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ETHICS ROUNDS

A Case of Quality Improvement

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In recent months, national attention has been focused on deficiencies in health care quality. Notably, the Institute of Medicine report entitled Leadership by Example called upon the federal government to take the lead in improving the quality of care provided by the nation's health care programs, while lauding VA's quality improvement (QI) efforts as "among the best in the nation."

Another topic that has received national attention lately is the system for protecting human research subjects. The media has been full of stories about major university research programs being shut down, research participants being injured or dying, and national commissions calling for the system to be overhauled. In response, institutions are intensifying their efforts to assure ethical research practices.

While quality improvement and research oversight have been sharing the limelight, they are connected in another way as well. Some worry that intense scrutiny of the research oversight system - although well intentioned and necessary - will have the unintended effect of impeding the progress of QI. Why? Differentiating between QI and research is not always easy. Moreover, QI projects may raise some of the same ethical concerns that apply to research (e.g., consent, privacy, fairness). Some institutions are reacting to these pressures by treating QI projects as if they were research - that is, by requiring IRB review. This is problematic for several reasons. First, IRBs are already overburdened and not equipped to handle a substantial increase in workload. Second, the standards that apply to IRBs are in some ways ill-suited to QI. Third - and probably most importantly - IRB processes can be cumbersome and therefore discourage improvement efforts.

Consider the following example. The National Center for Ethics in Health Care launched the Ethics Self-Assessment Toolkit (ESAT) Project as a QI initiative. The project is developing two tools to evaluate the quality of clinical and organizational ethics. One, the ESAT Staff Survey, will characterize ethical culture, knowledge, and perceived practices. The second, the ESAT Facility Workbook, will be used by facility leaders to assess the structure, process and outcomes of ethics-related activities at VA medical centers. Both tools are intended to help facilities focus their QI efforts on issues relating to ethics.

The plan for developing the tools involves: conducting patient focus groups to discuss ethical issues they encountered in receiving VA health care, pilot-testing the tools at several VA facilities, and eliciting feedback on the tools from clinical and administrative staff.

Ethics Center staff contacted three VA medical centers to invite their participation in pilot testing the ESAT Staff Survey and Facility Workbook. At the first site (site #1) the Chief of Staff reviewed and approved the ESAT project as a quality improvement initiative. At the other two sites, however, Center staff members were referred to the IRB chair, primarily due to uncertainty over whether the project met the definition of research and was therefore subject to regulatory oversight. At both site #2 and site #3, the pilot testing on the Facility Workbook was viewed as a "quality improvement" activity that did not require IRB approval. The IRB responses differed, however, with regard to the Staff Survey.

At site #2, the head of the university-affiliated IRB reviewed the plans for developing Staff Survey. The project was deemed to be a QI activity and exempt from formal IRB review or approval. The Ethics Center was told, however, that IRB review would be required in the future if any of the following modifications occurred: (1) the purpose of the activities changed from QI to something else, (2) the results of the data were to be generalized to non-VA settings, (3) a secondary analysis was desired which would require reviewing patients' charts, (4) publishing the results became a goal, or (5) the data gathered was later used to answer research questions. The response from site #2 took less than 1 week.

In contrast, at site #3, the VA IRB determined that development of the Staff Survey constituted research. A formal review process took place, involving a critical assessment of the recruitment strategy and planned advertisements, the draft survey, the focus group protocol, the information in the participants' statement, the assurances about voluntary participation, and the contact information for questions or additional information. The IRB gave three primary reasons why this proposal was processed as a research proposal: (1) it was too difficult to draw a line separating research from QI, (2) a formal IRB review would minimize institutional risk, and (3) the Staff Survey might be used later for more generalized purposes and possibly even publication. The IRB at site #3 was especially attentive to the component involving patients in focus groups, suggesting several editorial changes to informed consent forms and flyers to stress voluntary participation, data anonymity and privacy protections. The site #2 IRB also suggested an explicit mechanism for responding to potential patient complaints. The review and final approval at site #3 took approximately 2.5 months.

This experience illustrates the prevailing uncertainty and confusion surrounding the issue of whether QI projects should be reviewed by IRBs, senior leadership, or some independent body. In rare cases where an activity is not easily categorized as either QI or research, an IRB chair can help clarify whether IRB review is appropriate. But for activities that are easily identified as QI, IRB review is neither required nor desirable. Instead, a new model is needed to ensure the ethical conduct of QI.

In the meantime, QI practitioners and institutions should proactively attend to ethical concerns raised by QI projects, irrespective of IRB review. As a resource, the VHA National Ethics Committee has recently released a new report entitled

Recommendations for the Ethical Conduct of Quality Improvement. Its recommendations are intended to balance the ethical imperative to adequately protect patients against the ethical imperative to continuously improve patient care. Readers with VA Intranet access can view the report at: http://vaww.va.gov/vhaethics/download/QIReport.doc.

As the National Center for Ethics in Health Care looks for ways to operationalize the recommendations contained in this report, input from the field will be invaluable. If you have comments on this issue or would like to be involved in this effort, please contact us at vhaethics@hq.med.va.gov