

Research in the sciences of improvement, implementation, and pediatric patient safety

Peter I. Lachman¹

THE RATIONALE FOR QUALITY IMPROVEMENT

The imperative for the provision of safe care and the continuous improvement of care is now a central part of health-care delivery. *Pediatric Research* journal has recognized this development with the introduction of a new section on Quality and Patient Safety. Quality and safety were once thought to be the inevitable consequences of the professional responsibility of clinicians. It is now understood that one cannot rely on the good intention of professionals to be safe or to deliver high-quality care. The complexity of health-care delivery has changed the way evidence-based care can be implemented. Health-care delivery relies on the integration of many different processes, all prone to potential failure. Over the past 20 years, the theoretical basis underpinning the delivery of high-quality safe and effective care has evolved, with the development of the sciences of improvement, implementation, and patient safety.

THE CHALLENGES IN THE RESEARCH OF IMPROVEMENT, IMPLEMENTATION, AND PATIENT SAFETY

Improvement Science is the study of how to improve different aspects of care, whether it be safety, processes, or effectiveness. The theories are based on the integration of different streams of research on systems, psychology, behavior, and manufacturing processes. Improvement Science can be defined as developing an understanding of the factors and processes that lead to the continual improvement of care, usually developing the solution locally or adapting a solution to the local context. The challenge to know how to bring what we know into everyday work is studied by Implementation Science, which considers what it takes to implement what is already known at scale. The study of Patient Safety considers a wide range of different areas of inquiry, such as ergonomics or human factors, safety culture and team work, mechanisms of different harms, and the interventions required to mitigate against harm, including reliability theory, microsystem theory, and the study of complex adaptive systems and human behavior.

The Quality and Patient Safety section aims to cover these new areas of scientific inquiry. Most research in these fields has been within adult clinical care with extrapolation to pediatrics. We want to attract research in pediatrics quality and safety that has the same rigor and validity as other fields of scientific endeavor. The development of the new scientific fields has required the evolution of a new taxonomy, methodology, and evidence base. Research in quality improvement has been problematic due to the wide range of definitions, the lack of consistency in the use of the various methodologies, the difficulty of comparing outcomes, the lack of attention to generalizability, and suspect fidelity. Miltner *et al.* (1) summarize the challenges to research in implementation of improvement, stating that there is a need for innovation that can lead to generalizability of improvement. This occurs within an inhospitable milieu with limited funding to support research or difficulty in attracting recognition. They identify the real challenges to be the lack of agreed methodologies, diversity in academic perspectives, and the lack of a theoretical foundation and evidence base to improve health care (1).

DEVELOPING THEORIES OF CHANGE

The importance of having a defined theory of change has been explored by Davidoff *et al.* (2), who bring clarity to the problem of research in improvement. They note that most of the work in quality improvement to date has not been driven by research but rather by the desire to improve, and that most studies have not included an explicit description of the theories for the change or improvement that has been reported. They call for a “demystification of theories” and provide a framework, which could be applied for publication of research on improvement and implementation. Research will need to demonstrate the relationships between the constructs; an ability to test the theory to establish causality and to measure the processes and outcomes with a defined statistical methodology; and have a parsimonious conclusion, which can be generalized within an evidence base. This is essential if research into improvement and implementation is to be taken seriously.

¹International Society for Quality in Health Care (ISQua), Dublin, Ireland.
Correspondence: Peter I. Lachman (www.isqua.org)

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The research into patient safety, which is more developed, also requires the testing of theories so that we can generalize and apply the learning in different contexts. As patient safety has led the way in research in the quality arena, it has also been the area of study with many failures in generalizability of findings and reported solutions. Foy *et al.* (3) contend that this is a result of the lack of attention to the theories of change. They call for research on patient safety to be founded on explicit theories that consider organizational structure, cultures, and context. Prerequisites are studies of the mechanisms of change and the way these are introduced into the specific context, leading to a change in human beliefs systems and behaviors.

CREATING THE METHODOLOGY AND TAXONOMY

Once there is a clear idea of the hypothesis or theory for change, the development of a consistent method to study the change process or the context for change is required. Unfortunately, there has been great variability in the improvement or implementation research methodology and how projects are reported. The lack of a clear taxonomy or method has made the generalizability and learning about improvement difficult to achieve. The traditional research methodologies that we use in biomedical research, as well as the statistical basis for reporting significance, are necessarily the best way to undertake research in quality improvement implementation.

The type of research we are looking to publish falls within several specific fields of quality and safety; the first is epidemiological studies on the incidence prevalence of harm and adverse events. Currently, research has indicated variable rates of harm, and as our understanding of the types of harm that exist becomes more apparent, so the study of harm must increase. This will include the development of theories of causation and followed by studies of interventions that decrease harm. As health care is a complex adaptive system, studies of how systems deliver quality care, the impact of organizational and individual culture on quality, and the interaction of the different components of care are now essential components of realistic solutions to health-care delivery. The study of the cultures of different teams and how this may change will require a different approach to the way we study change. While impressive results have been reported, the actual study of what it takes to change complex systems is limited. The types of research studies that have made a difference have concentrated on several key areas. The study of the cultures of different teams and how this may be

modified will require a different approach to the way we study change.

Eccles *et al.* (4) and Portela *et al.* (5) provide overviews of the different methods that can be used for the study of improvement. We expect papers submitted to follow a clear methodology to allow for learning and spread of outcomes. Portela *et al.* (5) call for us to move away from the philosophical approach of “what should happen” to the continual study of “how to improve health care.” The methodologies that are employed are usually not the standard randomized controlled trial type of research. Rather, they include time-series analysis, realistic evaluation, and qualitative research. This also requires a different type of statistics using statistical control charts.

PUBLISHING IN THE JOURNAL

In summary, the study of improvement of care, the implementation of what works and new research on how to improve care, decrease harm, and to deliver care safely, effectively, and equitably will be areas that we want to see published in *Pediatric Research* (6). The SQUIRE guidelines provide the framework to report improvement research (6). We intend *Paediatric Research* to become the journal of choice for the publication of research in pediatric quality and patient safety.

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REFERENCES

1. Miltner RS, Newsom JH, Mittman BS. The future of quality improvement research. *Implement Sci* 2013;8:S9.
2. Davidoff F, Dixon-Woods M, Leviton L, Michie S. Demystifying theory and its use in improvement. *BMJ Qual Saf* 2015;24:228–38.
3. Foy R, Ovreteit J, Shekelle PG, et al. The role of theory in research to develop and evaluate the implementation of patient safety practices. *BMJ Qual Saf* 2011;20:453–9.
4. Eccles M, Grimshaw J, Campbell M, Ramsay C. Research designs for studies evaluating the effectiveness of change and improvement strategies. *Qual Saf Health Care* 2003;12:47–52.
5. Portela MC, Pronovost PJ, Woodcock T, Dixon-Woods M. How to study improvement interventions: a brief overview of possible study types. *BMJ Qual Saf* 2015;24:325–36.
6. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. *BMJ Qual Saf* 2016;25:986–92.