The Science of Safety Improvement: Learning While Doing

Dr. Jane Jones is the chief quality officer for a hospital where the chief executive officer has repeatedly emphasized the need to reduce readmission rates. Dr. Jones found an article (1) about an innovative program called "reengineered discharge" (RED) that dramatically reduced the rates of readmissions and emergency department visits within the first 30 days after hospital discharge. This program was tested in a block randomized trial and involved using a nurse discharge advocate to arrange follow-up appointments and medications and a pharmacist to follow up with patients several days after discharge.

Dr. Jones was impressed by the abstract but then read the full article and learned how complex the intervention actually was. The nurse discharge advocate and pharmacist were members of a research team whose efforts supplemented those of hospital employees. Dr. Jones wondered what ingredients of RED as originally tested were essential for success, how the intervention might be adapted to work at her hospital, and how her hospital could begin to adapt it.

We in the field of researching patient safety improvement would struggle to answer these questions with any meaningful level of confidence now. How might our endeavors in patient safety research and evaluation better assist hospitals and clinicians who aspire to provide high-quality, safe care to the patients whom they serve? In other words, how can we design and analyze our studies to facilitate their implementation on the front lines of care?

Shekelle and colleagues' article in this issue (2) provides a framework for enhancing research in patient safety improvement by proposing criteria for the design and reporting of studies to facilitate the translation of the studies into practice. Their article is an important step toward making patient safety practices in health care delivery more evidence-based, replicable, and sustainable. Increasing our knowledge about what works in patient safety and other quality improvement efforts, as well as why and under what conditions these efforts work, is a critical component of programs to make health care safer.

Components of an Ideal Study

Shekelle and colleagues emphasize how important it is that researchers clarify why they believe the intervention should work—that is, a study should articulate a theory of action (3). The authors also stress that patient safety studies need to adequately describe the nature of interventions that improve patient safety—in other words, to explain what was done. For example, RED outlined 10 specific steps aimed at reducing postdischarge adverse events and subsequent rehospitalizations. Finally, Shekelle and colleagues remind us that context is important: Studies need to clearly document the characteristics of the settings and external environments in which an intervention took place to guide potential implementation in similar and alternate settings (4).

Given these components of an ideal study, what analytic framework explains how variations in results reflect differences in context, the precise nature of the intervention, and the fidelity with which the intervention was implemented? Shekelle and colleagues' report to the Agency for Healthcare Research and Quality (5), from which the article in this issue is derived, describes these questions as an effort to explain "context heterogeneity" and provides numerous statistical approaches to answer these questions.

As Shekelle and colleagues note, appropriate designs for controlling threats to internal validity remain uncertain. The RED program randomly assigned patients at 1 urban academic hospital by using a block method, but a follow-up study would probably test the intervention across settings, with hospital wards or entire hospitals as units of analysis. Many investigators would consider a study in which such units were randomly assigned to be rigorous (6). However, there are at least 2 barriers to random assignment: provider willingness and our current lack of knowledge about the relevant characteristics to test true randomness.

If appropriately implemented, other study designs, including regression discontinuity, stepped wedge, and interrupted time-series designs, can help to address threats to internal validity (7). These quasi-experimental designs are also more likely than randomized designs to provide opportunities to discover and measure variations in context and implementation processes across settings and to integrate such contextual variables as staffing, available health information technology and other resources, leadership, teamwork, and external demands into analyses of findings.

Research in Complex Systems

Shekelle and colleagues are by no means the first investigators to explore how researchers can build knowledge of context and of detailed, local mechanisms into their designs. For 20 years, a large community of students of "realistic evaluation" has been making progress in incorporating better methods that are more sensitive to context and in incorporating mechanisms into research in complex systems (8, 9). Last year, The Health Foundation convened a major international conference on research methods in complex systems, and a fellowship on these methods is now in progress (10). Researchers of health services in general, and students of patient safety in particular, would benefit from noting this progress and mapping it into their approaches to learning.

Shekelle and colleagues' suggestions about what safety researchers should routinely report conform well to the SQUIRE (Standards for Quality Improvement Reporting and Evaluation) guidelines for reporting on quality im-

provement projects, which Davidoff and colleagues proposed in 2008 (11). It is time to use these guidelines more often as the relevant standard.

These new proposed criteria for designing and reporting studies of interventions of patient safety improvement will not be easy to implement. They are analogous to the criteria for pragmatic clinical trials, emphasizing both internal and external validity. These criteria are further consistent with Andermann and colleagues' (12) requests on behalf of the World Health Organization for "core competencies" for researchers of patient safety and with requests for a reconceptualized science of improvement (13, 14). As Andermann and colleagues note, the criteria are not just for the academic research community but, in an optimal setting, would be used by all persons who implement improvements in patient safety interventions.

It is clear that demands for patient safety and for improvement interventions that are evidence-based and context-sensitive should not stop until we identify the perfect research designs. As in all other fields of science and practice, useful knowledge will emerge from successive iterations that build on each other (15) and from systematic evidence reviews, perhaps under the rubric of system design–focused, patient-centered outcomes research (16).

At a recent conference of the Agency for Healthcare Research and Quality that focused on health delivery research, leading experts noted the opportunity to concurrently accelerate the development of knowledge suitable for translation into practice and implement patient safety practices. Doing so will require measurement of organizational variables and clinical outcomes within a common evaluation framework to facilitate comparisons of implementation strategies (17, 18).

Recent studies indicate that important challenges in patient safety persist (19–21). Despite the growing library of published articles containing numerous initiatives to make care safer, a substantial gap persists between our aspirations and public expectations on the one hand and actual performance on the other. Recent initiatives with large, positive, sustained results (22) are encouraging and deserve further dissemination at the same time that they receive further evaluation using expanded sets of criteria. We need to know more about the "how" and "why" of successful interventions in order to meaningfully translate our research into practice.

Study designs that build upon Shekelle and colleagues' criteria, the SQUIRE guidelines, and the lessons from realistic evaluation will help such persons as Dr. Jones, who need to take action on patient safety, to select the most effective strategies. This process will demand new partnerships among researchers, front-line practitioners, health care leaders, and patients and families. The will to make care safe has steadily grown over the past decade. It is past the time to build and spread the learning required to translate our highest aspirations into practice. The public expects and deserves no less.

Carolyn M. Clancy, MD
Agency for Healthcare Research and Quality
Rockville, MD 20850

Donald M. Berwick, MD, MPP
Centers for Medicare & Medicaid Services
Washington, DC 20201

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Requests for Single Reprints: Gail Makulowich, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850; e-mail, AHRQPubs@ahrq.hhs.gov.

Current author addresses are available at www.annals.org.

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Current Author Addresses: Dr. Clancy: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850.

Dr. Berwick: Centers for Medicare & Medicaid Services, 200 Independence Avenue SW, Mailstop 314G, Washington, DC 20201.