parties may hold each other accountable over different content areas. For example, a hospital may evaluate the activities of its physicians, but then in turn be accountable to

government regulators, contracting health plans, and the public.

Within the clinical accountability system, the arrangements for ensuring that QI is conducted ethically should be designed to be flexible. The specific practices should be able to vary across organizations to accommodate variation in the local environment and in the QI activities conducted. The interaction between the characteristics of a QI activity and the characteristics of the local setting is critical in determining whether the activity is ethical and what kind of review and supervision it should receive. In general, if participants are at more than minimal risk, there must be more clarity about review and more supervision. However, for a given level of risk, an organization whose employees are very familiar with QI methods and ethical requirements can allow QI to be done with a lower level of supervision than an organization whose employees have lesser skills. A large organization may choose to have a specialized QI oversight system that a small organization cannot afford; however, the small organization may not need any formal review if its QI activities are simpler and its size allows everyone in the organization to know what is going on. For example, an HMO with multiple delivery sites might have formal procedures, while a small nursing home might simply require an informal review by the nurse executive.

The practices should be able to vary over time. Since QI is part of a process of continual change in health care, it would be a mistake to impose an ethical oversight structure that cannot respond quickly and appropriately to

changing conditions. If the QI regulatory procedures erect artificial barriers to new ways to organize care delivery and reimbursement in health care, they may prevent desirable change, or even create perverse incentives that encourage undesirable change.

The practices should be designed to ensure that ethical oversight produces its benefits at affordable cost. The administrative complexity of doing QI should be as low as possible so that people employed in direct care are not discouraged from initiating QI projects. This consideration reinforces the conceptual arguments for building ethical oversight of QI into the ongoing management of care delivery.

We recommend that the primary responsibility for the ethical conduct of QI be lodged in individual organizations, where it should be seen as a normal clinical care obligation and integrated into normal supervision and management, with the organizations' leaders responsible for seeing that the integration occurs and is effective. The organization doing QI could be, for example, a practice of one or a few physicians and support personnel, a large multispecialty physician group practice, a hospital, a nursing home, a hospice, a staff model HMO, or a more loosely configured managed care plan. It could also be a hospital chain, a nursing home chain, or an integrated, comprehensive multisite managed care organization like Kaiser or Intermountain Health Care. It could be the Veterans Health Administration. Whatever the organization is, it must have a set of practices in place to ensure that QI activities are done, and that they are done in conformity with ethical requirements. The organization must also have a procedure in place to provide basic information to patients and staff about the organization's QI activities. We call this *internal accountability* for the ethical conduct of QI.

We recommend that there also be procedures to ensure that individual health care organizations and their leaders are held accountable for having well-designed, functioning internal accountability practices in place to carry out their QI-related responsibilities. We call this *external accountability* for the ethical conduct of QI, and we argue below that it should be integrated into the overall system of accountability for the quality and safety of clinical care.

Internal Accountability for Ethical Conduct of QI

Activities in a health care facility require management and supervision for many reasons besides the protection of the human participants in QI. Sometimes the reasons are directly related to other ethical issues in health care delivery. For example, management and supervision are required to ensure that an organization fulfils its ethical responsibilities to employees, ethical responsibilities of stewardship of the organization's resources, and ethical responsibilities to patients who have been given implicit or

explicit promises about the kind of care they will receive. Sometimes the reasons are not directly related to ethical issues but to other organizational concerns. For example, the organization may be seeking to maintain market position and reputation, remain financially solvent, avoid lawsuits, or prevent bad publicity. The ethics-related oversight of QI, including the oversight of the protection of human participants, must be incorporated into the overall system of management and supervision of health care delivery.

In discussing how this can be done, it is useful to distinguish three broad categories of oversight: professional responsibility for QI; local management review and supervision of QI; and QI-IRB review for QI that is also human subjects research. In addition, there should be procedures in place for ethical oversight of QI activities that are carried out through collaborations across organizations.

Professional responsibility for QI

Some QI activities are so closely tied to clinical practice that no additional oversight beyond normal management supervision and professional ethics is needed. Activities appropriate for this category are of minimal risk, in the sense that confidentiality is protected and no additional risk or harm is imposed on patients compared to that expected from clinical care in the absence of the activity. (And often, a priori evidence exists that suggests that substantial benefits are likely for the patients or staff involved.) Therefore, specific informed consent is not required. The activities are simple in design, so there is no need for methodological review. The effects of the activities are very local, in the sense that their success or failure will have no repercussions on other parts of the organization. The activities do not use significant additional organizational resources beyond the usual resources for clinical care.

This category includes most of the routine performance-enhancing improvement activities undertaken by individual health professionals. Here are two examples of it:

- A doctor wants a test order tracking system that makes it easy for him to remember what tests have been ordered for a patient, access the test results, and make timely and appropriate adjustments in the patient's care. He develops his own patient tracking system, monitors its performance, and refines it over time in response to his observations until he is satisfied with it.

- Several nurses find that they are each using a different method to perform a routine nursing procedure. The methods are within standard nursing practice and are used interchangeably in various clinical settings; however, the nurses wonder whether the methods differ in the time they take and the effect they have on the patients. The nurses try each method in sequence over a few months, keep track of how long the procedure takes

with each method, and ask patients whether there is any difference in comfort. At the end of this QI activity, they conclude that one method works better than the others in their local setting and all decide to use it.

Activities in this category do not receive any added oversight other than discussion among the participants, and they may not even be written down in any formal manner; however, the clinicians who engage in them are responsible for protecting the participants by following the ethical requirements of their profession and their organization. It is worth noting that the monitoring initiated by the clinicians carrying out the QI activity ensures that patients' interests are protected. If anything were going awry, the altered process would quickly be abandoned.

Local management review and supervision of QI

This category consists of activities designed to improve care in the local setting that require at least some monitoring by management. The minimum management element in this category is a method for tracking the QI activities in progress. In a small organization, this could be as simple as an informal discussion with a QI manager or other designated executive staff member. In a larger organization, it could take the form of standardized reporting about QI activities to a quality management staff member.

To establish a physical record of QI activities, a simple registration process might be used. Such a process could also serve as an educational tool to help people doing QI think through the design of the activity and recognize the ethically important aspects, and as a screen to identify activities with attributes that indicate the need for more elaborate review and approval. In a small organization, registration could take the form of answers to a set of structured questions kept in a locally available file. QI activity registration that met the requirements outlined by the questions in the registration form would constitute approval to perform the activity. In a large organization, registering and informing management might be accomplished through an interactive, Web-based registration form. The initiator of the activity would enter a short description on the form and answer a set of questions. As each question is answered, the individual would be directed to carry out the activity or to obtain a specific form of oversight, depending on activity characteristics and potential for risks. After completion, the form would be stored in a database to be used as a tool for ongoing monitoring of QI activities, as a source of information about past and present QI activities for members of the organization, and as a basis for systematic organizational reflection on the patterns and outcomes of its improvement work.

For some activities, registration is sufficient. If a registered QI activity uses few organizational resources, imposes minimal additional risks on patients besides the use of protected health information, and has confidentiality measures in place, it would be unusual to require further

review by supervisors to verify that it meets ethical requirements. Usually, the activity could simply go forward within the ordinary supervisory framework.

Other activities in this category may need explicit review and supervision by someone other than the people engaged in them. When a QI activity takes more resources, has the potential to impose more disruption or risks, or makes use of unusually sensitive protected health information, supervisors and immediate managers should be aware and should take the opportunity to be sure that the endeavor is prudent and that the participants are brought in on a fair and appropriately informed basis. Again, two examples:

- After doctors develop patient test order tracking systems, they ask the nurses who care for their patients to use them. The nurses point out that using a dozen different doctors' systems would create complexity for them and lead to mistakes. They recommend that test order tracking be made into a QI activity to develop a common tracking system incorporating the best features of the individual systems. The QI activity is then carried out under the supervision of the management level that

Organizations should establish specialized Quality Improvement IRBs to review activities that are both QI and research on human subjects.

covers all parts of the organization affected by the change, with one supervisory task being review of the activity's design for conformity with ethical requirements.

- An activity that imposes no more than minimal additional risks on patients does not require specific informed consent on ethical grounds, but sometimes an informal consent to additional data gathering or minor annoyances is appropriate. "We're working on improving the way we move patients through the radiology department. Would you mind filling in a brief survey about your experience during today's visit?" For such QI activities, management may wish to introduce measures to ensure that any written surveys and patient interviews are properly structured and that the activities are coordinated so that even minor burdens are spread fairly across patients.

As a QI activity changes along the dimensions of increasing levels of organizational resource use, methodological complexity, potential health risk, burden of participation, and confidentiality risk, more intense review and oversight becomes necessary in order to ensure that the QI practitioners understand the ethical requirements and that

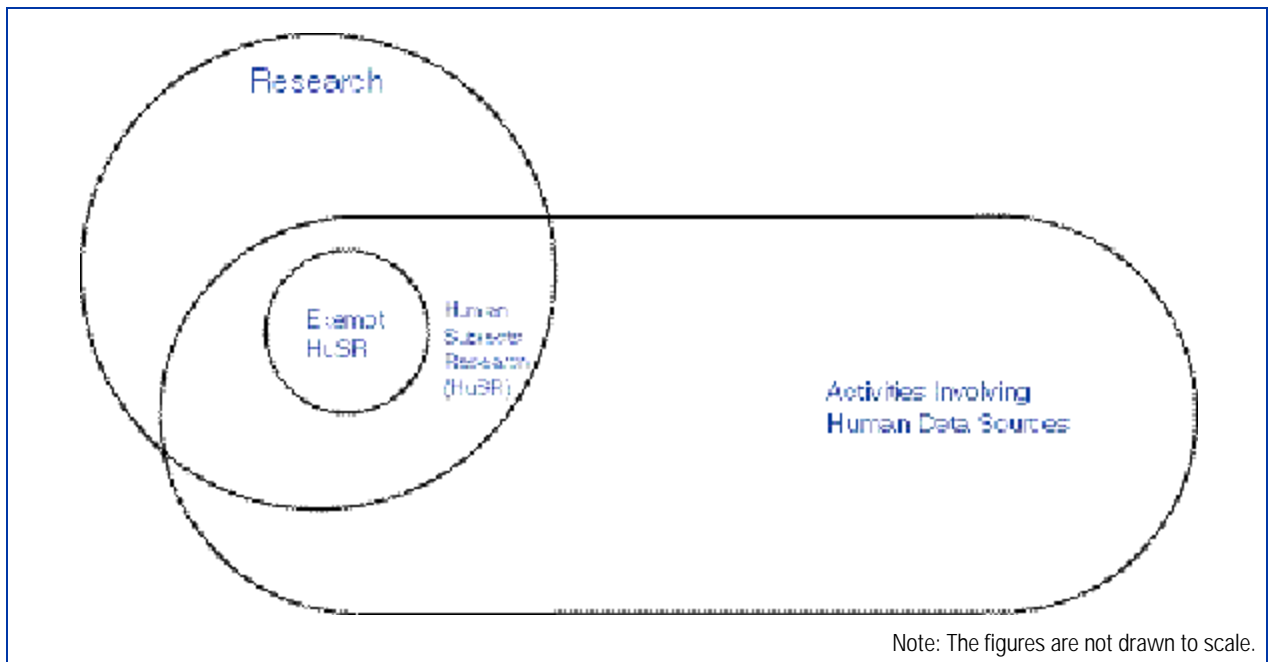


Figure 2.

the QI activity meets them. When QI activities have substantial resource or staffing implications, major changes in the providers' or patients' expectations, or more than minimal additional risk to patients compared to ordinary clinical care, then they require active approval by management above the level of the immediate managers involved within the organization. The registration process outlined above could identify activities with characteristics that make additional management approval necessary. Depending on an organization's structure, form, or size, approval could be provided by a quality management staff member, QI director, facility manager, or other staff member who is schooled in QI methods and the ethical requirements for QI. Clinical leaders most responsible for the patient population affected (a department chair or nurse manager, for example) should also be part of the process of approval.

Activities that pose more than minimal risks compared to those in ordinary clinical care require specific informed consent and explicit review by at least one person who is not directing the project and who is knowledgeable about both ethical issues and management perspectives. This is true even if the proposed project also holds the potential for substantial benefits to the subjects. The possible harms make it desirable to create "distance" between the organizational units that favor the proposed changes and the oversight structure. A patient safety committee or clinical policy committee could perform a structured review. In any case where an outsider might think the internal process could involve a conflict of interest, it would be appropriate to refer the proposed activity to a committee with representation from outside the organization. This

committee could be the organization's IRB or the QI-IRB described in the section below. An outside perspective would also be useful in cases where an organization's staff members lack the technical skills to assess the benefits and burdens of the activity; in such a case, the organization might contract with a group such as a quality improvement organization.

We believe that an organization should develop its own approach to bringing the QI activities in this category into conformity with ethical standards. QI methods themselves attach considerable importance to identifying the components of the existing system that must be involved in a QI activity in order for it to be done well. In each organization, the categories that managers use will be defined by combinations of attributes, some relevant to ensuring ethical conduct of QI and others relevant to other supervisory goals. A wide variety of QI management configurations are likely to emerge. As long as these different configurations are effective in ensuring that QI activities meet ethical requirements, they should be acceptable.

It is worth noting that, from an ethical perspective, external review of individual QI activities is not generally inherently better than internal review. On the one hand, an outsider might provide a useful community perspective on the acceptability of the risks involved, and for some kinds of risks, this perspective should definitely be sought. On the other hand, an outsider might not understand the internal environment well enough to understand the true nature of the risks and benefits and the relationship of the activity to the organization's current standard of care and allocation of resources. As we will discuss below, there is a need for external oversight, but it should be primarily fo-

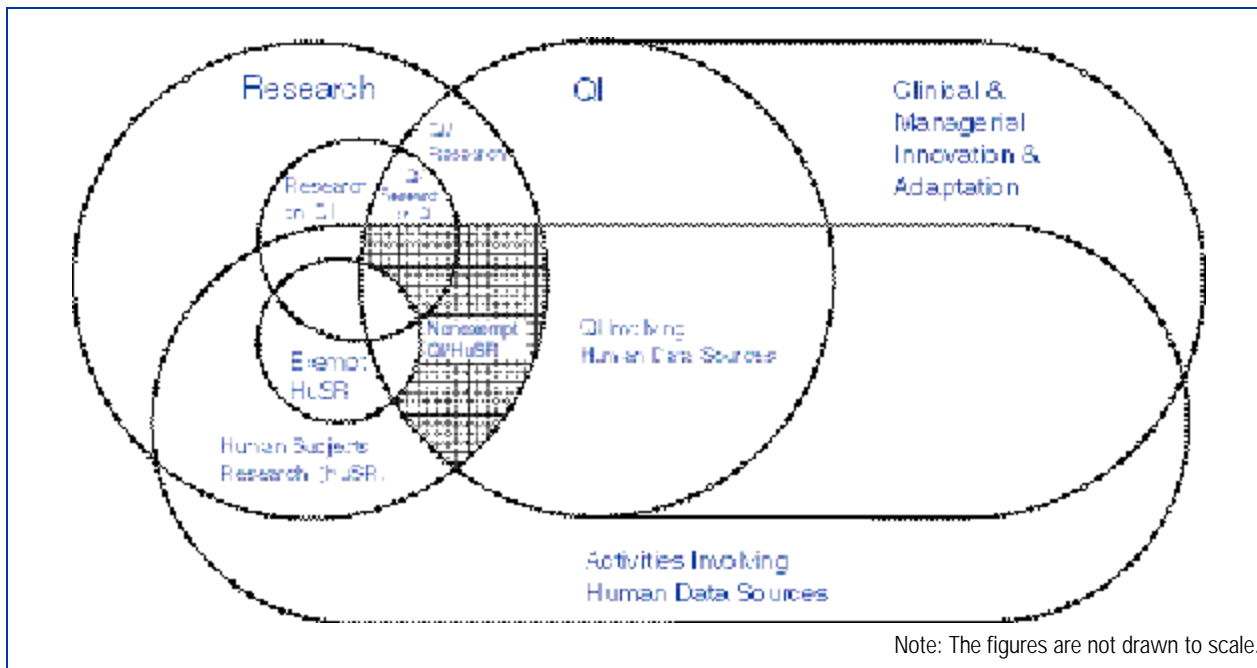


Figure 3.

cused on review of the structure and functioning of the organization’s procedures for ensuring the ethical conduct of QI, rather than on the review of individual QI activities.

QI-IRB review and supervision

As noted earlier, some activities are both QI and research involving human subjects. The DHHS regulations require any activity meeting the definition of human subjects research to be treated as such even when it is also another kind of activity, such as QI, education, or public health surveillance. Therefore, these hybrid activities must comply with the regulations if they are supported by federal funds or are covered by the assurance many organizations give that all their human subjects research will comply with the DHHS regulations whatever the funding source.

Unfortunately, it can be difficult to determine whether an activity is only QI or both QI and human subjects research, given the ambiguity of the phrase “designed to develop or contribute to generalizable knowledge” in the regulatory definition of research. The matter is of some consequence, given the sanctions that may be imposed on organizations that violate the human subjects protection regulations. This section considers approaches to review and supervision of the activities that belong in this hybrid category. The section that follows discusses approaches to their identification.

We begin with a brief discussion of the activities to which the regulations apply (Figure 2). The regulations define a human subject as “a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or

interaction with the individual, or identifiable private information.” In the figure, the long oval is the set “Activities Involving Human Data Sources,” where a human data source is defined as “a living individual about whom a person conducting the activity obtains data through intervention or interaction with the individual, or identifiable private information.” (The awkward term “human data source” is used rather than “human subject” because, as shown, the regulations *define* a human subject as someone about whom data is obtained *for research purposes*.) The overlap between this long oval and the circular Research set (defined earlier for Figure 1) is the subset “Human Subjects Research.” Within this subset, the smaller oval labeled “Exempt” consists of human subjects research that falls into any of the categories of research that have been officially declared exempt from the regulations. (These include, for example, some research in educational settings using normal educational practices; some research involving tests, surveys, interviews, and public behavior observations; some research using existing data and specimens; and some research by public benefit programs.⁴²) The remaining area is the subset of human subject research activities covered by the regulations.

Figure 3 combines the diagrams in Figures 1 and 2 to show the cross-hatched subset “Nonexempt QI/Human Subjects Research Overlap (Nonexempt QI/HuSR),” the set of QI activities that must be reviewed by an IRB and conform to other regulations, such as the requirements relating to informed consent. Although the figure does not show it, the boundaries of this subset are currently fuzzy, given the lack of clarity about precisely which QI activities also meet the definition of human subjects research.

6. Requirements for IRB Membership From 45 CFR 46.107

- A minimum of five members with varying backgrounds must sit on the board.
- Members must not all be from one profession.
- At least one member must have primary concerns that are “scientific” (a term the regulations do not define).
- At least one member must have primary concerns that are “nonscientific” (also left undefined).
- At least one member must be unaffiliated with the institution in which the IRB resides and not an immediate family member of a person affiliated with the institution.
- Members cannot have a conflicting interest in any project that comes before the IRB for initial or continuing review.
- The IRB may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB, but these individuals may not vote with the IRB.
- The IRB shall be sufficiently qualified through its members’ experience, expertise, and diversity, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
- The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice, and shall therefore include persons knowledgeable in these areas.
- If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

How do we ensure that all of the hybrid activities conform to the regulations, especially given the fuzziness of the boundary? Since the current IRB review process is not suitable for most QI, simply sending all QI activities to existing IRBs would not be a good approach. A second approach would be to send no QI activities to IRBs, and instead authorize the development of a robust but separate internal accountability system. This separate system would be based on the ethical requirements developed in this report (Box 5) and designed for all types of QI, including activities that are both QI and human subjects research. The hybrid activities could then be exempted from the DHHS regulations but required to submit to this alternative pathway. Unfortunately, modification of the existing DHHS regulations to allow this is a project that would take years and is not assured of a satisfactory outcome.

A third approach, and the one we recommend, is for organizations to establish specialized Quality Improvement IRBs (QI-IRBs) to review the hybrid activities. The QI-IRB would be a committee that meets the minimum regulatory requirements for IRB composition and has standard operating procedures that conform to IRB regulations; however, it would design its process specifically to meet the review and supervision needs of an activity that is both QI and human subjects research. This approach seems compatible with the current regulatory framework. Although many IRBs have chosen to operate under relatively rigid rules and procedures, there is actually substantial flexibility in the regulations. OHRP’s *Guidance on Written IRB Procedures, July 11, 2002*, summarizes the activities IRBs must carry out (the distribution of materials on research projects to IRB members, initial and continuing review of the materials, issuance of approval or disapproval of the project, review of changes to the research protocol, and so on) but also says:

OHRP has not developed a model written IRB procedures document for institutions to adapt because procedures appropriately can vary significantly among institutions as the result of differences in institution size, the type of research activities, institutional administrative practices, number of IRBs, and local and state laws and regulations. For each required element, the written IRB procedures should provide sufficient step-by-step operational details so that an independent observer can understand how an IRB operates and conducts its major functions.

The minimum regulatory requirements for IRB composition (shown in Box 6) allow IRBs to have as few as five members and also to incorporate considerable flexibility into the specification of member qualifications. Thus the specialized IRB—that is, an IRB whose members are chosen to have the expertise needed to review the specific types of research activities usually submitted to that IRB—is compatible with the regulations.

Organizations could make use of the flexibility in the regulations to tailor the membership and process of the QI-IRB to the QI/HuSR activities conducted within their organizational environment. A QI-IRB should be integrated with the managerial and professional supervisory structure of the organization and should have members who are thoroughly familiar with the local environment. A QI-IRB should also have members with expertise in the theory and practice of QI and at least one nonaffiliated member who can provide an outside perspective. (Of course, all members must also have a basic understanding of both the ethical requirements for QI and the human research protection regulations.) With the right membership and a flexible process for review and supervision in place, it should be relatively straightforward for the QI-IRB to ensure that the QI/HuSR activities it reviews are designed to meet ethical requirements. As the discussion in Section II summarized in Box 5 indicates, the ethical requirements for QI and human subjects research have much in common.

The one significant difficulty lies in the strong presumption of voluntariness on the part of researcher and research subject. When human subjects research is combined with an activity in which participation cannot be completely optional, problems tend to arise in applying informed consent requirements. In the case of QI/HuSR activities, the proper course is clear if the combined activity presents more than minimal risk; specific informed consent is ethically required for either QI or human subjects research activities of more than minimal risk. If the hybrid activity presents no more than minimal risk, however, the research regulations and QI ethical requirements seem to conflict, since specific informed consent is not ethically required for a QI activity of that degree of risk.

In fact, informed consent is not quite an absolute requirement for research under the DHHS regulations. An IRB may waive or alter the specific informed consent requirement if these four conditions all hold: (1) the research “cannot practicably be carried out” without the waiver; (2) the subjects’ rights and welfare will not be adversely affected; (3) the research involves no more than minimal risk; and (4) when appropriate, subjects will be provided with additional pertinent information after participating. Unfortunately, we believe that at this time, research IRBs are likely to interpret these requirements narrowly (particularly the “not practicable” requirement) and be unwilling to grant waivers of informed consent for QI/HuSR activities.

We believe that a waiver would generally be appropriate in cases in which the QI/HuSR activity represents no more than minimal risk (and especially where strong a priori evidence suggests that substantial benefits to subjects are likely). First, remember that consent to QI is required, but takes the form of background consent to inclusion in routine minimal risk QI activities, given as part of consent to receive health care from (or work for) the organization.

This consent is given with the understanding that confidentiality is protected and no identifiable participant information from the QI activity is shared outside the organization without participant authorization. Also, general information about the QI program is available, and it is expected that participants in a QI activity will be informed of any findings that are clinically relevant to their own care. In other words, participants are already aware of and have consented to their possible inclusion in minimal risk QI with their rights and welfare protected. In these circumstances, the IRB might reasonably determine that it is unnecessary and even confusing to patients to require specific informed consent to a QI project that could be done ethically without it, simply because the QI activity also contributes to a minimal risk research endeavor.

In fact, the IRB could reasonably decide that requiring informed consent would impose additional burdens, since obtaining specific informed consent has a cost in patient time and energy. The costs to the organization might also make it impractical. Often, requiring specific informed consent to a hybrid activity would be a poor use of resources needed for patient care, as well as a disincentive to an organization to add low cost, minimal risk design elements to a QI activity that would allow it to serve a research purpose as well as bring about a local improvement. All in all, it seems reasonable for the IRB to interpret the term “not practicable without the waiver or alteration” to apply, and thus to permit specific informed consent to be waived for most minimal risk QI/HuSR activities in health care settings.

As in the local management review and supervision of the QI category, this category of QI-IRB review and supervision can—and should—be constructed and used in different ways in different organizations. The membership composition and the operating procedures of the QI-IRB should be appropriate to the nature of the organization and the QI activities it conducts.

An organization that carries out traditional human subjects research activities as well as QI/HuSR activities will probably find it worthwhile to establish both a QI-IRB and a separate IRB for research. The research IRB would not need to be as integrated into ongoing management of the organization as the QI-IRB, could meet less frequently to review the fixed protocols typical of research, and would normally have a different composition in terms of scientific and statistical methodological expertise. If there are separate IRBs, there should be excellent lines of communication between them to ensure that their members have a basic understanding of the similarities and differences between the roles of the QI-IRB and the research IRB within the organization.

Finally, each organization should have at least one person who is trained and authorized to sort activities—to decide which activities are required to go to the QI-IRB, which are required to go to the research IRB (if there is one), which are not covered by or are exempt from the

DHHS regulations altogether, and which do not fall under the regulations but should nevertheless go to the QI-IRB because the organization deems them to need the kind of review and supervision the QI-IRB provides. It is not an efficient use of an IRB or QI-IRB to use it to perform this sorting task. The proposal to designate and train one or more specific persons to perform the task is compatible with the DHHS regulations.

Separating QI from Research and Defining the Overlap

We have proposed a specialized QI-IRB to review the QI activities that are also human subjects research and are subject to the DHHS regulations. Now we must address the vexing question of how to determine whether a QI activity falls into this category.

This report has defined QI as “systematic, data-guided activities designed to bring about immediate positive changes in the delivery of health care in particular settings.” So understood, QI is just a systematic, data-guided form of the clinical and managerial innovation and adaptation that has always been an integral part of clinical and managerial practice. The fact that QI is a normal health care operation focused on improving local care has been critical to our argument that ethical review of QI should be incorporated into the system of accountability for clinical care.

We have noted that in the process of making local improvements, QI may produce information that is of use to people in other settings. The regulations define research as “a systematic investigation, including research development, testing and evaluation, *designed to develop or contribute to generalizable knowledge*.” Depending on one’s interpretation of the last clause, one might argue either that nearly all QI or that no QI should count as research. We are persuaded that neither extreme is appropriate. QI reports can provide useful insights, just as individual patient case reports, success stories, and cautionary tales provide useful insights. Nevertheless, like these examples, most QI activities are not research as understood by those who framed the human subjects protection regulations. Nevertheless, some QI activities are genuine hybrids: systematic investigations designed to bring about local improvement and develop generalizable knowledge simultaneously. Such activities are an extremely useful and cost-effective way to deal with quality and safety problems, and they must be encouraged if we want to make real progress in improving the American health care system.

Drawing lines separating categories of activities is a difficult task in a regulatory system. We have tried to shape our proposals for ethical oversight of QI to minimize the need for bright lines separating categories of activities while remaining in accordance with current DHHS regulations. The category called local management and supervision covers QI that requires oversight but is not human subjects research (either because it does not meet the regulatory definition of research or because it qualifies as re-

search but does not involve any people who meet the regulatory definition of human subjects). The organization itself sets the boundary between this category and the category of professional oversight of QI, and it draws whatever lines it needs within the category to sort activities and direct them to receive appropriate management and supervision.

Specialized QI-IRB review should eliminate some of the problems in having QI/HuSR activities reviewed by research IRBs; nevertheless, clarifying which QI activities are subject to the regulatory requirement of IRB review is still important. Dithering over ambiguous classifications wastes time and tends to produce inconsistent decisions that undermine respect for the review system. Moreover, if organizations cannot tell which activities are in the QI/HuSR category, they may overload the QI-IRBs with activities that don’t need to go there, just to be safe, when these activities could receive effective management and supervision at lower cost within the purely QI oversight system.

Developing a clear rule for separating QI from QI/HuSR can be seen as a conceptual task or as a practical regulatory task, but of course it is both. What should one look for in a sorting rule? The rule should use easily observed aspects of an activity to determine whether it belongs to the hybrid 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 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.

Some aspects of the history and purpose of human research protection shape the possibilities. The origins of the regulation of research to protect human subjects lie in risky biomedical research and public outrage over incidents in which researchers conducted research on patients and members of the public without their knowledge or consent, or wasted public or shared resources, or took unreasonable risks with little prospect of gain. What was before the National Commission in the late 1970s was a series of scandals and a growing research enterprise that had shown itself to allow, at times, threats to the wellbeing of its human subjects. In responding to this situation, the National Commission saw as the domain of research not just insights that were “generalizable” in that they would be true of some other situations, but facts that are essential to the nature of the human body and its reactions to drugs and treatments, as well as other facts that would be expected to be true for all time and in all places. In its re-

port on the provision of health services by the Department of Health, Education, and Welfare, the Commission highlighted the importance of audit and improvement activities and contrasted these activities with research, noting that the practitioners in improvement activities did not have the conflicts of interest that make human subjects vulnerable to abuse in research.⁴³

Over time, this understanding of research has altered. The IRB-based human subjects protection system embodied in the DHHS regulations has been the only substantial professional or governmental activity that aims to protect human subjects. When questions on the scope of research have been posed to the regulators, virtually any activity that might provide insights of use in another situation has ended up being included in the category of research potentially subject to the regulations. This process has engendered long-running controversies over, for example, the status of ethnography, oral history, and reporting on public programs. The shift toward a very broad interpretation of research is also seen in recent OHRP assertions that public health surveillance is generally research, and likewise in tentative OHRP determinations that research includes administering surveys to clients as required under the Government Paperwork Reduction Act, which establishes practices to limit fraud and to ensure government contractors' accountability.

Given the tendency to interpret research broadly and the severity of the penalties available to OHRP and to those who enforce the HIPAA Privacy Rule, organizations have been afraid to develop their own guidelines for sorting activities into the categories of QI, research, and QI/HuSR. Though many parties know that improvement activities are increasingly important and that imposition of IRB requirements is a major barrier to their implementation, each organization is best served by avoiding any dispute with OHRP and any risk of penalty under HIPAA. At the same time, OHRP has shown little inclination to provide highly specific guidance on how to do the sorting.

Given the great variety and the significant change currently under way in the kinds of QI and research being conducted in clinical settings (not just clinical research, but organizational, managerial, and health services research), this may be a prudent decision on OHRP's part. It would be very difficult to produce consistent, practical guidance at the regulatory agency level. We believe that such guidance would be more easily developed by combining reflection on the nature of research and the aims of the human research protection system with the practical experience in managing QI and QI/HuSR activities gained by a variety of organizations. The goal would be an interpretation of the definition of human subjects research that enabled QI and QI/HuSR activities to receive the type of review and supervision needed to ensure ethical conduct without imposing excessive costs.

Below, we give an initial delineation of the divides, discussing both the kinds of QI activities that should count presumptively as research, and those that should not. We want to underscore that learning about these divides should entail some deliberate innovation with reporting cases in the professional literature and having discussions in policy settings. It is not likely that we will have hit upon just the right dividing characteristics, or that we have articulated them well enough for implementation without case studies.

For the purpose of the DHHS regulations, we propose 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*. Researchers might also be clinical service providers, but their research role is to be kept distinct and identifiable to patients. Although the word "research" is used in more informal ways, such as "library research for a high school term paper" or "research by an investigative journalist," we think this definition is appropriate for implementation of the DHHS regulations. The proposed narrative definition accords with the regulatory definition but gives voice to

"Research" refers to activities designed to learn something enduring about the nature and function of human beings and their environment. Under this interpretation, most QI is not research.

what could be meant by "designed to develop or contribute to generalizable knowledge."

Under this interpretation, most QI is not research. 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. Therefore, even though the activities represent "system changes," these changes are within the discretion of clinicians and managers to make. In fact, they have an ethical and sometimes also a legal duty to make such changes. Changes of this type include adoption of evidence-based practice guidelines and best practices issued by respected medical authorities, introduction of process modifications designed to reduce the probability of medical error, and replacement of a practice that is dangerously below the standard of care with one that is acceptable.

Introducing these changes may require adjustments in practice over and above what is specifically mentioned in a description of the new practice, and the adjustments are likely to differ from one organization to another. QI is about “moving fast but checking on progress as you go”—identifying the adjustments that may be required, tracking what happens as practices change, and being alert for unexpected effects—and thus may be the best way to protect patients as the system adjusts to the change. Ensuring that this very specific and local knowledge is developed in a manner that appropriately protects patients is the essence of QI. It is not an activity “designed to develop or contribute to generalizable knowledge,” and in fact, the idea that implementing a new evidence-based guideline in a local delivery setting is a research project requiring IRB review seems indefensible.⁴⁴ This type of activity would not require review by a QI-IRB or a research IRB; it would generally belong in the category of “local management review and supervision of QI.”

Nevertheless, some QI activities really do have a research component in the sense that they are designed to learn something enduring about the nature and function of human beings and their environment in addition to improving care in the local setting. Perhaps a project is designed to improve compliance with guidelines regarding a particular treatment, but includes design elements that allow the formal testing of a few strategies to gain that compliance, such as having some sites use QI (while others use other methods). Perhaps a project employs a new treatment that has not yet been fully accepted as the standard of care, but embeds that treatment in a QI process aimed at bringing about compliance with other aspects of care. Projects like these might well require review as research, as well as review as QI.

What characteristics of projects would make it likely that the project is both QI and research and should be reviewed by a QI-IRB? Here is a starter set.

- Randomization of patients into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection (but not randomization done to achieve equitable allocation of a scarce resource)
- Testing of issues that are beyond current science and experience, such as new treatments
- The involvement in key project roles of researchers who have no ongoing commitment to improvement of the local care situation (and who may well have conflicts of interest with the patients involved), even if others on the team do have professional commitments
- Delayed or ineffective feedback of data from monitoring the implementation of changes, especially if feed-

back is delayed or altered in order to avoid biasing the interpretation of data

- Funding from an outside organization with a commercial interest in the use of the results

As outlined below in the section on strategies for implementation, this initial list deserves to be tested in some practical settings, aiming to modify it to fit the actual risks and projects that arise. Organizations with substantial investment in overlap projects might well be among those best situated to develop QI-IRBs, which are described above.

Ethical Oversight for Collaborations across Organizations

Multi-organization QI activities, such as QI collaboratives, often combine QI activities focused on bringing about change in individual organizations into a larger project with an overarching goal of sharing information about the experience of bringing about positive change. The collaborative structure may provide for the initial transfer of technical information about a new practice to a QI team in each organization, group discussion of how best to introduce it using QI methods, and periodic group meetings to boost morale and exchange information about failures and successes.

The initiators of the collaboration should take the requirements for ethical conduct of QI into account in the design of the entire enterprise. In deciding whether to participate, each organization should subject the QI activity at the core of the collaboration to its internal QI accountability process (assigning it to the appropriate category of review and supervision). The aim is to ensure that the activity is consistent with organizational goals and is designed so that participants within the organization are properly protected.

The main additional issue raised by collaborating with other organizations concerns the sharing of information about the QI activity outside the organization. Care must be taken to ensure patient confidentiality and conformity to HIPAA rules. The initial transfer of technical information to participants can include assistance in clarifying the requirements for ethical conduct of the activity, including the management of protected health information in the sharing of results. If patient information might sometimes be shared, or if follow-back to identify patients is plausible, then the affected participants should be bound to honor confidentiality through a Business Associate Agreement or an Organized Health Care Arrangement.⁴⁵

Typically, QI collaboratives generate substantial insight about the effective strategies for QI around a given topic, but this does not automatically mean that the collaborative project amounts to research involving human subjects and is therefore subject to IRB review. In general, it does not even make it research, since the insights are still tied to place and time and are acquired while pursuing improve-

ment in the clinical services. Even when the design does have some characteristics of research (such as a starting agreement to implement some key changes in a staggered fashion so that their effects can be identified), the fact that the organizations cooperate to share insights about the process of change within each organization would usually make any research component an instance of research on organizational behavior, not research on human subjects.

External Accountability for Ethical Conduct of QI

The established accountability approaches used by the health care system to measure, identify, and demonstrate quality and safety in the delivery of clinical care should be used to hold health care professionals, managers, and organizations accountable for the ethical conduct of QI.⁴⁶

A first line of accountability is through the professional organizations of those who work in health care—physicians, nurses, health care managers. These organizations should inform their members about their professional obligation to improve quality, identify the basic QI skills they should have, and ensure that they understand and uphold the standards for ethical conduct of QI. Quality improvement can be incorporated into professional Codes of Ethics. For example, the American Nurse 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.” The Code of Ethics of the American Medical Association offers as one of nine core principles the rule that “A physician shall continue to study, apply, and advance scientific knowledge,” and on the basis of this statement, AMA policy calls on physicians and their organizations to “(1) strive continuously to improve the quality of health care; (2) encourage the ongoing evaluation of continuous quality improvement models; (3) promote implementation of effective quality improvement models; and (4) identify useful approaches for assisting physicians in implementing quality improvement procedures in their medical practices and office management.”⁴⁷

Accountability at the organizational level can be fostered through the accrediting bodies that set standards for health care organizations, assess compliance with those standards, and in some cases focus on the operation and effectiveness of internal quality improvement systems. In some areas, 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 quality improvement, the standards of the major private 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 to their review of the conduct of QI in organizations a review of the extent to which the organization has procedures in place to ensure that the QI meets ethical requirements. Eventually, outcome and process indicators for ethical quality improvement could be part of a set of regularly collected quality measures.

Public sector mechanisms for accountability include the federal HIPAA Privacy Rule and other federal and state statutory privacy laws that regulate the protection of identifiable health information. The HIPAA Privacy Rule requires that “covered entities”—persons and organizations that acquire, use, disclose, or store health informa-

The established approaches used by the health care system to ensure quality and safety in clinical care should be used to establish accountability for the ethical conduct of QI.

tion—protect the individually-identifiable health information they create or receive by establishing and adhering to privacy protections. These protections include providing notice to patients about their privacy rights and the entity’s policies regarding disclosure of identifiable information, implementing internal privacy policies and procedures, establishing safeguards to protect data privacy, training employees to understand privacy laws, and assisting health consumers to exercise their rights under the Privacy Rule. The Privacy Rule allows covered entities to use protected health information to perform activities defined as normal health care operations provided specified procedures are followed and includes QI in this category. Research is not included in normal health care operations and is subject to different standards regarding the use and disclosure of identifiable health information.

Some authors have argued that privacy risks may be the key potential harm to patients from quality improvement projects. The broad applicability of the Privacy Rule across the health care system could protect patients from privacy breaches when their data are used for quality improvement initiatives. The HIPAA Privacy Rule includes provisions for the protection of data from unauthorized review, requires that only the “minimum necessary” data be used, and introduces HIPAA privacy boards to monitor the use of protected health information within organizations. It has 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 from a breach of privacy and/or confidentiality.

For those QI activities that fall into the QI/HuSR overlap category, the federal human subject protection regulatory system acts as an external accountability mechanism for the specialized QI-IRBs proposed as part of the internal accountability structure for the conduct of QI within organizations.

Finally, the health care market may enforce a degree of accountability through the ability of purchasers to make the observance of ethical standards in the conduct of QI a

factor in their choice of provider. This effect is limited, however, since the information available to patients is also limited, and they rarely have full control over decisions about the care that is purchased on their behalf. Market forces are most likely to have an effect when they act through third party purchasers. Health care purchasing groups and other payers could encourage quality improvement and its ethical practice by including outcome and process standards for the ethical practice of QI in the contracts they make with providers.

IV. Implementation

Improving the quality and safety of American health care is of vital importance. Health professionals, managers, health care delivery organizations, patients, and government all have an ethical responsibility to cooperate with one another in pursuing this goal. In this report, we have discussed the ethical issues raised by the use of QI methods to improve health care. Using the principles of research ethics that underlie the current human research protection system as a point of departure, we have defined the requirements for ethical conduct of QI activities and then considered the institutional arrangements needed to ensure that QI conforms to them. We have discussed the use of IRBs for ethical oversight of the conduct of QI and concluded that IRBs as currently constituted are not appropriate for this purpose. Instead, we argue that ethical review of QI activities for purposes of protection of human subjects should be integrated into a trustworthy accountability system for managing the quality of clinical care.

We recommend that the primary responsibility for the ethical conduct of QI be lodged in individual organizations, where it should be seen as a normal clinical care obligation and integrated into supervision and management, with the organizations' leaders responsible for overseeing the integration. We call this "internal accountability" for the ethical conduct of QI, and we distinguish three broad categories of oversight: professional responsibility for QI; local management review and supervision of QI; and QI-IRB review for QI that is also human subjects research. We recommend that there also be external accountability for the ethical conduct of QI in the form of procedures to ensure that individual health care organizations have well-designed, functioning internal practices in place to carry out their QI-related responsibilities. These procedures should be part of the overall system of holding health care providers accountable for the quality and safety of clinical care.

We have recommended a variety of specific steps by which the ethical conduct of QI might be ensured, but these recommendations bear summarizing.

■ *Clarify professional and organizational obligations toward QI*

Organizations of health professionals (physicians, nurses, health care managers, and so on) should inform members about their professional obligation to improve quality. They should also identify the basic QI skills their members should have, educate members about standards for ethical conduct of QI, and even incorporate quality improvement into professional codes of ethics. Organizations of health care provider organizations (hospitals, nursing homes, health plans, and so on) should educate their members about their quality improvement obligations, the need to ensure that their employees have basic QI skills, and the standards for ethical conduct of QI. Leaders in professional education should press for greater emphasis on the obligations of health professionals toward the quality of care and the development of QI skills in educational curricula.

■ *Clarify patients' obligations toward QI*

When people seek health care, they should be told about the importance of QI activities for maintaining and improving the quality of their care and informed that consent to receive care includes consent to a minimum level of cooperation with ongoing QI. They should be given basic information about the organization's QI program and told how they can obtain more information if they want it.

Health care organizations should develop educational materials for their patients on the conduct of QI within an organization and on patient rights and responsibilities with respect to QI. Organizations, such as JCAHO and the Institute for Healthcare Improvement (IHI), and associations of organizations, such as the American Hospital Association (AHA), might assist with this by promoting the development and dissemination of model educational materials that individual organizations could adapt for their own use.

■ **Develop guidance on QI methodology**

QI uses—and should use—a somewhat different range of methodologies from traditional research. Moreover, as a relatively newly rediscovered field of endeavor, QI's methods are in a state of rapid evolution. QI practitioners need ongoing guidance on appropriate methodological standards in order to meet the ethical requirement that QI activities be properly structured to achieve their goals. Groups that are already active in developing and promoting QI and educating people about QI methods, such as IHI and AHRQ, are well placed to perform this function.

■ **Develop new models of management and supervision of QI and QI/HuSR**

We have given a rough outline of the internal accountability arrangements that should be in place to ensure that QI and QI/HuSR activities receive appropriate oversight. The next step is to translate this rough outline into models that will work in real health care settings. We suggest that one promising way to move this forward is through collaborative efforts to develop such models by organizations that are leaders in introducing QI methods into their operations.

OHRP could take the lead in encouraging some leadership organizations to undertake the task, or the leadership organizations could take the initiative themselves. IHI might be able to play a coordinating role, perhaps along the lines of the role it plays in its “Breakthrough Collaboratives.” The goal would be for the individual organizations to develop systems of internal management and supervision for their QI activities, establish QI-IRBs for activities that are both QI and human subjects research, devise practical rules for identifying the activities that should be reviewed by QI-IRBs, and develop QI-IRB review processes tailored to the types of QI/HuSR carried out in their organizations. As they launched these efforts, the organizations could share their experiences with one another regularly, engaging in robust discussion of the ethical issues they encounter and the practical wisdom they generate. Ideally, organizations such as OHRP, AHRQ, and JCAHO would also be involved in this endeavor.

A federal agency could also undertake to lead an effort to develop practical rules and models, under the exemption in the DHHS regulations for public benefit programs. This effort could be instead of, in addition to, or even in collaboration with an effort by private organizations. The obvious candidate would be the Centers for Medicare and Medicaid Services, since it sponsors QI and research and has accepted the mission of improving care for Medicare and Medicaid patients. However, the Health Resources and Services Administration (HRSA), the Department of Veterans Affairs, and the Department of Defense could also carry out such efforts under the public benefit agency exemption.

The consensus of this work should be clearly articulated from time to time, as the categories become more set-

tlled and the interpretations of the language of the DHHS human subjects regulations become clearer. This work would be greatly enhanced by robust discussion in the professional literature and at meetings. The topics discussed would include the criteria used to sort projects, the merits of particular methods of review and supervision, and actual case studies that illuminate the work.

The cooperation of OHRP would be very important, especially for efforts to develop practical guidance on the classification of activities as QI or QI/HuSR. One might expect that OHRP would be especially anxious about such a process, since it has been a long practice to extend the scope of research broadly. However, keeping OHRP involved and reflecting upon the actual situations that arise would be helpful in developing sound public policy. Having AHRQ or another agency sponsor some ongoing descriptive research into the nature of the projects and the review approaches that are implemented would help guide the process. If some adverse occurrences arise during this process of exploration and consensus building, then a coordinated response among the concerned parties would help to ensure that all the issues are carefully weighed and that overly rigid rulings are not made and transformed into permanent precedent.

As consensus develops on promising models for the management and supervision of QI and QI/HuSR and on rules for sorting activities into the appropriate category, IHI, JCAHO, OHRP, the various trade organizations, and professional journals should disseminate the results. Public Responsibility in Medicine & Research (PRIM&R) could also help to educate IRBs and the research community in general on the similarities and differences between QI and research, and the standards for ethical conduct of QI. In particular, PRIM&R could help the IRB community to understand the developing consensus on the management of activities that are both QI and human subjects research, and ensure ongoing consideration of the issues such hybrid activities raise through its Annual Human Research Protection Program (HRPP) Forum.

■ **Develop and expand external accountability for QI**

Accrediting bodies such as JCAHO and NCQA have already begun to include quality improvement requirements in the accreditation process. They should continue to develop and expand these efforts to include review of the extent to which organizations have effective mechanisms in place for managing QI and ensuring that it meets ethical requirements in the accreditation process.

■ **Disseminate QI results**

The ethical analysis in this report supports the conclusion that the intent to publish (or actual publication) does not make a QI activity into a research project, nor does it establish that IRB review is ethically required. The analysis also implies that QI results can have social value outside

the setting in which they were developed, and therefore, dissemination by a variety of means should be encouraged. There has been considerable confusion in the past about the relationship of publication to IRB review and the designation of QI as research; however, at this point, OHRP and others now seem to be in agreement with these conclusions.⁴⁸

The next step is to develop strategies that facilitate the sharing of QI results. For example, publication of QI results should be encouraged, and the results should be published in a standardized format so that it is easier to compare different QI activities and evaluate the extent to which the conduct of the activities met ethical requirements.⁴⁹ By allowing wider scrutiny of the methods used in QI, removal of the current bias against publication of

QI articles would also promote the development and clarification of QI methodological standards.

Editors of medical and other health care-related journals could adopt a standardized format for the reporting of QI activities for publication, encourage the submission of articles on QI methods and results, and become educated about what falls outside of the QI/HuSR range so that they do not reject articles that report QI activities just because they were conducted without informed consent or IRB review. AHRQ, CMS, and other federal agencies could develop and implement ways of providing financial support for the conduct of QI, the dissemination of results, and the development of QI methods, and provide ongoing guidance on the application of HIPAA privacy rules to QI activities that involve collaboration across organizations.

V. Conclusion

Although the findings and conclusions we have arrived at during the course of our research on ethical issues and health care quality improvement are complex and nuanced, they can be summarized as follows:

- QI is any systematic, data-guided activity that is designed to bring about the immediate improvement of care in a local setting.
- QI is both appropriate and vital to health care.
- QI is marked most distinctly by the prompt feedback of the effects of deliberate changes to the same care delivery setting that is making the changes.
- QI is intrinsic to health care delivery and obligatory for both professionals and patients.
- Though QI is often driven by a priori evidence that suggests substantial benefits are likely for the patients and/or staff involved, QI can pose some risks to some patients.
- Not undertaking QI in the face of recognized quality deficiencies also puts patients at risk.
- QI should itself be implemented ethically.
- Low-risk QI should generally have the same review and standards as routine health care delivery.
- Higher-risk QI should undergo routine and orderly review within the usual arrangements for clinical supervision or by an advisory group.

- Some projects are correctly counted both as QI and as research involving human subjects and should meet the requirements for review of protection of human subjects in research.

- Meeting those requirements might be more readily accomplished with a QI-IRB that met regulations, but whose policies and procedures were also tailored to the needs and expectations of QI.

- Certain issues might trigger the requirement for formal review of a proposed QI project: randomized designs, novel treatments, involvement of researchers, delayed feedback of monitoring, or external funding.

- Federal agencies and voluntary organizations should cooperate in further developing and implementing these ideas.

Resolving the uncertainty about what is ethically and legally required to safeguard participants in QI activities is essential if QI methods are to be available to help transform the culture of American health care delivery into a culture committed to continuous quality improvement. In this report, we have outlined what must be done to protect patients' and staff members' rights to privacy, informed consent, and justice when carrying out QI activities. The challenge now is for the regulatory community and health care management and professionals to put the appropriate standards and practices for QI in place. The goal—a better and safer health care system—is worth the effort.

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2. Because fourteen other federal departments and agencies have codified Subpart A in their own departmental regulations, it is known as the "Common Rule." An additional agency (the Central Intelligence Agency) is required by executive order to comply with all parts of 45 CFR 46. In addition to these human subjects protections, some federal agencies have issued regulations specific to human research conducted under their jurisdiction (for example, the Environmental Protection Agency regarding pesticide research), and several states have statutes and/or regulations governing research with humans (such as the California Health and Safety Code).
3. See M.P. O'Kane, "Do Patients Need to be Protected from Quality Improvement?" background paper prepared for The Hastings Center project, "The Ethics of Improving Health Care Quality and Safety."
4. K.N. Lohr, ed., *Medicare: A Strategy for Quality Assurance* (Washington, D.C.: National Academy Press, 1994), quoted in Institute of Medicine, *Crossing the Quality Chasm* (Washington D.C.: National Academy Press, 2001), 232; see also Institute of Medicine, *Envisioning the National Health Care Quality Report* (Washington D.C.: National Academy Press, 2001).
5. See IOM, *Crossing the Quality Chasm*, 5-6.
6. *Ibid.*
7. See IOM, *Envisioning the National Health Quality Report*, 9. The committee notes that "specific causes of inefficiency, such as repeat procedures due to error, overuse, fragmentation of care, and unnecessary delays, are included under the appropriate component of quality."
8. The issue of changes that involve trade-offs between quality and cost—that is, accepting a lower level of quality in exchange for lower resource costs—is discussed later in this report.
9. M.A. Schuster, E.A. McGlynn, and R.H. Brook, "How Good Is the Quality of Health Care in the United States?" *Milbank Quarterly* 76 (1998): 517-63.
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15. C. Schoen et al., "Taking the Pulse of Health Care Systems: Experiences of Patients with Health Problems in Six Countries," *Health Affairs* 24 (2005): w509-w525 (published online November 3, 2005; 10.1377/healthaff.w5.509).
16. Professional societies have recently made this clear. See ABIM Foundation, ACP-ASIM Foundation, and the European Federation of Internal Medicine, "Medical Professionalism in the New Millennium," *Annals of Internal Medicine* 136 (2002): 243-46; Institute of Medicine, *Health Professionals Education: A Bridge to Quality* (Washington D.C.: National Academy Press, 2003); and the description of "the six competencies" developed by the Accreditation Council for Graduate Medical Education (ACGME) and endorsed by the American Board of Medical Specialties (ABMS) at: <http://www.acgme.org/outcome/comp/compFull.asp>.
17. See President's Commission for the Study of Ethical Problems in Medicine, *Securing Access to Health Care, Volume One: Report* (Washington D.C.: U.S. Government Printing Office, 1983).
18. See M. Wynia et al., "Physician Ethics and Participation in Quality Improvement: Renewing a Professional Obligation," background paper prepared for The Hastings Center project, "The Ethics of Improving Health Care Quality and Safety."
19. N. Lang, "Healthcare Quality Improvement: A Nursing Perspective," and G. Agich, "Healthcare Organization Responsibility for Quality Improvement," background papers prepared for The Hastings Center project, "The Ethics of Improving Health Care Quality and Safety."
20. We acknowledge that the United States has so far failed to actually fulfill this obligation. Nevertheless, the ongoing debate about health care reform and the existence of programs like Medicare, Medicaid, State Children's Health Insurance Programs, and other programs that provide assistance to various categories of the poor are evidence of recognition of an obligation, although there is no consensus about the extent of it or the public policies that should be used to fulfill it.
21. See N. Dubler et al., "Informed Participation in the QI Process," background paper prepared for The Hastings Center project, "The Ethics of Improving Health Care Quality and Safety."
22. See IOM, *Crossing the Quality Chasm*, 5-6.
23. The argument here contrasts with the position in the ethics of QI in which great importance is attached to the extent to which an individual QI participant, or a majority of participants, benefits directly from the specific QI activity. See D. Casarett, J.H. Karlawish, and J. Sugarman, "Determining when Quality Improvement Initiatives Should Be Considered Research: Proposed Criteria and Potential Implications," *Journal of the American Medical Association* 283 (2000): 2275-80.
24. See Department of Health and Human Services, "Code of Federal Regulations: Protection of Human Subjects," June 23, 2005, <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>, section 46.102(d). Emphasis added.
25. See Dubler et al., "Informed Participation in the QI Process."
26. Research on the quality improvement process is sometimes referred to as "QI Research," but we prefer the terminology of "Research on QI" to distinguish this set clearly from the set, "QI/Research," the overlapping region of the QI and Research sets.
27. See E.J. Emanuel, D. Wendler, and C. Grady, "What Makes Clinical Research Ethical?" *Journal of the American Medical Association* 283 (2000): 2701-2711. We used the framework of this article because it is a brief, readily accessible, recent synthesis of generally accepted ideas in research ethics and includes all the topics we wish to discuss in this report. We recognize that it is a variegated list of topics consisting of fundamental ethical principles and both substantive and procedural norms. For an extended, more rigorous discussion and classification of these topics, see R.J. Levine, *Ethics and Regulation of Clinical Research*, second edition (New Haven, Conn.: Yale University Press, 1988).
28. The questions in italics with each requirement paraphrase the questions posed for research in Emanuel, Wendler, and

Grady, "What Makes Clinical Research Ethical?" 2701-2711.

29. See F. Davidoff, "Publication and the Ethics of Quality Improvement Projects," background paper prepared for The Hastings Center project, "The Ethics of Improving Health Care Quality and Safety."

30. For an entertaining discussion related to this point, see the satirical article by G.C.S. Smith and J.P. Pell, "Parachute Use to Prevent Death and Major Trauma Related to Gravitational Challenge: Systematic Review of Randomised Controlled Trials," *British Medical Journal* 327 (2003): 1459-61, and responses by M. Diaz and D. Neuhauser, "Pasteur & Parachutes," *Quality & Safety in Health Care* 14 (2005): 140-43.

31. Emanuel, Wendler, and Grady, "What Makes Clinical Research Ethical?" 2705.

32. In practice, the DHHS regulations allow informed consent to be waived for minimal risk research provided that several other stringent requirements are met. Such waivers are considered incompatible with ethical principles by some ethicists, however.

33. See Dubler et al., "Informed Participation in the QI Process."

34. See discussion of "notification" in Levine, *Ethics and Regulation of Clinical Research*, 178-81.

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36. See J. Lynn, "When Does Quality Improvement Count as Research?" *Quality and Safety in Health Care* 13 (2004): 67-70; and R.J. Levine, "Institutional Review Boards: A Crisis in Confidence," *Annals of Internal Medicine* 134 (2001): 161-63.

37. See Institute of Medicine, *Responsible Research: A Systems Approach to Protecting Research Participants* (Washington D.C.: National Academy Press, 2002).

38. The IRB is required to regularly monitor the research. For example, it must

"receive and review reports of local, on-site adverse events and unanticipated problems involving risks to subjects or others and any other information needed to ensure that its continuing review is substantive and meaningful. In addition, institutions and IRBs may require additional information for continuing review at their discretion." See Office for Human Research Protections, "Guidance on Continuing Review," July 11, 2002, <http://www.hhs.gov/ohrp/human-subjects/guidance/contrev2002.htm>.

39. One might object that a review carried out by the organization doing the QI is not an independent review. Note, however, that the research ethics requirement is for review by individuals unaffiliated with the research project, not review by individuals unaffiliated with the organization in which the research is carried out. Under current rules, IRBs must have at least one member unaffiliated with the organization, but the rest can be affiliated. Moreover, the name "institutional review board" reflects the original concept of IRBs as entities responsible for carrying out an institution's obligation to protect the human subjects in the research conducted under its auspices. Human subjects protection was deliberately located at the institutional level so that reviewers would have knowledge of local conditions and the opportunity for ongoing oversight (limited though it is). In other words, locating primary responsibility for the protection of human participants in QI within the organization doing the QI is not a significant departure from independent review as it currently occurs in research.

40. A. Gauthier and M. Serber, *A Need to Transform the U.S. Health Care System: Improving Access, Quality, and Efficiency* (New York: The Commonwealth Fund, 2005).

41. M. Bottrell, "Accountability for the Conduct of Quality Improvement Projects," background paper prepared for The Hastings Center project, "The Ethics of Improving Health Care Quality and Safety."

42. The regulations are complicated and difficult to summarize briefly or reduce to a simple diagram. For more details, see Office of Human Research Protections, "Human

Subjects Regulations Decision Charts," September 24, 2004, <http://www.hhs.gov/ohrp/humansubjects/guidance/decision-charts.htm>.

43. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Ethical Guidelines for the Delivery of Health Services by DHEW: Report and Recommendations* (Washington, D.C.: U.S. Government Printing Office, 1978).

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