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Proposed Ethical Guidelines for Quality Improvement

Quality initiatives must be made within an ethical framework.

During the last few decades there has been growing recognition of the importance of quality improvement interventions to ensure healthcare is effectively and efficiently delivered. Many healthcare organizations have created improvement offices and identified improvement leaders to foster these efforts. The result has led to the implementation of countless improvement initiatives to enhance the quality of patient care. For example, a hospital implemented and assessed an approach to obtain advance directives. Another hospital implemented and assessed the use of a checklist to reduce central line infections in its intensive care unit.

Similar to ethical issues arising in human subject research, ethical issues can arise in QI activities. However, unlike with research, there has been limited focus on creating ethical guidelines for QI activities.

The development of ethical requirements for human subject research grew out of scandals surrounding human experimentation. Morally repugnant research was not only carried out during World War II—there also have been hundreds of unethical research studies conducted in the United States. The public and scientific community's recognition of unethical research was a driver for the development of formal ethical standards and codes of ethics to guide human subject research.

Similar to ethical issues arising in human subject research, ethical issues can arise in QI activities.

Even though there have been no scandals involving quality improvement activities, there certainly are situations when QI activities create ethical concerns. For example, because QI activities are data-guided interventions designed to bring improvement to specific settings, using an inappropriate methodology to achieve the stated goals will render the resulting findings meaningless. Such a situation is an ethical concern because of the wasted resources resulting from use of an inappropriate methodology.

QI activities can create harm when privacy and confidentiality are breached or have unfairly affected patients. Furthermore, the lack of a clearly applied distinction between QI and research along with the lack of QI ethical standards serves as an incentive for some to designate a research study as a QI activity, thus circumventing the more rigorous research review process. The extent of this problem is not known, yet it does present another ethical concern.

As a result of both the sheer growth of QI activities and the potential for patient privacy breaches, wasted resources and violations in professional integrity, there is support for the need to ensure QI activities be conducted within the context of ethical behavior. These activities ought to be facilitated and monitored within the context of an ethical framework to protect participants and the validity of the activity.

Creating an Ethical Framework for QI Activities

For quite some time there was no comprehensive description of an ethical framework for QI activities. However, that has changed. A group of clinicians, improvement leaders, ethicists and other healthcare professionals authored an important manuscript proposing requirements for the ethical conduct of quality improvement. The suggested ethical requirements were offered in an article in the May 1, 2007, issue of *Annals of Internal Medicine* by Joanne Lynn, MD, and colleagues. The authors' suggested requirements include that a QI activity have:

- Social or scientific value—The anticipated improvement from the QI activity should justify the effort in the use of time and resources.

- Scientific validity—The QI activity must be methodologically sound.
- Fair patient selection—The participants in the QI activity should be selected to achieve fairness in the benefits and burdens of the intervention.
- Favorable benefit/risk ratio—The QI activity should limit risks, such as privacy and confidentiality, and maximize benefits to participants.
- Respect for participants—The QI activity is designed to protect patients' confidentiality and make them aware of findings relevant to their care. Also, participants should receive basic information regarding the activity.
- Informed consent—When the activity is more than minimum risk, informed consent should be sought.
- Independent review—The proposed activity should be reviewed to ensure it meets the ethical standards in place.

Strategies for Reviewing QI Activities

As described in the suggested ethical framework, there is a need to thoughtfully and systematically review quality improvement activities to ensure they meet the ethical framework for QI. Unlike the federally required institutional review boards (IRBs) that assess and monitor research protocols, there currently is no required mechanism for providing review and oversight of QI activities.

Despite the lack of a federal requirement, healthcare leaders should ensure QI interventions conform to an ethical framework to protect patients and foster the integrity of the organization. To achieve independent review of QI activities, several issues need to be addressed.

First, what is the appropriate mechanism by which to conduct the review for your organization? To date there is no uniformly applied mechanism or procedure for reviewing QI activities. For some institutions the review is facilitated within the clinical department or section. In other settings the ethical review might be facilitated by the QI office or an independent advisory board. Unfortunately, in many organizations there is no review.

The lack of an established review structure and process can create problems for both quality improvement professionals and the organization. For example, requiring a QI activity to be reviewed forces a healthcare professional to draft a protocol for the proposed improvement activity. The sheer process of thinking through the activity in terms of its goal, design method, intended benefit, potential risk, assessment of findings and dissemination of findings enhances the credibility of the QI activity and prevents poorly developed interventions from being implemented. The level of review, similar to the review of research protocols, will relate to potential risks or burdens of the QI activity. Despite the lack of a uniform QI ethical review model, it needs to be conducted in every facility by professionals who are knowledgeable in both quality improvement and ethics.

Related to this structural issue is the frequently encountered problem related to the difference between QI and human subject research. Because IRB members do not have the time, the interest nor the QI expertise to review QI activities, there needs to be a consistently applied approach to differentiating between a human subject research initiative and a QI one. Unfortunately, healthcare professionals, QI professionals, researchers and IRB members do not agree on the distinction.

For years the distinction focused on whether the findings would be published; if an activity was going to be published, it was research. Appropriately, that criterion for making the distinction has been fading. For example, *VHA Handbook 1058.05*, October 2011, notes, "Publication or presentation outside VA of findings from non-research operations activities … does not, in and of itself, constitute research." However, inconsistency remains prevalent in making the distinction between research and QI activities. I suspect that if a healthcare system has various facilities, variation exists among the various facilities in their approach to distinguishing QI initiatives from research.

Even if a QI review mechanism does exist, the likelihood of organization-wide consistency in differentiating between research and QI is small. This is particularly challenging because there are activities that are pure research—such as randomized clinical trials to assess a new medication—just as there are pure QI activities, such as an intervention to decrease patient wait time in a specific outpatient clinic.

However, there are activities that fall in the middle territory, such as a multi-institutional study of a checklist to improve the efficiency and safety of colonoscopy procedures.

To assist in distinguishing between QI and clinical research, Greg Ogrinc, myself and colleagues published "An Instrument to Differentiate between Clinical Research and Quality Improvement" in the September/October 2013 issue of *IRB: Ethics & Human Research*. In the article we offer a checklist that can be used by IRB members, QI review staff, researchers and quality improvement professionals to increase consistency in determining whether a particular protocol is to be reviewed by the IRB or through the organization's QI review mechanism.

The screening instrument starts with four basic questions addressing important considerations in making the assessment, including considering if the activity is within the standard of care. A "no" response to that question would be a strong indicator that the activity should be IRB reviewed. Following these basic questions, the instrument lists six attributes that further distinguish research from QI. Next to each of the six attributes are two columns: one for QI and the other for research. Each column lists characteristics that are consistent with research ethics regulations and the proposed QI ethics framework for the attribute. If any item is checked in the clinical research column, then the proposal is likely research and ought to be reviewed by the IRB. If any of the items are checked in the QI column, then the proposal should be reviewed according to the organization's QI review mechanism.

The tool is not an absolute adjudicator, but it is helpful in framing a discussion and confidence regarding these decisions. Early pilot findings have verified the value of the research-QI checklist instrument. Such a checklist could benefit healthcare organizations' need for a consistently applied understanding of what is research and what is QI, leading to the appropriate review mechanism.

Recommendations for Action

Healthcare executives need to recognize not only the importance of quality improvement activities but the need to foster such activities within the context of an ethical framework. Fundamental to the ethical framework is the requirement to systematically review and monitor QI interventions.

Because there is no one best model for ensuring the QI activity is conducted in an ethical manner, healthcare executives should determine in consultation with quality improvement professionals and research professionals what is the most appropriate internal management mechanism and process for their organization. The creation of a process for QI ethics review could contribute to the quality of QI intervention and prevention of unethical activities. ▲

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