Editorial

**QUALITY IMPROVEMENT OR RESEARCH? THE ETHICS OF HOSPITAL PROJECT OVERSIGHT**

By Peter E. Morris, MD, and Kathleen Dracup, RN, DNSc

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
A key difference between research and quality improvement is how patients are exposed to risk.
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. There is an evolving understanding about the individual and community partnership responsibilities for both QI and research activities.

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.

REFERENCES


To purchase electronic or print reprints, contact The InnoVision Group, 101 Columbia, Aliso Viejo, CA 92656. Phone, (800) 809-2273 or (949) 362-2050 (ext 532); fax, (949) 362-2049; e-mail, reprints@aacn.org.
Quality Improvement or Research? The Ethics of Hospital Project Oversight
Peter E. Morris and Kathleen Dracup

Am J Crit Care 2007;16 424-426
Copyright © 2007 by the American Association of Critical-Care Nurses
Published online http://ajcc.aacnjournals.org/

Personal use only. For copyright permission information:
http://ajcc.aacnjournals.org/cgi/external_ref?link_type=PERMISSIONDIRECT

Subscription Information
http://ajcc.aacnjournals.org/subscriptions/

Information for authors
http://ajcc.aacnjournals.org/misc/ifora.xhtml

Submit a manuscript
http://www.editorialmanager.com/ajcc

Email alerts
http://ajcc.aacnjournals.org/subscriptions/etoc.xhtml