Special Review

# The Science of Quality Improvement

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Scientific rigor should be consistently applied to quality improvement (QI) research to ensure that healthcare interventions improve quality and patient safety before widespread implementation. This article provides an overview of the various study designs that can be used for QI research depending on the stage of investigation, scope of the QI intervention, constraints on the researchers and intervention being studied, and evidence needed to support widespread implementation. The most commonly used designs in QI studies are quasi-experimental designs. Randomized controlled trials and cluster randomized trials are typically reserved for large-scale research projects evaluating the effectiveness of QI interventions that may be implemented broadly, have more than a minimal impact on patients, or are costly. Systematic reviews of QI studies will play an important role in providing overviews of evidence supporting particular QI interventions or methods of achieving change. We also review the general requirements for developing quality measures for reimbursement, public reporting, and pay-for-performance initiatives. A critical part of the testing process for quality measures includes assessment of feasibility, reliability, validity, and unintended consequences. Finally, publication and critical appraisal of QI work is discussed as an essential component to generating evidence supporting QI initiatives in radiology.

**Key Words:** Quality improvement; metrics; research methods; public reporting.pay-for-performance.



## INTRODUCTION

Fundamental differences between quality improvement (QI) research and traditional scientific research can be best understood by articulating the goals of these two distinct activities. QI research is designed to achieve positive change in a specific process or service that tends to be highly dependent on the local environment. These projects usually focus on a well-defined problem, build in feedback on immediate outcomes to allow for the adjustment of interventions, and are generally not dependent on a deep understanding of the mechanisms of change involved in the interventions (1,2). Traditional scientific research is designed to explicitly test a hypothesis, eliminate or minimize bias, and yield new generalizable knowledge with a focus on the mechanisms of cause and effect. Some features of QI and traditional research overlap. Hypothesis-driven testing constitutes a critical part of QI, although QI includes other systematic activities distinct from scientific research such as goal-setting, performance measurement and feedback, standardization, and education (3). Scientific rigor should be consistently applied to QI research to ensure that patients do not suffer harm in the name of QI.

Considerable debate exists regarding the use of health-care interventions designed to improve quality and patient safety without clear evidence that benefits outweigh costs and harms. Proponents of implementing large-scale health-care interventions without compelling evidence note that in many instances, it may be costly, difficult, or impossible to generate evidence. This difficulty may relate to problems blinding investigators or participants, inability to establish causality, or issues related to interventions that are highly dependent on local context and culture (2). Opponents argue that if the evidence is not compelling, well-intentioned interventions may fail to improve health or may even cause harm, while costing dearly (4). One example of a QI initiative in radiology that has been successfully implemented in many different local environments is the Image Gently campaign, which also serves as one of the National Quality Forum's (NQF) Safe Practice guidelines to reduce unnecessary exposure to ionizing radiation for children (5,6).

The goals of this review are to (1) provide a review of QI research methodologies and study designs that can generate high-quality evidence regarding QI interventions in radiology, (2) review the ethics of QI research, (3) discuss the rationale and process for developing quality measures, and (4) provide guidance on the preparation and review of manuscripts regarding QI initiatives. The Association of University Radiologists Radiology Research

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Alliance convened a task force to explore this topic with the results presented in this review.

## QUALITY IMPROVEMENT STUDY DESIGNS

Many QI study designs draw from health services research, social science, and other disciplines, each with advantages and disadvantages in dealing with the complexities of clinical practice (1). These designs attempt to establish a causal relationship between an intervention and a change in outcome. The choice of design depends on both the purpose of the study and the degree of control the investigators have over delivery of the intervention (7). Campbell et al suggest that the evaluation of complex interventions should follow a sequential approach that provides increasing evidence (8):

- Explore relevant theory to ensure the best choice of intervention and hypothesis and to predict major confounders and strategic design issues;
- Identify the components of the intervention and the underlying mechanisms that will influence outcomes, predicting how the intervention and mechanism relate to and interact with each other;
- Describe the constant and variable components of a replicable intervention and a feasible protocol for comparing the intervention with an appropriate alternative;
- Compare a fully defined intervention to an appropriate alternative using a protocol that is theoretically defensible, reproducible, and adequately controlled in a study with appropriate statistical power;
- Determine whether others can reliably replicate the intervention and results in uncontrolled settings over the long term.

The following section provides an overview of the various study designs that can be used for QI research depending on the stage of investigation, scope of the QI intervention, constraints on the researchers and intervention being studied, and evidence needed to support widespread implementation.

## QUALITATIVE METHODS

The effectiveness of QI interventions can be highly dependent on the perspectives, attitudes, and behaviors of patients and health-care professionals in the context of their organizations and health-care teams (9). The use of qualitative methods involves the systematic collection, organization, and analysis of textual information that emphasizes the understanding of meanings and experiences useful for quality assessment (9). Qualitative research methods allow researchers to identify what matters to patients and health-care providers, form the theoretical basis for why an intervention leads to improvement, detect obstacles to changing performance, and explain why improvement interventions succeed or fail (1).

### Interview-based Qualitative Methods

These methods may be either semi-structured or in-depth, determined by the structure of the questions used to explore experiences and attitudes (9). These approaches may uncover issues or concerns that the researchers had not anticipated or considered. Focus groups use the interaction of a group of people to generate data, allowing group members to talk to one another, argue, and ask questions that can be useful for learning about shared experiences.

### Observational-based Qualitative Methods

Allow researchers to discover everyday behavior rather than rely on interview accounts of the organizational setting, team behavior, and interactions. These methods are fundamental to process improvement methodologies such as Lean and Six Sigma. The goal is to see what truly happens in particular health-care settings. Common approaches include participant observation, direct observation, and professional patient "shoppers" (10).

## QUALITY IMPROVEMENT PROJECTS

Many small-scale QI projects use process improvement techniques adapted from industry such as the continuous QI model by Deming, Lean, and Six Sigma. These techniques are based on incremental, cyclically implemented changes using a structured approach to selecting, implementing, testing, and refining interventions. Examples include Plan–do–study–act and Define, Measure, Analyze, Improve, and Control (1). Chassin and Loeb outline a broad framework of improvement strategies defined as "Robust Process Improvement" tools that involve "reliably measuring the magnitude of a problem; identifying the root causes of the problem and measuring the importance of each cause; finding solutions for the most important causes; proving the effectiveness of those solutions; and deploying programs to ensure sustained improvements over time" (11). Kruskal et al and Rawson et al directly apply these tools to radiology practice, incorporating strategies that involve both the improvement team and institutional leadership (12,13).

In QI projects, it is important that the process be "data driven" or quantitative. The target of change should be measured and monitored, combining the power of statistical significance tests with chronological analysis of data to generate evidence supporting the effectiveness of interventions. For example, identifying patients "on time" for computed tomography (CT) examinations can be accomplished with the display of the distribution of data over a specific time interval using a histogram. The histogram provides a visual depiction of the distribution of the data into consecutive, nonoverlapping bins or intervals. It therefore portrays numerous aspects of the overall data distribution, including the central tendency, spread, and asymmetry. Using averages or means is not sufficient because these measures do not provide information about variation. For example, reporting an average wait time of 5 minutes for patients undergoing CT examinations obscures instances in which patients waited over an hour, which would be the greatest opportunities for improvement. A second aspect of the histogram is a "specification limit" serving as the "voice