Recommendations for the Ethical Conduct of Quality Improvement

A Report by the National Ethics Committee of the Veterans Health Administration

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Founded in 1986, the National Ethics Committee (NEC) of the Veterans Health Administration (VHA) is an interdisciplinary group authorized by the Under Secretary for Health through the National Center for Ethics in Health Care. The NEC produces reports on timely topics that are of significant concern to practicing health care professionals. Each report describes an ethical issue, summarizes its historical context, discusses its relevance to VHA, reviews current controversies, and outlines practical recommendations. Previous reports have been useful to VHA professionals as resources for educational programs, guides for patient care practices, and catalysts for health policy reform. Scholarly yet practical, these reports are intended to heighten awareness of ethical issues and to improve the quality of health care, both within and beyond VHA.

Executive Summary

The Veterans Health Administration (VHA) is a national leader in quality improvement (QI). QI activity is essential and has brought tremendous benefits for patients. Yet, while widely accepted ethical standards exist for other activities in the clinical arena, including medical treatment and research, no analogous ethical standards currently exist for QI.

This report by VHA's National Ethics Committee (NEC) is a preliminary attempt to fill this gap by providing practical recommendations for the responsible conduct of QI. The following guidelines are intended to balance the ethical imperative to adequately protect patients and the ethical imperative to continuously improve patient care:

1) Health care organizations should recognize that QI cannot always be meaningfully differentiated from other activities that occur in the clinical arena, notably treatment and research.

2) Health care organizations should ensure that the rights and interests of patients involved in all health care activities – including QI – are adequately protected.

3) Health care organizations should take care that efforts designed to protect patients do not unnecessarily encumber the QI process.

4) Health care organizations should clearly define the locus of responsibility for the ethical conduct of QI.

5) Health care organizations should proactively promote the ethical conduct of QI.

6) QI activities should produce benefits that outweigh their potential burdens or risks.

7) QI activities should respect each patient's right to self-determination.

8) QI activities should preserve patients' privacy and confidentiality.

9) QI activities should be distributed fairly across patient groups.

10) Health care organizations should develop specific policies and procedures that fit their unique circumstances and needs.

These recommendations are intended as a starting point for discussion and elaboration of standards for the ethical conduct of QI. Further discussion will be needed within health care organizations, between and among organizations, and at the societal level to assure that all patients receive the ethical treatment they deserve.

Introduction

In the last few decades, QI activities have assumed increasing importance and influence in health care. While there is no single definition of QI that is widely agreed upon, QI activities are generally understood to be cycles of action, linked to assessment, whose goal is to improve the process, outcomes, and efficiency of health care services.[1-3] Health care quality is now routinely assessed through customer satisfaction surveys, clinical performance measures, and analyses of patient databases. But quality assessment does not always translate to QI – for QI to occur, the information produced by quality assessment must be translated into systematic improvements in health care practices. A wide range of approaches has been used to promote improvement. These include educational interventions, performance incentives, regulatory and policy requirements, and information technologies such as automated alerts to provide feedback to providers. When linked with the ongoing assessment of quality, such approaches have been lauded as highly effective in improving the quality of care.[3-6]

The basic principles of health care ethics are well established and include respect for autonomy, beneficence, non-maleficence, and justice.[7] More specific ethical standards relating to medical treatment are described in a variety of sources including codes of ethics, professional guidelines, consensus statements, published scholarly literature, and organizational policies. Ethical standards relating to research are also described in, for example, the Belmont Report, reports from the National Bioethics Advisory Commission (NBAC), and federal regulations.[8,9] In contrast, ethical standards for QI have not been clearly or thoroughly articulated.[10] For example, how do the ethical standards for treatment or research, such as those pertaining to confidentiality and informed consent, apply to QI activities? The answer is far from clear.

This report by the VHA's NEC is a preliminary attempt to fill this gap by providing practical recommendations for the responsible conduct of QI. VHA is a leader in QI and, as the largest integrated health care system in the U.S., maintains many complex databases and information management systems and conducts innumerable QI activities.[4] Offices are devoted to QI at every level of the organization: facility, network, and national. Ethical challenges pertaining to QI are therefore of considerable interest to VHA and its NEC. Such challenges are by no means limited to the VA system, however. The considerations raised in this report are relevant to all health care organizations that rely on QI activities to improve patient care.

Recommendations for the Ethical Conduct of QI

To provide guidance regarding the responsible conduct of QI activities, VHA's NEC offers the following recommendations:

Recommendation #1: Health care organizations should recognize that QI cannot always be meaningfully differentiated from other activities that occur in the clinical arena, notably treatment and research.

While the field of QI is progressing rapidly, the concept of QI is constantly evolving and the dividing line between QI and other activities is not always clear. Although most activities can be easily categorized either as QI or not QI, some activities can be more difficult to categorize. At times, for example, it may be difficult to distinguish between QI and research.[11-15] In 45 CFR 46 (the "Common Rule"), research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[9] Although elegant in its simplicity, this definition is

problematic in several respects. First, the definition is tautological in that the word "research" is contained in the definition itself. Second, it is not clear when knowledge should be considered "generalizable." A recent attempt by the Department of Health and Human Services (DHHS) to address this question gives no clear-cut answer:

> We understand knowledge to be generalizable when it can be applied to either a population inside or outside of the population served by the covered entity. Therefore, knowledge may be "generalizable" even if a research study uses only the protected health information held within a covered entity, and the results are generalizable only to the population served by the covered entity.[16]

Another problem with the Common Rule definition of research is that it hinges on the purpose for which the activity was designed (i.e., the investigator's intent). But intent may be difficult to define, even for the investigator.[13] Moreover, projects may be intended for more than one purpose. For example, a single project may be designed both to improve health care operations in a particular setting as well as to produce knowledge that can be applied in other settings. DHHS regulations have attempted to clarify this issue by classifying QI activities as health care operations (rather than research) "provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities."[16] When the primary purpose of an activity changes over time, such as when a QI project unexpectedly yields results that are worthy of publication and therefore generalizable, Institutional Review Board (IRB) review should be performed as soon as it is recognized that an activity meets the definition of research.

A variety of other criteria to clarify the distinction between QI and research have also been proposed. These include whether the clinician-patient relationship is disrupted, whether an activity requires specific recruitment, whether the patients involved in an activity directly benefit from the knowledge to be gained, and whether additional risks are imposed in order to make the results generalizable.[13,17,18] In addition, as stated by NBAC, a key distinction is whether the program in question is new or already established:

> If the purpose is to assess the success of an established program, and the information gained from the evaluation will be used to improve that program, the activity should not be considered research involving human participants. Evaluation is a program monitoring tool, and the information gained will immediately benefit the program and/or the individuals involved. However, when quality improvement involving human participants is undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective and can be used elsewhere, the activity is human participant research and subject to the oversight system.[19]

While all of these criteria are plausible, no clear consensus has yet developed on how to distinguish QI from research. Furthermore, some activities – such as demonstration projects or program evaluations – may not be "pure" examples of either QI or research but rather a "hybrid" of the two. This problem was aptly summarized in a recent report by the Institute of Medicine:

> As an applied field of study, Health Services Research (HSR) is closely related to nonresearch investigations that are directed toward assessing and improving the

> quality of operations in health care organizations. Indeed, HSR and health care operations form two ends of a continuous spectrum. Some HSR projects are clear examples of research; applying scientific methods to test hypotheses and produce new, generalizable knowledge. Other projects are certainly clear examples of internal exercises to assess the quality of the operations of the specific organization with no intention of producing generalizable knowledge. Many of these quality assessment or quality improvement (QA or QI) exercises are never intended to have any application beyond the specific unit within the organization that carries out the operation. In fact, many projects may start out as operations assessment and then become more like research, and many research projects involve doing very much what would be done in an internal operations assessment. As a result, for many projects, it is difficult to decide whether they are more like research, or more like QA or QI.[20]

As with the distinction between QI and research, the distinction between QI and treatment is not always clear. For example, it is a common practice in medicine for physicians to try therapies or administer drugs in a manner than differs from generally accepted practice standards.[19] Presumably, physicians also monitor the outcomes of these activities, at least informally, in an effort to improve care. When should such activities be considered QI as opposed to treatment?

DHHS defines treatment as follows:

> Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to the other.[16]

QI, on the other hand, is one of several activities included within DHHS's definition of "health care operations," as distinguished from treatment and research:

> Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.[16]

DHHS further explains, "Treatment refers to activities undertaken on behalf of a single patient, not a population." Therefore, when a physician administers a therapy with the intent of improving care for that patient alone, the activity should be considered treatment; but if the physician administers the same therapy as part of a larger activity that is designed to improve care for a population of patients, the activity should be considered QI. This distinction may not be particularly helpful, however, since many activities are intended to improve care for individual patients and for a population. Just as projects can be "hybrids" between QI and research, so too can projects be "hybrids" between QI and treatment.

Although some activities are clear-cut examples of either treatment, QI, or research, some activities cannot be so easily categorized. To the extent that QI differs from research and treatment, the ethical frameworks that have been developed for these other areas may not be applicable to QI. This report presents a new framework for thinking about the ethical conduct of QI.

Recommendation #2: Health care organizations should ensure that the rights and interests of patients involved in all health care activities – including QI – are adequately protected.

In the United States, as in other countries, a range of specific safeguards protects patients in the clinical setting. For example, physicians and other health care professionals have a widely recognized fiduciary duty to promote the interests of their patients. Professional ethics standards also require health care providers to protect patient confidentiality and assure informed consent. Clinical behaviors are routinely scrutinized by peer review and other oversight mechanisms. Licensing standards, accreditation requirements, and statutory and case law further protects patients' interests. Health care providers who violate professional, regulatory, or legal standards are subject to a variety of sanctions and disciplinary actions.

Similarly, various government regulations, organizational policies, and professional guidelines have been developed to protect patients involved in human subjects research.[21-23] For example, federal law requires that, except for carefully-defined exceptions, research at organizations that receive federal funding for research be reviewed by IRBs. This review must assure that informed consent is obtained from each subject, if appropriate, and that research risks are reasonable in comparison to expected benefits, and that subjects are selected equitably.[9]

In contrast, there are no equivalent procedures to protect the rights and welfare of patients in QI activities. Yet there are at least four reasons why patients involved in QI activities may warrant special protections. First, the lack of a clear-cut distinction between QI and research paired with the absence of clear ethical standards for the conduct of QI provide a powerful incentive for investigators to "game" the existing system of protections by designating projects as QI rather than as research.[13] By doing so, they can avoid many of the time-consuming processes of research review, including stringent requirements for informed consent.[9] Until parallel standards are developed for QI, there will be a strong motivation to circumvent the system of research protections in favor of the more permissive environment of QI. For example, in one QI project, investigators initiated a program of preoperative ultrasound screening in an attempt to prevent preoperative blood clots, but later discontinued the program when it proved ineffective.[24] Some would argue that this project, approved as QI, was actually research and should have been reviewed as such. Although the prevalence of this problem is not known, several other examples of research-like projects that have been labeled QI – and many more projects that are neither clearly QI nor clearly research – have come to the attention of the NEC.

Second, while QI is essential to good patient care and has brought tremendous benefits, QI activities are not entirely without potential burdens or risks to the patients involved. For example, psychosocial or financial harm can result from improper disclosure of personally identifiable information from databases. Patients may be inconvenienced by data collection efforts. Embarrassment or resentment can result from being asked to address personal or sensitive topics in questionnaires. The actual frequency and severity of the potential burdens

or risks associated with QI is completely unknown, however, because QI projects are rarely tracked and reported in a systematic fashion.

Third, QI projects can create potential conflicts of obligation. Whereas treatment activities are primarily designed to enhance the well-being of an individual patient,[19] QI activities are primarily designed to improve the process, outcomes, and efficiency of health care services. When health care providers are involved in QI activities, they may face conflicts between their obligations to each individual patient and their obligations to all patients cared for by the system. For instance, a QI project might call for functional assessments to be performed on all patients in a new intensive case management program after one, three, and six months. Though such assessments may seem harmless, they are not entirely without risk. For patients who do not have paid medical leave from their jobs, the extra time required to complete these assessments might have a significant financial impact. For mental health patients with paranoia or obsessive thinking, repeated assessments could conceivably exacerbate these problems. Under such circumstances, physicians participating in the QI project would need to weigh their obligations to the individual patient against their obligations to improve care for all patients through QI.

Fourth, patients involved in QI may not always be able to protect their own interests. Patients may assume, incorrectly, that everything done to them in the clinical setting is intended to benefit them and them alone. Or patients who are dependent on the health care system for their care may feel compelled to do whatever is asked of them for fear that they may jeopardize the care they receive. In this sense, patients involved in QI projects could be unwittingly used as means toward an end.

Finally, most health care professionals have easy access to patients and patient records, but not all are trained in QI principles and methods. While ongoing QI efforts are encouraged, some QI activities may be poorly designed and unlikely to yield useful results, in which case not even minor burdens to patients can be justified. These concerns may be amplified as health care organizations offer financial rewards for involvement in QI activities.[24]

Thus, activities that are determined to be QI (as opposed to research or treatment) are not immune from ethical concerns about protecting patients. Instead of focusing on the distinction between QI and other activities, health care organizations should focus on assuring that the rights and interests of all patients are adequately protected, including those involved in QI. This report contains specific suggestions for how patient protections can be assured.

Recommendation #3: Health care organizations should take care that efforts designed to protect patients do not unnecessarily encumber the QI process.

Care should be taken to minimize any detrimental effects on an organization's QI activities that may arise from pursuing other objectives, such as expanding patient protections. Indeed, health care professionals and organizations have an ethical obligation to monitor and improve the quality of care they provide.[25] By ensuring that health care providers adhere to standards of care, and by making efforts to minimize deviations from standards, an organization is taking important steps to safeguard the well being of its patients. Therefore, efforts to protect individual patients should take into account the potential consequences of impeding ongoing improvements in overall patient care.

Recommendation #4: Health care organizations should clearly define the locus of responsibility for the ethical conduct of QI.

The effectiveness of protections for patients involved in a QI activity depends upon the identification of a person or group who is responsible for the ethical conduct of a particular activity. For research activities, this person is the principal investigator; in medical practice it is most often the attending physician. For QI projects, however, the responsible person is not always clear. Indeed, QI activities may be conducted across organizations or units of service, and may be the product of collaboration between clinical and administrative personnel. Nevertheless, it is important to identify the individual who is ultimately accountable for the appropriate conduct of a given QI project, and who has the authority to assure that applicable ethical standards are followed.

In addition to the need to define a locus of responsibility for individual QI projects, there is also a need to define an administrative locus of responsibility for all QI activities that take place within a health care organization or an organizational subunit. QI is not an activity performed by an individual acting in isolation, but by a group of individuals acting on behalf of an organization. Furthermore, to be effective QI must have organizational support: specifically, it must involve individuals with the authority to impose corrective action in response to assessment results.[25] Organizations should have one or more designated QI program office, standing committee, or other administrative entity that has specific responsibility for QI oversight.

Recommendation #5: Health care organizations should proactively promote the ethical conduct of QI.

As a matter of good management, organizations should not wait for problems to arise, but rather promote the ethical conduct of QI proactively using a systematic approach. This approach should include educating individuals about relevant policy, tracking QI projects, handling questions and complaints, assessing adherence to requirements, and instituting corrective action when necessary. Responsibility for promoting the ethical conduct of QI should normally rest with the same administrative entity that oversees other aspects of QI.

For all QI activities, consideration should be given to potential ethical concerns before an activity is performed. The level of scrutiny should correspond to the potential burdens and risks of the QI activity: activities that involve greater burdens or risks require more thorough scrutiny. For those that involve minimal burdens or risks beyond those inherent to the clinical encounter itself (e.g., projects involving only retrospective or concurrent review of existing clinical data, routine patient satisfaction surveys, or educational interventions designed to promote evidence-based practices), a brief conversation between the QI activity leader and the office that oversees QI may be sufficient for that office to exercise its obligation to assure that ethical issues have been adequately addressed. But for other types of QI activities (e.g., those involving evaluation of an innovative clinical program or service, collection of new data from patients other than by routine satisfaction surveys, or systematic assignment of interventions) a formal review process may be appropriate. Whenever burdens or risks are substantial enough to warrant formal review, and whenever there is an expectation of results worthy of publication, it is prudent to consider whether the QI activity contains one or more components that meet the definition of research found in the Common Rule and therefore require IRB review.

Who should conduct a formal review, if necessary? Possibilities include an interdisciplinary group convened specifically for this purpose; a preexisting group outside the QI office but within the organizational unit, such as an ethics committee; or a group outside

the organizational unit, such as a multi-site review committee. In any case, the group should include individuals familiar with QI methods and those familiar with ethical standards, but should not include individuals involved in the QI project under review.

Recommendation #6: QI activities should produce benefits that outweigh their potential burdens or risks.

In QI, as in treatment and research, it is unacceptable to impose even relatively minor burdens on patients unless a project can reasonably be expected to be valuable.[26] Therefore, QI projects should be well designed and the measures they use should be reliable and valid. To increase the likelihood of benefit, QI projects should be conducted by well-supervised personnel with adequate training or access to consultative advice.

In addition, efforts should be made to anticipate and minimize even minor harms to patients that could result from QI activities. For any given QI project, potential inconveniences or other burdens to individual patients should be justifiable when weighed against the expected benefits to be gained, including benefits to participating patients, future patients, or the health care organization. Because the goal of QI is to improve the process, outcomes, and efficiency of health care services, the benefits of a QI project should be considered in relation to that goal.

Recommendation #7: QI activities should respect each patient's right to self-determination.

A patient's right to self-determination is well established in law[27-29] and ethics.[30,31] Respect for patient autonomy can be of important instrumental value, in that the effects of a medical intervention on a patient's well-being are dependent in part on that patient's specific values and preferences. In addition, autonomy has inherent value apart from its consequences. Because the ability to make moral choices is uniquely human, respect for human beings implies respect for their moral choices.

The right to have one's health care choices respected deserves the same consideration in QI as it receives in treatment or research. Although informed consent is the standard process by which respect for patient choices is ensured,[30,32,33] an exhaustive informed consent process is not always practical. In practice, many minor treatments or procedures (such as splinting a broken finger or drawing blood for routine tests) are made on the basis of "presumed consent" or after only a cursory informed consent discussion.[34] Furthermore, only a minority of treatments or procedures requires signature consent.[35] In research, too, there are accepted circumstances under which the requirement of informed consent is waived entirely, or for which verbal consent but not signature consent is required.[9]

In general, the thoroughness of the informed consent process should be proportionate to the potential burdens or risks associated with the intervention. For instance, in clinical practice, physicians typically explain potential burdens in greater detail as the risks of a test or treatment increase.[34] Similarly, in research, standards are codified in federal regulations in which the need for written documentation of informed consent depends upon the study's risks.[9]

In most cases, informed consent for a specific QI project is not required. Instead, "general" or "blanket" consent to QI activities (as might occur during a patient's admission to an inpatient facility) is generally sufficient for QI activities that pose no significant burdens or risks beyond those the patient would otherwise experience. On the other hand, when activities require the patient's cooperation (as in, for example, a customer satisfaction survey), patients should be informed that their participation in the activity is optional and

that refusal to participate will not jeopardize their care. In addition, explicit informed consent is necessary whenever a QI activity involves significant burdens or risks. In some cases, consent may not be a reasonable option (e.g., a QI project in which attempts at cardiopulmonary resuscitation are videotaped). For such cases, formal provisions should be made for proxy consent or waivers of consent, just as they are in clinical care and research.[9,36]

Recommendation #8: QI activities should preserve patients' privacy and confidentiality.

In both research and treatment, demonstrating respect for patients' privacy and confidentiality is essential. In research, investigators often use codes to identify individuals, and may de-link these identifiers to protect the privacy of individual patients. These strategies offer important protections. Indeed, federal regulations that determine the need for research review[9] are tied to the extent to which data can be recorded anonymously. Similarly strict requirements exist in the treatment setting. Perhaps the best known of these are in the requirements for certification by the Joint Commission on Accreditation of Healthcare Organizations.[37] In addition, DHHS's Final HIPAA Privacy Rule requires specific privacy protections for medical treatment, health care operations, and research.[16]

To assure that privacy is protected and confidentiality maintained, all QI activities should be conducted within the context of a health care setting in which accepted clinical standards for privacy and confidentiality are upheld. QI activities are an integral part of the health care organization's activities, and as a result the systems and protection that support privacy and confidentiality standards for clinical practice must be present. For example, access to confidential patient information should occur on a "need to know" basis and information should generally be stripped of patient identifiers before it is exported.

To fully assure adequate privacy and confidentiality protections, the individual responsible for the QI project should take several additional steps. Staff members with access to QI data should receive formal training regarding their organization's privacy and confidentiality policies and should agree as a matter of record to respect these policies. The organization might also maintain systems – such as an audit trail of access to information – to monitor and trace breaches of confidentiality. Finally, data analysis should make use of anonymous, or "de-linked," data whenever possible. Where this is not possible, QI activities should identify patients by codes to limit potential breaches of confidentiality. In both linked and de-linked databases, data privacy officers may be very helpful; for example, they can ensure that the codes for linked data are maintained securely and that de-linked data are rendered anonymous before they are released.[13,38,39]

Recommendation #9: QI activities should be fairly distributed across patient groups.

Fairness is a central principle of the ethical conduct of research, and of the ethical practice of clinical medicine.[8] In research, fairness includes equal access to the potential benefits of research, and equal exposure to its burdens.[8,40] In clinical care, fairness requires that patients have equitable access to medical services and are not treated in a discriminatory fashion.

In QI activities, justice suggests two requirements. First, the potential burdens or risks of any QI activity should be distributed fairly across the population under study. For instance, risks of a loss of confidentiality, or burdens of surveys or questionnaires, should not be borne disproportionately by a single group, unless that group would also be expected to disproportionately benefit from the QI activity. Second, the potential benefits of a QI

activity should be distributed fairly. For instance, an intervention designed to improve cardiac care should be implemented across a broad cross section of cardiac patients for whom the results would be relevant.

Recommendation #10: Health care organizations should develop specific policies and procedures that fit their unique circumstances and needs.

Beyond the general recommendations above, this report will not suggest any specific policies or procedures for assuring the ethical conduct of QI. Before a particular approach can be recommended, a variety of approaches should be tried and their results compared. Moreover, we are not convinced that there is one best solution for all health care organizations or even for all of VHA. A policy developed for a large tertiary care medical center might be wholly inappropriate for a community clinic or nursing home. Similarly, a policy developed for a setting in which QI includes large-scale, methodologically rigorous data collection efforts might not make sense for another setting in which QI includes only small-scale Plan-Do-Study-Act cycles. For these reasons, we recommend that health care organizations use the general guidance provided in this report to develop their own unique policies and procedures that are appropriate to the types of QI activities they perform.

Conclusion

The distinction between QI, research, and clinical care has never been clear, and is evolving over time. Nonetheless, QI activities, like research and treatment activities, may raise ethical concerns. Health care organizations need to assure that patients involved in all of these activities are adequately protected.

This report has proposed a set of recommendations that can guide health care organizations in developing such protections. It is important to note, however, that these recommendations are not proposed changes to federal regulations and do not affect current VA policy. Instead, these recommendations are intended to provide guidance for the responsible conduct of QI activities, which is currently lacking.

Therefore, these recommendations are intended as a starting point for the protection of patients involved in QI activities. However, focused discussion will be needed at several levels. First, further discussion is needed within health care organizations to translate these general recommendations into specific policy guidance. Second, discussion must take place between and among organizations, to ensure that the protections function well and to develop consistency and ensure fairness. Finally, discussion is needed at the societal level to assure that all patients – and not just veterans – receive the ethical treatment they deserve.

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