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The Ethics of Using Quality Improvement Methods in Health Care

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Quality improvement (QI) activities can improve health care but must be conducted ethically. The Hastings Center convened leaders and scholars to address ethical requirements for QI and their relationship to regulations protecting human subjects of research. The group defined QI as systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings and concluded that QI is an intrinsic part of normal health care operations. Both clinicians and patients have an ethical responsibility to participate in QI, provided that it complies with specified ethical requirements. Most QI activities are not human subjects research and should not undergo review by an institutional review board; rather, appropriately calibrated supervision of QI activities should be part of professional supervision of clinical practice. The group formulated a framework that would use key characteristics of a project and its context to categorize it as QI, human subjects research, or both, with the potential of a customized institutional review board process for the overlap category. The group recommended a period of innovation and evaluation to refine the framework for ethical conduct of QI and to integrate that framework into clinical practice.

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Americans expect high-quality health care—safe, effective, patient-centered, timely, equitable, and efficient (1). Unfortunately, reality falls short of this ideal. A growing literature documents serious problems, such as unnecessary surgery, inappropriate use of medications, inadequate prevention, avoidable exacerbations of chronic conditions, and long delays before important research findings become standard (1–4).

We discuss deliberate efforts of providers to meet their obligations to improve the quality of patient care through clinical and managerial changes in the processes of care. Health care practices have always evolved, but mostly in a scattershot way. In recent years, providers have initiated new methods, some of which were modeled first in manufacturing to make ongoing improvements more systematic, data-guided, and efficient (5, 6). These continuous quality improvement methods are commonly referred to as *QI.*

Ethical issues arise in QI because attempts to improve quality may inadvertently cause harm, waste scarce resources, or affect some patients unfairly. For example, efforts at earlier administration of antibiotics for pneumonia may lead to overuse, or efforts to encourage cancer screening may prompt useless, risky, and expensive tests in people who are too near death to benefit. In addition, some activities using QI methods have been categorized as research that uses patients as subjects, which brings the activities under the ethical and regulatory requirements governing human subjects research, including review by institutional review boards (IRBs) (7). Putting improvement activities under research regulations can precipitate substantial delays, costs, and conflicts (8–11). Key federal agencies have disagreed about the boundaries between research and QI, and QI practitioners, health care organizations, agencies that fund research, policymakers, and IRB members are uncertain about ethical and legal requirements. The situation has already generated disincentives to engage in QI.

Beginning in 2003, The Hastings Center convened a group of experts to address the ethical issues associated with QI methods in health care. Ethicists, clinician leaders, experienced managers, regulators, authors of relevant publications, and others met repeatedly, considered published and newly commissioned scholarly papers, and discussed options with experts and affected parties. The project presented interim findings at national meetings on research ethics, general internal medicine, health services research, and quality improvement, and the project sponsored a listserv to share progress and issues with everyone who expressed interest in the work. The project has published a comprehensive report (8) and a set of commissioned papers (12). We present a summary and explanation of the report's main conclusions, along with recommendations for developing policy and practices to protect patients from both the harm that QI activities might cause and the harm that quality and safety deficits do cause. The full report contains more details on the process, the arguments, and our conclusions.

QI Activities: Part of Normal Health Care Operations

The project group addressed 3 questions: What is QI, and what role does it play in health care? What ethical requirements should QI activities meet? What arrangements do we need to ensure the ethical conduct of QI?

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Defining QI

The group defined QI as systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings. Quality improvement uses an array of methods and can look like practical problem solving, an evidence-based management style, or an application of a theory-driven science of system change. Quality improvement methods often encourage health care workers to use their experience, along with insights from others, to identify promising improvements, implement changes on a small scale, monitor and interpret effects, and decide about additional changes and wider implementation. Alternatively, a QI activity might start with management review of the organization's performance from aggregate data or with similar analyses of data across multiple organizations. At its heart, QI is a form of experiential learning that regards improvement to be part of the work process and always involves deliberate actions expected to improve care, guided by data reflecting the effects.

Quality improvement is an intrinsic part of good clinical care, in which data from clinicians' own settings guide them in improving their practices. Quality improvement assumes that quality and safety are largely characteristics of systems, and its methods enable workers to gain insight about their system's relationships and functions. Many QI activities rely on groups of clinicians, managers, and staff cooperating to improve procedures, such as scheduling, medication handling, and record keeping. Organizations that accredit the education and certify the competence of health care professionals have come to require practitioners to be competent in improving their own practices (13, 14).

As health care workers engage in QI, they deepen their understanding of their processes of care and how to improve those processes. Over time, successful QI transforms organizational culture so that everyone is committed to continuous quality improvement and everyone has the requisite skills. In sum, QI is a structured, data-guided form of the innovation and adaptation that has always been part of normal health care operations, and it has proven to be effective in improving U.S. health care (15–19).

Requirements for the Ethical Conduct of QI

The project group began by examining how the existing ethical framework that governs research on human subjects might apply (20). **Table 1** shows the group's conclusions, organized under 7 topics considered important for ethical research (21). This analysis highlights the responsibility that health care providers have to improve quality and the responsibility that patients have to cooperate with improvement efforts. Physicians, nurses, and other clinicians have long professed a special ethical responsibility to serve the interests of their patients, including the responsibility to maintain and continually strive to improve the quality of care (22, 23). As health care delivery has come to require complex interdependent systems, a similar ethical responsibility falls on health care organizations and their managers (24). Participation in QI activities is a systematic way to fulfill this responsibility.

Because QI activities are, and should be, part of normal health care operations, patients also have a responsibility to participate in quality improvement, which often requires direct cooperation (for example, permitting collection and use of data about their medical conditions, treatments, and outcomes) (25). A patient who will not be involved in QI constrains the efforts of that care system to improve itself and thereby jeopardizes the very benefits sought. The interests of patients in receiving reliably high-quality health care depend on all patients cooperating with QI activities. Hence, the responsibility to cooperate need not turn on whether the particular patient directly benefits from a particular QI activity (although this is often the case); rather, it is justified ethically by the benefits that each patient receives because all are cooperating in the overall QI enterprise. Reaping the benefits of the QI enterprise without participation would be unfair.

Of course, the patient's responsibility to cooperate is subject to standards of reasonableness, which require that patients have access to general information about QI activities and be kept safe from harms and from violations of their rights. For example, patients should be able to count on the confidentiality of their personal health information and on the opportunity to choose whether to participate in a QI activity that exposes them to more than minimal incremental risk (measured relative to the risks of usual medical care). Health care workers (employees and nonemployee professionals who provide care within an organization) who participate in QI activities should also be able to count on confidentiality and the opportunity to opt out of QI activities that present more than minimal incremental risk to themselves. In the case of workers, however, confidentiality and risk are measured relative to the normal work situation; an organization has no ethical requirement to allow a worker to opt out of a QI activity because that activity might reveal that the worker is incompetent or unnecessary (**Table 1**).

The ethical responsibility to cooperate with QI activities contrasts with the fundamental ethical claim that research is voluntary (26). Health care professionals and organizations have no ethical responsibility to do research, and every person is entitled to choose whether to be a research subject. This ethical claim emerged in response to research that imposed substantial risk on nonconsenting persons without offering them any direct benefit (27, 28). Research ethics springs from society's conclusion that the interests of researchers often conflict with those of subjects and that research is conceptually distinct from health care delivery. Indeed, most published clinical research results have been found to be of little relevance to clinical practice (29). A person's decision to be a subject in research must be voluntary and fully informed to prevent exploitation. To ensure that researchers meet their ethical obligations to

Table 1. **Ethical Requirements for the Protection of Human Participants in Quality Improvement Activities***

Requirement	Explanation
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 (i.e., properly structured to achieve its goals).
Fair participant 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 limit risks while maximizing potential benefits and to ensure that risks to an individual human participant are balanced by expected benefits to the participant and to society.
Respect for participants	A QI activity should be designed to protect the privacy of participants and the confidentiality of their personal information. Participants in a QI activity should receive information about findings from the activity that are clinically relevant to their own care. All patients and workers in a care delivery setting should receive basic information about the program of QI activities. The QI results should be freely shared with others in the health care system, but participant confidentiality should be protected by putting results into nonidentifiable form or obtaining specific consent to sharing.
Informed consent	Consent to inclusion in minimal-risk QI activities is part of the patient's 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 to patients should be measured relative to the risk associated with receiving standard health care. Workers (employees or nonemployee professionals who provide care in an organization) should participate in minimal-risk QI activities as part of their job responsibilities. Workers should be asked for their informed consent to be included in a QI activity that imposes more than minimal risk. The risk to workers should be measured relative to the risk associated with the usual work situation. This does not include any risk to economic security (for example, if a QI activity reveals that the worker is incompetent or that the organization can provide quality care without that worker).
Independent review	Accountability for the ethical conduct of QI should be integrated into practices that ensure 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.

* The 7 topics are derived from reference 21. QI = quality improvement.

human subjects, representatives of the relevant community (IRBs) should review the design, sample, informed consent process, and risk–benefit relationship of most research projects involving human subjects. In contrast, QI generally aligns with patients' interests, presents lower risks than continuing with usual care (and certainly less risk than making the same changes without collecting data to monitor its impact), demands the participation of all to be effective, arises from a responsibility of professionals and patients alike, and has no history of ethics scandals. It is appropriate, therefore, that the ethical management of QI should be accomplished through processes and social arrangements that differ substantially from those designed to protect human research subjects.

Arrangements to Ensure That QI Meets Ethical Requirements

Although QI practitioners must meet the ethical requirements in **Table 1**, we concluded that requiring IRB review would not be the most effective approach to ensuring reliable performance. First, the IRB review process requires substantial resources to prepare the submission and perform the review (9–11, 30). Because many QI activities are of small scale, these costs would often be larger than both the resources available for the activity and the likely benefits. These disproportionate costs would bar small-scale QI and would inhibit many larger projects as well, making it more difficult to improve processes of care and to realize the obligations of professionals. Moreover, the structure of IRB review is generally inappropriate for QI. The IRB process requires registering a fixed protocol with a clearly delineated method and usually a period of analysis after complete data collection. In contrast, QI activities are designed to achieve immediate local improvements in clinical performance and then to sustain them. The activities usually proceed incrementally, and interventions, measurements, and goals are frequently adjusted over time, guided by insights from data and actual clinical experience. Ethical oversight procedures must allow QI activities to remain flexible and be integrated into ongoing service delivery, which the IRB process does not allow. Changes in QI lie within clinical and managerial discretion and are expected to be beneficial; QI methods should ensure that QI practitioners introduce changes in a careful, data-guided way. If QI activities were to entail a costly, cumbersome review process that is minimally relevant to the structure and process, however, managers would have reason to make changes without monitoring effects or to leave malfunctioning care arrangements unchanged.

In our view, therefore, instead of exporting QI into IRB-based research review, ethical oversight of QI should become part of an enhanced accountability system for professional responsibility and the supervision and management of clinical care. The arrangements for ensuring ethical conduct of QI should encourage data-driven changes and data-guided assessments and decisions. Organizations should calibrate the rigor of their supervisory procedures for QI activities to key characteristics, such as resource use, expected impact, methods used, and additional risk to patients compared with usual care. Consent to receive care should include consent to participate in routine, minimal-risk QI activities, whereas activities that entail more than minimal incremental risk (additional physical or psycho-

logical harm or burden related to the change itself or to additional surveys or medical procedures required for monitoring) should require specific informed consent and a more formal review, potentially including a reviewer from outside of the organization.

The social arrangements that normally hold health care professionals, managers, and organizations responsible for the quality of care should also ensure that they meet requirements for the ethical conduct of QI. Health care professionals and organizations need a robust understanding of the ethical requirements for QI, and organizations must have procedures to ensure that QI activities meet ethical standards. Because quality of care is a core management responsibility, leaders should ensure that each health care organization's accountability procedures are working well.

Overlap between QI and Human Subjects Research

QI and Federal Human Subject Protection Regulations

The regulatory system implemented by the Common Rule (7) applies to research involving human subjects, in which research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge," and a human subject is "a living individual about whom an investigator . . . conducting research obtains data through intervention or interaction with the individual, or identifiable private information." The regulations cover federally supported research, with exceptions for certain exempt categories; moreover, organizations engaged in federally funded research ordinarily have federal-wide assurances that promise that the organizations will apply the regulations to all nonexempt research, however funded.

The confusion about whether a QI project comes under the regulations stems mainly from differences in the interpretation of the phrase "designed to develop or contribute to generalizable knowledge." A classic randomized clinical trial of a drug provides the paradigm case for a systematic investigation that is "designed to develop or contribute to generalizable knowledge" and therefore exemplifies the category of research. Quality improvement projects can also provide new insights of various sorts, such as learning that a published improvement strategy was ineffective outside of its original setting or that motivating clinicians to adopt a change required a sequence of interventions. Usually the knowledge that results from QI is most applicable to the local situation and arises naturally as a byproduct of the effort to improve care in a particular setting, but insights about one setting ordinarily have some applicability to other settings or to the original setting in the future.

The scope of the term "generalizable" requires interpretation. If a QI project must yield insights that are applicable to most similar situations, now and in the future, to be counted as generalizable, then very few QI activities will qualify. If, however, a QI project's insights are taken to be generalizable whenever they might be expected to apply to any other people or situations, then almost every QI activity will qualify. Once local practice and facility standards ensure accountability for QI activities, the Hastings Center project group concluded that the scope of generalizability should be narrow; in which case, most QI projects would not also qualify as research under the Common Rule. However, if a QI activity is designed both to improve local care and to produce broadly generalizable knowledge, it is both QI and research. If that activity has participants who meet the definition of human subjects, it is both QI and human subjects research and the regulations treat it as human subjects research.

Resources for QI usually come from clinical care, not federal research funds; nevertheless, overlap activities (being both human subjects research and QI) often come under the research regulations because of federal-wide assurances that include all research or because institutions apply the procedures broadly on their own. Organizations that anticipate problems in reviewing overlap activities as research have 2 options: revise their federal-wide assurances and practices to include only federally funded research or establish specialized QI IRBs to fulfill the requirement for IRB review. Existing flexibility in the regulations governing IRB membership and the process of review allows tailoring the IRB process to the special characteristics and ethical requirements of QI and should make it more effective and efficient for overlap activities (8).

Determining whether a QI Activity Is Also Human Subjects Research

Identifying a project as QI is usually straightforward: It is a systematic, data-guided activity designed to bring about immediate improvement in a local setting. Deciding which QI activities are also human subjects research and may be subject to the regulations is more challenging.

Previous authorities have split the categories of human subjects research and QI activities on the basis of their primary intent or project design. The Health Insurance Portability and Accountability Act (HIPAA) regulations say that "[h]ealth care operations means . . . conducting quality assessment and improvement activities . . . provided that the obtaining of generalizable knowledge is not the primary purpose of any studies . . ." (31). (A published report by our group [8] discusses patient protections in QI under the HIPAA privacy rule.) The National Bioethics Advisory Commission explained that "some data collection and analysis activities in health services are not intended to generate scientific knowledge, but rather are used as management tools to improve the provision of services to a specific health care population. . . . [I]f the purpose is to assess the success of an established program, and the information gained from the evaluation will be used to improve that program, the activity should not be considered research involving human participants" (32). The National

Institutes of Health guidance to researchers on the HIPAA privacy rules also relies on the primary intent (33). The Centers for Disease Control and Prevention considers a public health project not to be research when the "[i]ntent of the project is to identify and control a health problem or improve a public health program or service; intended benefits of the project are primarily or exclusively for the participants (or clients) or the participants' community; data collected are needed to assess and/or improve the program or service, the health of the participants or the participants' community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental" (34).

This approach does not determine whether an activity requires IRB review, because the regulations on research involving human subjects, as currently interpreted, require any activity that is combined with human subjects research to be treated as research, whatever its primary purpose. For regulatory compliance, QI practitioners therefore need substantive rules that separate QI projects from overlap activities. Constructing such rules requires a clear conceptual framework and a pragmatic set of classification procedures. One would want observable aspects of an activity's context or design to establish its category—avoiding, for example, reliance solely on the intent of the person initiating the activity. The rules should be as consistent as possible with use of the word "research" in ordinary language and the regulatory definition. Although some arbitrariness and misclassification is inevitable, someone familiar with the rules should be able to classify most projects with confidence, and accepted procedures should be available to resolve difficult cases. Finally, the overall approach should acknowledge that the risks to participants in QI activities are regularly less than the risks from allowing quality and safety deficits to persist or introducing changes without monitoring their effects.

Currently, the ethical rules for QI are not clear, and the situation is confusing. Since the Office for Human Research Protections (OHRP) interprets research broadly (see, for example, the report of a project to improve dialysis performance [8]) and can impose severe penalties for regulatory violations, organizations have been afraid to develop their own explicit guidelines for identifying QI activities that belong in the overlap category. At the same time, the OHRP has shown little inclination to provide specific guidance on how to identify such activities. Given the variety of QI projects and the evolution of QI methods, the stance of the OHRP may be prudent. Producing consistent, practical guidance at the regulatory agency level would be very difficult. Nevertheless, when pressed for guidance on specific situations, the OHRP has repeatedly interpreted the category of research as inclusively as possible.

Allowing the current confusion to continue would be unwise. It produces inconsistent decisions, increases costs, retards improvement, and undermines respect for research review. Fear of sanctions from the OHRP could lead some organizations to treat most QI activities as overlap activities, thus requiring IRB review. Even with QI IRBs and other streamlined review strategies, this policy is more likely to slow improvement and add costs than to protect patients. Publication prospects for QI articles are also affected. Many journals will not publish human subjects research without IRB review. In the past, many people assumed that the intent to publish automatically indicated that a project was considered research, but the OHRP has recently affirmed that publication is not confirmation that a project was research (35). Nevertheless, if editors cannot determine when QI is also human subjects research, they may reject manuscripts about QI activities that lack IRB review, even though review was not ethically or legally required. This would be unfortunate, because health care and the QI enterprise benefit from publication of methods and interventions that prove to be important (36, 37). We conclude that the necessary practical guidance can be developed most effectively by combining reflection on the nature of research and the goal of human research protection with experience in managing QI and overlap activities in various organizations. The goal is an interpretation of the definition of human subjects research that enables QI and overlap activities to receive the review and supervision needed to ensure ethical conduct without imposing excessive burdens that prevent health professionals from meeting their obligation of continuous movement to higher levels of performance.

As a starting point for such an effort, we propose that the category of research under the Common Rule be interpreted to comprise activities that are designed to increase enduring knowledge about the nature and function of human beings and their environment. This definition is in accord with that in the Common Rule and the concepts underlying it (27); moreover, our interpretation gives a workable conceptual meaning to the phrase "designed to develop or contribute to generalizable knowledge." We recognized that the Common Rule definition itself could also be revised but chose to work within the current regulatory definition.

Under this interpretation, most QI is not also research. Quality improvement implements changes that are within the current standard of care, for example, moving from "unacceptable" and "barely acceptable" to known and established "best" practices. The changes already fall within clinical and managerial discretion; in fact, professional responsibility imposes an ethical, and sometimes a legal, duty to make the changes. Quality improvement activities are generally based on existing knowledge about the enduring nature and function of human beings and their environment, rather than designed to create new knowledge of that sort. Examples include data-guided efforts to ensure adoption of an evidence-based practice guideline or to introduce procedures that will reduce medical errors. Quality improvement teams may gain insights about implementing change in other settings, but their activity is not "designed

to develop or contribute to generalizable knowledge" within the meaning that we recommend. Because improvement almost always involves experiential learning, as well as social and cultural change, it is usually contingent on particular times, places, and situations. Not being research, most QI activities do not require IRB review; however, they do come under local professional managerial review and supervision as required by the organization's arrangements to ensure accountability for the ethical conduct of QI and health services delivery.

When QI activities are designed to produce both local improvement and new, enduring knowledge about the nature and function of human beings and their environment, and they involve human subjects, they should be considered an "overlap project" with human subjects research. For example, an overlap project could seek to learn how best to improve adherence to treatment guidelines by randomly assigning various sites to test different adherence-promoting strategies. Another would be a project researching the effects of a new treatment but embedding that project in a QI process designed to bring about compliance with other well-established aspects of care. Such overlap projects should receive review as both human subjects research and QI. Organizations that sponsor many projects in the overlap group could improve their review process by establishing specialized QI IRBs.

Table 2 shows characteristics for use in the construction of guidelines for categorizing QI activities as overlapping with human subjects research. We did not intend this list to be definitive; rather, it provides a starting point for the development of practical models of ethical oversight for both QI and overlap activities, as recommended below.

Table 2. **Characteristics Helpful in Defining Activities as Both Quality Improvement and Human Subjects Research**

Testing of issues that go beyond current knowledge based on science and experience, such as new treatments
Random allocation of patients into different intervention groups to enhance confidence in differences that might be obscured by nonrandom selection (but not randomization for equitable allocation of a scarce resource)
Deliberately delayed or ineffective feedback of data from monitoring the implementation of changes, especially if this is done to avoid biasing the interpretation of data
Involvement in key project roles of researchers who have no ongoing commitment to improvement of the local care situation, even if others in the team do have professional commitments to it
Funding, sponsorship, or substantial participation by parties outside the clinical setting or organization in which the activity takes place

Recommendations for Action

Table 3 summarizes a broad agenda for implementing accountability for the ethical conduct of QI. The fourth recommendation in **Table 3** (to develop new models of internal management and supervision of QI and of QI–human subjects research overlap projects) requires additional discussion. We recommend that the arrangements for internal management of QI and overlap activities discussed in brief here and in the full report (8) be translated into models that work in real health care settings, through collaborative efforts by organizations that are leaders in QI. The OHRP could encourage some organizations to undertake this task, or QI organizations could take the initiative themselves, with central coordination.

Individual health care organizations should develop internal management and supervision for their QI activities and should create practical rules and structures for supervising QI, ensuring appropriate review of QI projects, and determining which projects are also research. Some organizations engaged in many activities that combine QI and human subjects research should develop experience with specialized QI IRBs. All involved should share their experiences on a regular basis. Such organizations as the OHRP, the Agency for Healthcare Research and Quality, professional societies, and the Joint Commission on Accreditation of Healthcare Organizations should support and evaluate this work.

Federal agencies should develop practical models for review and supervision of QI under the public benefit exemption, which exempts human subjects research from the federal regulations when it involves the study, evaluation, or examination of public benefit or service programs (38). Under the exemption, the agency has more flexibility in developing rules for identifying overlap activities than the OHRP might allow to nongovernment organizations. An obvious candidate agency would be the Centers for Medicare & Medicaid Services, because it already sponsors both QI and research and has accepted the mission of improving care for Medicare and Medicaid patients. The Health Resources and Services Administration, the U.S. Department of Veterans Affairs, and the U.S. Department of Defense could also lead some innovations under the public benefit exemption.

Over several years, we believe that this process will arrive at practical, substantive rules and procedures for identifying activities that are QI, human subjects research, or both. The cooperation of the OHRP will be very important in this endeavor, to monitor for adverse effects and to act as a consensus-builder for the development of practical guidance on both the classification of activities as human subjects research and the functioning of QI IRBs. As consensus develops, the Joint Commission on Accreditation of Healthcare Organizations, the OHRP, professional organizations, conferences, and journals should disseminate the results and help educate leaders of IRBs, researchers, clinical managers, and practitioners.

Protection of human subjects of research is a proud achievement of our society's commitment to ethics. Without threat to that achievement, the quality of health care in the United States urgently needs improvement. The most promising strategies for improvement use QI methods to guide the enterprise with data and insight. We have pro-

Table 3. **Recommendations for Implementing Accountability for the Ethical Conduct of Quality Improvement***

Recommendation	Explanation
Clarify professional and organizational responsibility for QI	Organizations of health professionals should inform members about their professional responsibility to improve quality, identify the basic QI skills members should have, educate members about standards for ethical conduct of QI, and incorporate QI into professional Codes of Ethics. Organizations of provider entities should inform members about their responsibility to improve quality, 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 responsibility of health professionals to improve the quality of care and the development of QI skills in educational curricula, including management of the ethical dimensions of QI.
Clarify patient responsibility for QI	People seeking health care should be told why QI activities are important to the quality of their care, be informed that consent to receive care includes consent to a minimum level of cooperation with ongoing QI, be given basic information about the organization's QI program, and be told how to obtain more information about the program if they want it. Health care organizations should develop patient education materials about patient rights and responsibilities with respect to QI and the conduct of QI within the organization.
Develop guidance on QI methodology and dissemination of QI results	Such groups as AHRQ should provide ongoing guidance on appropriate methodological standards for QI. Journal editors should adopt a standardized format for reporting of QI activities for publication†, encourage submission of articles on QI methods and results, and become educated about the boundaries of research in QI projects. The AHRQ, CMS, and other federal agencies should provide financial support for the conduct of QI, dissemination of QI results, development of QI methods, and ongoing guidance on the application of privacy rules to QI activities involving collaboration across organizations.
Develop new models of internal management and supervision of QI and of QI–human subjects research overlap projects	The arrangements for internal management of QI, including QI that is also human subjects research, should be translated into models that will work in real health care settings. The arrangements for deciding which QI projects are also human subjects research and should come under IRB review also should be tested in practical application, aiming to implement clear definitions and accepted procedures after a short period of gaining experience.
Develop and expand external accountability for QI	Accrediting bodies, such as JCAHO and NCQA, should expand existing QI-related accreditation requirements to include review of the extent to which organizations have effective mechanisms in place for managing QI and ensuring that it meets ethical standards.

* AHRQ = Agency for Healthcare Research and Quality; CMS = Centers for Medicare & Medicaid Services; IRB = institutional review board; JCAHO = Joint Commission on Accreditation of Healthcare Organizations; NCQA = National Committee for Quality Assurance; QI = quality improvement.
† See references 31 and 32.

vided a framework of key concepts and practices that can ensure responsible implementation of QI activities and also can protect persons used as subjects of research. Society needs a period of intentional innovation with structured evaluation, with the cooperation of many federal and private organizations to design practices that reliably protect human subjects of research and that also reliably engineer a high-quality health care system.

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