Guest Editorial

Quality Improvement and Evidence-Based Practice Change Projects and the Institutional Review Board: Is Approval Necessary?

There is often confusion in determining whether quality improvement (QI) projects and evidence-based practice (EBP) change projects require Institutional Review Board (IRB) approval. The distinction between research and QI-EBP change projects begins with an understanding of their distinct definitions. Research is defined in the U.S. Department of Health and Human Services Federal Regulations (45 CFR 46.102[d] and 45 CFR 164.501) as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (U.S. Department of Health and Human Services, 2009). QI in health care, unlike research, focuses on translating existing knowledge from research into clinical practice to improve the quality of health care for individuals and populations. The key difference between these two concepts is that research studies are intended to create new knowledge that can be generalizable to other populations and settings. QI in health care uses existing knowledge to improve healthcare outcomes within a local health care institution or setting (Institute of Medicine, 2001; National Strategy for Quality Improvement in Health Care, 2012). QI activities provide important information on the application of existing knowledge and changes that may be needed to achieve the best possible clinical outcomes.

A practice change to implement an evidence-based checklist to assess documentation of a central line care maintenance bundle or use of an algorithm for guidance on how often to assess low density lipoprotein, triglycerides, fasting blood sugar, and HgbA1c values in patients most at risk for heart disease are examples of how existing knowledge is used in QI projects. Implementing a research-based falls protocol to prevent falls on an inpatient medical surgical unit and assessing the number of falls in the year before and the year after implementation would be an example of an EBP change project.

In the last decade, healthcare institutions have evolved into systems that collect, aggregate, and analyze patient-level data allowing healthcare providers to make EBP decisions guided by general knowledge. These new systems of care are known as structured learning environments (Kass et al., 2013; Solomon & Bonham, 2013). Increased emphasis on obtaining patient-level data to guide practice change causes concern in determining whether these activities require human subjects' oversight. Continued debate among experts in the ethics of human subjects research makes it difficult for clinicians, those most involved in practice change, to know what direction to take when developing QI projects.

A common question in QI projects is: Should the project be submitted for IRB? IRBs are designated to protect the rights of human subjects involved in research and are able to determine whether a project is indeed research. In general, a QI project does not require IRB review and approval because it is not research that is subject to the federal human subjects' protection regulations. QI projects often involve the inclusion of people in an effort to evaluate an existing practice and attempt to improve it based upon existing knowledge. When the information from the project evaluation is specifically applied to individuals involved in the QI activity, then it is not classified as research and would not be subject to human research regulations. However, when an activity involves the inclusion of people to test a new, modified, or previously untested intervention, service, or program for which there is insufficient evidence to determine whether it is safe or effective, it involves humans and is subject to IRB review and approval. For example, a comparative intervention study evaluating two evidence-based methods with individuals randomized to one of the two methods to determine which is better is regarded as research involving humans. It is important to remember that QI projects not involving humans in research often require recording of identifiable private information; therefore, standard privacy and confidentiality considerations apply.

The following questions may be helpful in determining whether a proposed activity is a QI project and does not involve human subjects' research. When all questions can be answered as a "Yes," it is most likely a QI project.

- Is the project anticipated to improve care delivery while decreasing inadequacies within a specific healthcare setting?
- Is the project focused on evaluating current practice or attempting to improve it based upon existing evidence?
- Is there sufficient existing evidence to support implementing the project to create practice change?
- Are the methods for the project flexible and include approaches to evaluate rapid and incremental changes?

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- Are clinicians and staff who provide care or are responsible for practice change in the institutions where the activity will occur implementing the project?
- Will the project involve a sample of the population (patients or participants) normally seen in the institution where the activity will take place?
- Will the project only require consent that is already obtained in clinical practice, and could the proposed activity be considered part of usual care?
- Will future participants at the institution where the planned activity is implemented potentially benefit from the project?
- Is the risk to participants no greater than what is involved in the care they are already receiving?

There are times when an authoritative determination of a QI project might be required by institutional policy or as a condition of a training program. Likewise, some journals or conferences still require a formal project review prior to acceptance of a related manuscript for publication or presentation. When individuals must seek an authoritative determination, these proposed QI projects are submitted for evaluation by an IRB. The intent to publish is an insufficient criterion for determining whether a QI activity involves research (Solomon & Bonham, 2013). Planning to publish an account of a QI project does not necessarily mean that the project fits the definition of research. Individuals seek to publish descriptions of non-research activities for a variety of reasons including, for example, if they believe others may be interested in what worked at another institution. Since a major priority for the National Quality Strategy (2012) is to develop and share QI improvement efforts at the national and community level, dissemination requires timely publication and sharing of information. Spreading knowledge of QI projects that work well within each other's institutions creates awareness of lessons learned and does not require IRB approval for publication.

Additional examples of QI projects that are not identified as research involving human subjects are found on the U.S. Department of Health & Human Services website http://answers.hhs.gov/ohrp/categories/15

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