Editorial

Quality Improvement or Research? The Ethics of Hospital Project Oversight

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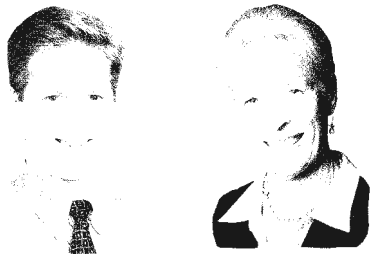

Determining appropriate hospital project oversight is a struggle commonly encountered by healthcare providers who perform quality improvement (QI) projects and hope to publish their findings. A typical question that comes up is this: "Were ethical standards upheld in the project reported in the submitted manuscript?" The essence of this question may instead be, *What degree of oversight should QI publications be able to demonstrate?*

Many journals and oversight organizations suggest to authors that they determine at the very outset of their project—not when a manuscript is actually being submitted—whether the work is research or QI. Knowing how to correctly place the project within these 2 categories may reduce risk to patients and save time for researchers, administrators, and institutions. Recent publications can aid healthcare professionals in finding the right label for their hospital activity based on certain key characteristics.[1-5]

Despite the available literature, a distinction dilemma remains for practitioners who engage hospital resources either in behavioral change (ie, in adapting practice to some new standard) or in time spent figuring out the best care at their facility. This dilemma is made all the more difficult by the often unique and specific needs of each institution. And it seems there are growing pressures to publish results from both activities—QI and research—not only from a traditional faculty point of view, but for use in the hospital administrative and marketing departments, which often think in terms of what a publication may mean for future share of local business or in terms of accreditation status.

Definitions and Distinctions

Since the appearance of the Health Insurance Portability and Accountability Act (HIPAA), the clinical research environment has become more complex in terms of regulatory oversight; overlap between QI and research has come under increasing scrutiny.[1,3,4] The Centers for Medicare & Medicaid Services define QI as "an assessment, conducted by or for a QI organization, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up." They continue, calling QI a "set of related activities designed to achieve measurable improvement in processes and outcomes of care. Improvements are achieved through interventions that target health care providers, practitioners, plans, and/or beneficiaries."[6,7]

Through the Office for Human Research Protections, the federal government has defined research as a "systematic investigation … designed to develop or contribute to generalizable knowledge"[8] about human disease and healthcare. Experts refer to this

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as the "common rule." QI and research are easily confused because they share similar characteristics: both ask clinically important questions, use patient data, download data from hospital or billing databases, apply complex statistical analyses to those data, retrieve patient information directly from the bedside, and have as their goal the improvement of patient care.

But clearly these activities are distinct, with a key difference being how patients are exposed to risk. In QI projects, patients may not be exposed to more than minimal risk,[9] whereas in research the risk to which the patient may be exposed is approved by the institutional review board (IRB) and typically is described in a consent form that gives patients a choice about whether they would like to participate. The unfortunate truth is that there is no easy algorithm for all situations, authors, or organizations to help distinguish QI from research. Local and regional medical communities operate under a spectrum of interpretation.

A recent publication and accompanying editorial that help clarify the QI versus research debate were part of a consensus conference on QI.[1,10] The group made several points in its report. One is about the necessity of QI for a medical institution. The report states that for medical institutions caring for patients, QI is a necessary, integral activity, but that human subjects research is not. The consensus group stated that although QI is not research, that does not mean that one should proceed without considering oversight. Although routine QI does not require oversight to the extent of an IRB review, it should receive supervision similar to that required by clinical practice. In essence, the degree to which oversight is rendered is one distinction between QI and research.

What this means for institutions conducting QI is that their clinical and administrative leadership is responsible for ensuring that QI projects do not expose patients to more than what is considered *minimal* risk. The consensus conference report[10] contrasts QI with research activities, noting, for example:

- QI is designed to bring about immediate improvements in healthcare delivery.
- QI is designed to have its findings applicable only to the local institution.
- QI is designed to sustain the improvements.
- QI does not require rigid, fixed protocols; within QI activities it is acceptable to adapt the project over time.

The report[10] also states that "[t]here is a responsibility that health care providers improve quality" and that patients are responsible to "cooperate with improvement efforts." Finally, the report suggests that patients' inherent responsibilities to an institution's QI efforts are subject to the institution's conduct of reasonable standards and that, with respect to QI projects, "patients must be kept safe from harms and violations of their rights."[1,9]

When Publication Is the Next Step

The preceding discussion applies to QI projects whose findings are kept within the confines of the sponsoring institution. Sometimes, however, it is reasonable to publish an appropriately designed and administered QI project. In such cases, the level of oversight authors are required to demonstrate is debated by authorities. When healthcare professionals decide that a QI project's findings are sufficiently important to share with the external medical community, a series of oversight questions once again come into play. Anticipation of publication should elicit internal and external questioning about oversight.

The overlap between QI and research is often difficult to identify; unfortunately, those entrusted with oversight responsibilities at the local and national levels vary about the degree to which they believe QI should be included under the umbrella of research.[10] In terms of confidentiality, there are regulations that address whether a project would be exempt from IRB full review depending on the presence of personal information.[11] A central concern is whether identifiable data about patients are incorporated into the manuscript. Even when data are expressed as averages and there are no unique patient identifiers, medical institutions often request that their authors submit protocols for IRB oversight for either "expedited" or "exempt" status of approval.

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In so doing, institutions can signal to the external medical community that there was IRB confirmation and that the project upheld ethical standards. When a hospital project is "exempt" from full IRB review, it does not mean that no interaction with the IRB is required; on the contrary, it has simply come to mean that the authors of the QI publication are expected to seek IRB approval with exempt status.

Those designing hospital projects may first want to examine the project's safety for patients. QI activity implies that the intervention is at least as safe as routine care. If there is more risk, IRB oversight is required at the outset to demonstrate to the internal and external medical community that the project is a thoughtful and well-designed research study.

Another determination to make at the outset of hospital work is whether publication of the project's findings is desirable. Dissemination of information outside the project's institution has implications for demonstration of oversight. If no upfront desire is expressed to publish the project's findings, the internally situated work is considered QI and the oversight deemed necessary falls at the level of routine internal oversight of good clinical and management practice. When there is no perceived extra risk to patients, IRB approval may be excluded.

The concern for practitioners who have completed a well-structured QI project and feel compelled to publish their results is showing how oversight was conducted. When a QI project was an intervention and the manuscript contains patient data (even if averaged and de-identified), some argue that such circumstances change the degree of demonstrable oversight. Confidentiality may be the most subtle topic on which to render a decision (ie, about whether HIPAA guidelines were maintained). An IRB review may thus be suggested to ensure that patient safety was upheld and that HIPAA rules were reflected adequately.

More Public Awareness

Ethical oversight of the systematic collection and analysis of patient data for any purpose is ultimately the responsibility of professionals and institutions.[4] There is an evolving understanding about the individual and community partnership responsibilities for both QI and research activities.[12]

In the future, QI and research will likely continue to distance themselves from the paternalistic approach that was pervasive before the Belmont Report. A great deal more dialogue is needed, however, among QI experts, researchers, oversight specialists, and institutional representatives. Most important is for these groups to include the public and to focus attention on the complexities of participation in QI and research. Increased community awareness about the purposes and goals of QI and research should promote better health delivery while improving respect for individual rights.

The statements and opinions contained in this editorial are solely those of the coeditors.

FINANCIAL DISCLOSURES
None reported.

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