Do the Right Study: Quality Improvement Projects and Human Subject Research—Both Valuable, Simply Different

THERESA WICKLIN GILLESPIE, PhD, MA, RN

From Emory University School of Medicine and Winship Cancer Institute, Atlanta, Georgia

Dr. Gillespie is a professor in the Department of Surgery and Department of Hematology & Medical Oncology at Emory University School of Medicine and Winship Cancer Institute, and a JADPRO Associate Editor.

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Correspondence to: Theresa Wicklin Gillespie, PhD, MA, RN, Department of Surgery, Emory School of Medicine, 1365C Clifton Rd NE, Winship Cancer Institute C2019, Atlanta, GA 30322
E-mail: tgilles@emory.edu

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Human subject research (i.e., research) has been traditionally defined in the literature and by institutional review boards (IRBs) as a systematic approach to answering a question that is hypothesis driven, or hypothesis generating, and leading to generalizable knowledge (Shirey et al., 2011). The study design for any sort of research study would depend on the question being asked, and could be a retrospective data review, a case-control study, a prospective randomized controlled trial, or whatever design was best suited to answer the question in the target population.

With the publication of *To Err is Human: Building a Safer Health System* in 2000 (Institute of Medicine) and *Crossing the Quality Chasm: A New Health System for the 21st Century* in 2001 (Institute of Medicine), health care became more focused on quality assurance (QA) and quality improvement (QI; sometimes referred to as continuous quality improvement, or CQI) initiatives in order to identify, explore, prevent, and resolve systems and processes leading to unintended or poor-quality outcomes (US Department of Health and Human Services, 2011). Examples of QI studies may include measuring staff compliance with clinical guidelines for toxicities from immunotherapy, interventions to reduce costs related to readmission rates, or strategies to decrease wait times for an infusion center.

DEBATE

The introduction of QI projects alongside research studies has created some confusion, and occasionally fervent debate (Johnson, Vermeulen, & Smith, 2006; Platteborze et al., 2010), relating to whether or how QI undertakings represent research. Such discussion is not simply academic, since a project that meets the criteria for research requires compliance with regulatory, ethical, and various research principles that a QI project may not (or may) involve. The intensity of the arguments of research vs.

QI has often been rooted in a sense of superiority by investigators that research is somehow perceived as "better" on some levels than QI projects (Johnson et al., 2006). In the same vein, those working in QI have sometimes responded defensively to champion the cause of, and need for, QI initiatives.

In reality, the argument about the comparative value of research vs. QI is pointless. Both types of studies are important. Both types of studies are needed. But whether a project one pursues is labeled as "research" or as "QI" depends almost entirely on the question being asked, and how *generalizable* the findings might be.

EXAMPLE

Think about a project, as an example, that looks at infection rates in one hospital's own ICU ("ICU A") over time. The ICU staff observes that the rates have increased over the past year. They ask the question: "Could certain interventions control or diminish those rates?" The ensuing project might well be classified as QI. The topic is clinically relevant, and the findings are crucial to ICU A patients. But the results might be extremely institution specific, and thus, would not necessarily apply to a different hospital in another location. The IRB for the hospital for ICU A would likely decide such a study does not meet the definition for research, and thus does not require IRB approval. However, staff in another ICU ("ICU B") might read of that project and attempt to use the same strategies as a model to try to reduce the infection rates in their own hospital. So, findings from QI projects also need to be disseminated, just like for research.

ALIKE BUT DIFFERENT

In thinking about the differences and similarities between research and QI projects, one might consider: "How could this same project about infection rates in an ICU be (re)constructed as a research study?" Perhaps the investigators from ICU A, who originally observed increased infection rates and decided an intervention was needed to reduce those rates, might hypothesize that following a specific infection prevention protocol could lead to decreased infection rates universally, not just for their own site. Investigators from ICU A would then recruit other collaborators from different hospitals, so that they now had ICU B, C, D, E, F, and G participating, representing diverse populations in varied regions of the country. The study would be designed so that each ICU team collected the exact same data and combined the data for analysis. The findings would then represent seven centers from around the country, and the results would be much more likely to be *generalizable* as well as *reproducible* at other ICUs that might try the same approach. The project has thus transformed from a single-site QI analysis of one ICU to a multicenter research study of diverse ICUs and patients. The outcomes, as for the QI project, should be presented, published, and disseminated to other centers for potential application and replication.

APPLICATION

In the first scenario, the QI project was a completely appropriate strategy to try to change infection rates in one hospital's ICU. The results would be applicable to that one setting, and the study team would hopefully discover the answers they needed as related to ICU A's infection rates in order to improve patient outcomes. In the revised scenario that included numerous hospitals collecting the same data, the multicenter research study design was appropriate in order to enhance the sample size and diversity and thus make the findings more generalizable beyond one or a few ICUs. Any claim that one design was superior to another is unfounded. Both designs are correct. Both designs answer the questions driving the specific project.

In this issue of *JADPRO*, Christina Cone and Mary Lou Affronti observed that their institution had a clinically important neuro-oncology program, yet it lacked sufficient training of practitioners in that subspecialty. As a result, staff turnover, especially among advanced practitioners, was high, representing significant financial losses. To address these identified needs, the authors designed a program to provide neuro-oncology advanced practitioners at their center with adequate and detailed core competencies to ensure they had the needed expertise to deliver high-quality, specialized care, with the anticipated additional goal of enhanced retention. The team followed established methods in QI: the focus, analyze, develop, execute, and evaluate (FADE) QI methodology, and disseminated the results through presentations and this publication.

The Cone paper represents an excellent example of a QI project and the impact it can have on clinical care. Based on the question being asked ("How can we make sure our neuro-oncology practitioners all have adequate expertise to care for our patients and to be retained at this venue?"), the study design was chosen with this question in mind. Both this question and resulting answers are unlikely to require IRB approval or generate generalizable findings, thus underscoring that the work does not meet the basic definition for research.

The gaps in the literature related to patient care in oncology, particularly for issues that lie in the advanced practitioner's domain, are enormous. Significant needs exist for both research and QI initiatives led by advanced practice experts. Oncology practice, in many cases, has not been modified for more than 50 years, so that the practice is based on longevity of performing a particular way, rather than relying on high-level evidence. Important questions remain to be answered. When faced with these crucial questions, we can ask ourselves: "Do we want to do nothing?", "Do we want to do something?", or "Do we want to do the right study?" The right strategy will be the study design that best answers the question, regardless if it is a research or a QI approach. Both are valuable as means to contribute to closing the gaps.

Disclosure

The author has no conflicts of interest to disclose.

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