

### **331: IMPLICATIONS OF THE US POLICY FOR HUMAN SUBJECTS PROTECTION ON QUALITY IMPROVEMENT INITIATIVES: ETHICAL AND REGULATORY ISSUES AND RECOMMENDATIONS**

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#### **Objectives:**

This effort sought to: 1) describe implications of the US research review policy on current quality improvement (QI) initiatives; and 2) outline ethical and regulatory issues associated with independent review of QI projects; and 3) provide recommendations for a collaborative effort to address the issues identified.

#### **Methods:**

Recent adverse experience in US medical research has intensified the need for adequate protections for human research subjects. Simultaneously, unfavorable reports on the quality of American health care have generated numerous QI projects. Insufficient and inconsistent criteria for classifying QI projects as research may lead to excessive oversight and delayed implementation of QI initiatives nationally.

In a 2002 American Medical Association (AMA) report, we studied the relationship between QI projects and human subjects research and the potential impact of the US research review system on QI efforts. We described the regulations of the US Department of Health and Human Services (DHHS), explained the responsibilities of Institutional Review Boards (IRBs), and outlined examples of current QI projects. Various perspectives on the QI/research issues were identified through literature searches and consultation with staff at relevant government agencies and private sector groups engaged in QI initiatives. We also consulted experts in medical ethics and research, including investigators at The Hastings Center, an independent bioethics research institute.

#### **Results:**

The US policy on human subjects protection requires that all human subjects research subject to DHHS regulations be submitted to an IRB for review and approval. Research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. Exemption from review is permitted for educational research or other projects that safeguard the confidentiality of subjects and their personal information. Determination of exemption may be made by an institution's IRB or some authority other than the investigator, in accordance with the institution's policies.

Attempts to determine if QI initiatives qualify as human subjects research, based on existing definitions, have produced ambiguous results. One federally funded network of dialysis facilities was advised by the funding agency that its QI projects were exempt from IRB review; subsequent assessment by another agency reversed the first determination. Systematic IRB review of *all* QI initiatives, advocated by some institutions, would put additional strain on an overburdened IRB system. The "generalizability" of the knowledge produced is an inadequate criterion for classifying QI projects as research; other criteria have been proposed but lack broad support.

Our experience with a federally funded QI project illustrates the dilemma. A multi-state partnership will implement physician performance measures as a means of improving chronic care. Although physicians will participate voluntarily and patient confidentiality will be safeguarded, an independent IRB determined that the scope of the project disqualifies it from IRB exemption. A full review by the IRB will determine if the project qualifies for a waiver from patient informed consent; the project will otherwise be too cumbersome to conduct.

In an effort to standardize review criteria, The Hastings Center will address the complexities of the QI/research review system. The project will convene a multidisciplinary task force of leaders in QI, healthcare management, research, ethics, law, and public policy. The task force will study the underlying goals and methods of QI, delineate the ethical values and dilemmas associated with QI projects, and seek to develop a set of ethics standards by which QI studies can be assessed.

**Conclusions:**

No clear consensus has emerged on criteria for classifying QI projects as research, resulting in ambiguous determinations. A collaborative, multidisciplinary effort is needed to standardize the evaluation and review of QI initiatives and to ensure that patients are adequately protected from research risks and the confidentiality of personal information is safeguarded.