Quality Improvement and Ethical Oversight

Quality improvement (QI) activities and human subjects research have each made significant contributions to the improvement of health care. Many argue that QI differs from human subjects research in its purpose and scope. Quality improvement aims to improve health care quality and outcomes through local innovations and adaptation in the processes and systems of care. Human subjects research, in contrast, is defined as a “. . . systematic investigation . . . designed to develop or contribute to generalizable knowledge” (1) about health and illness. Although distinctions in purpose and scope may have once justified a different approach to research oversight, differentiation between research and QI activities has become murkier in recent years. Scrutiny of the oversight of human subjects research has increased, and QI activities have more often used the methods of research, generated information that is useful beyond local needs, and published their findings. The result has been uncertainty and disagreement about whether QI differs enough from clinical research to justify a less intense form of oversight. Some people believe that if a QI activity is a form of human subjects research, it should fall under the existing regulations and oversight framework for the latter activity. Others feel that QI is not research and therefore does not require the kind of oversight required for human subjects research, despite the similarities between the 2 entities (2–6).

The confusion about whether or when QI is human subjects research has reportedly resulted in lengthy delays in QI projects, criticism by regulatory authorities, rejection of manuscripts by journals for lack of informed consent procedures, and feelings of considerable frustration on the part of QI professionals and other interested parties (7–9). These factors can be serious disincentives to engage in QI activities (10). Furthermore, QI could suffer if its practitioners designed less rigorous studies in an effort to avoid the label of human subjects research. The result has been uncertainty and disagreement about whether QI differs enough from clinical research to justify a less intense form of oversight. Some people believe that if a QI activity is a form of human subjects research, it should fall under the existing regulations and oversight framework for the latter activity. Others feel that QI is not research and therefore does not require the kind of oversight required for human subjects research, despite the similarities between the 2 entities (2–6).

In this issue, Lynn and colleagues (10) report on a multiyear process of deliberation, review, and analysis of ethical requirements for QI activities and their relationship to regulations protecting human research subjects. Although other papers on the ethics and oversight of QI methods have been published (2, 6, 12), this credible and timely project, supported by the Hastings Center and the Agency for Healthcare Research and Quality, involved leaders and scholars from multiple disciplines and culminated in a comprehensive report (13) and a set of commissioned papers that are likely to have a major impact. The authors urge organizations to consider creating a specialized QI IRB rather than using the extant IRB to review QI activities classified as human subjects research or overlap research. They maintain that because health care organizations have a moral imperative to improve health care quality, patients should generally consent to QI when they consent to care. However, QI practitioners should obtain specific consent when the QI activity involves “more than minimal incremental risk” or burden (10).

In my opinion, the authors’ struggle to make a sharp conceptual distinction between QI and human subjects research is unlikely to succeed. Both activities encompass a heterogeneous set of data-gathering and data-generating activities whose goals extend beyond the immediate interests of the participants. Surely, great care and attention are required for any activity whose purpose extends beyond what is directly needed for the care of an individual patient and that might add burden or incur risk. Depending on the specifics of the project, both QI and human subjects research can fall along a spectrum that ranges from passive observation and description to a middle ground (changing interventions, processes, or the environment) to controlled experimentation. Each project—whether it is QI or human subjects research—is more or less ethically acceptable, depending on its details. Oversight of an activity by competent, independent, disinterested individuals is a time-honored strategy for safeguarding the interests of patients. This line of reasoning leads me to believe that, regardless of whether an activity is QI or human subjects research, some form of independent review is ethically important.

A key motivation behind efforts to distinguish QI from human subjects research is the desire to circumvent the perceived burden of compliance with research regulations and review by IRBs. Indeed, Lynn and colleagues describe IRB review as cumbersome, inflexible, and “minimally relevant to the structure and processes of QI” (10). Others appear to agree. Motivated by similar concerns, social scientists, oral historians, epidemiologists, health services researchers, and educational researchers have tried to distinguish their activities from the kind of human subjects research for which IRBs were created (14–17). Human subjects researchers also express frustration over considerable variation in IRB decisions, which often include demands for minor changes that appear to offer little in terms of protecting participants (18–20). Although independent that most QI is not human subjects research, and consequently does not require review by an institutional review board (IRB), but should receive supervision similar to that of clinical practice.

Lynn and colleagues recognize, however, that some QI activities qualify as human subjects research, and still others fall into a middle category that overlaps with human subjects research. The authors urge organizations to consider creating a specialized QI IRB rather than using the extant IRB to review QI activities classified as human subjects research or overlap research. They maintain that because health care organizations have a moral imperative to improve health care quality, patients should generally consent to QI when they consent to care. However, QI practitioners should obtain specific consent when the QI activity involves “more than minimal incremental risk” or burden (10).

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