CE

How Quality Improvement Practice Evidence Can Advance the Knowledge Base

Hannah M. O'Rourke, Kimberly D. Fraser

Abstract: Recommendations for the evaluation of quality improvement interventions have been made in order to improve the evidence base of whether, to what extent, and why quality improvement interventions affect chosen outcomes. The purpose of this article is to articulate why these recommendations are appropriate to improve the rigor of quality improvement intervention evaluation as a *research* endeavor, but inappropriate for the purposes of everyday quality improvement *practice*. To support our claim, we describe the differences between quality improvement interventions that occur for the purpose of practice as compared to research. We then carefully consider how feasibility, ethics, and the aims of evaluation each impact how quality improvement interventions that occur in practice, as opposed to research, can or should be evaluated. Recommendations that fit the evaluative goals of practice-based quality improvement interventions are needed to support fair appraisal of the distinct evidence they produce. We describe a current debate on the nature of evidence to assist in reenvisioning how quality improvement evidence generated from practice might complement that generated from research, and contribute in a value-added way to the knowledge base.

Keywords
quality improvement
evaluation
feasibility
research ethics
evidence-based practice

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Background

Minimizing the gap between what we know and what we do in clinical care settings has been of interest since Donabedian's seminal quality assurance work in the 1960s (Donabedian, 2005; Graham et al., 2006) and has been further propelled by the current climate of healthcare service accountability, cost-effectiveness, and calls for evidence-based care (Graham et al., 2006). Within this climate, many quality improvement interventions have been developed to increase the use of care practices with proven benefit to patients (Grimshaw et al., 2006) by targeting individual healthcare provider behaviors or redesigning systems (McIntyre and Shojania, 2011). Quality improvement (QI) is "any type of planned organizational change or intervention designed to improve some aspect of quality of care" (Alexander and Hearld, 2009, p. 236). Impact evaluation is necessary to determine whether a QI intervention was justified given the effort required to implement it (Graham et al., 2006), but such evaluative work has been challenging.

Systematic reviews of planned change interventions indicate that more rigorous evaluation is needed to advance knowledge about which QI interventions work and why (Grimshaw et al., 2006; Harvey and Wensing, 2003; Ovretveit and Gustafson, 2002; Wagner et al., 2001). In an effort to strengthen the evidence base, researchers have developed standards for reporting the findings from evaluations of QI interventions conducted as a *research* endeavor (which we refer to as QI research or *QIR*) (Davidoff et al., 2008; Ogrinc et al., 2008). However, similar standards for QI intervention evaluation conducted as a *practice* endeavor (which we refer to as QI practice or *QIP*) remain under development (Rubenstein et al., 2008).

In this article, we call for the careful development of new recommendations to enhance evaluative rigor that are specific to QIP for reasons of feasibility, ethics, and the distinct aims of QIP. We define QI interventions generally and then differentiate between interventions implemented in QIP as compared to QIR. We then argue that the recommendations to improve the rigor of QIR intervention evaluation are inappropriate for application in QIP. To prompt development of appropriate recommendations for QIP, we consider how the debate about the nature of evidence may assist QI practitioners and researchers to see the

products of QIP and QIR as distinct, complementary, and of equal value.

Quality Improvement Interventions

Quality improvement interventions, whether conducted for purposes of research or practice, are complex social processes introduced into healthcare systems (Ovretveit and Gustafson, 2002). They may be discrete interventions or more generalized approaches to process improvement (Alexander and Hearld, 2009). Some examples of discrete interventions include audit with feedback, reminders, implementation of clinical practice guidelines, and practitioner education (Alexander and Hearld, 2009; Grimshaw et al., 2003). An example of a more generalized approach is "continuous quality improvement" (CQI) (Shortell et al., 1998). Discrete QI interventions (e.g., education, reminders) are used to cause a planned change in response to an observed quality issue as part of the CQI process. Defining qualities of CQI include the use of data and statistics to identify and control processes; the use of benchmarking; an emphasis on the need for teams to identify problems, processes, and solutions; and the use of improvement processes, such as Plan, Do, Study, and Act cycles (McLaughlin and Kaluzny, 2006; Sales, 2009).

Interventions in Quality Improvement Research and Quality Improvement Practice

Quality improvement interventions may be applied within the practice environment (i.e., QIP) or assessed in a research study (i.e., QIR). As an example of QIP, a team working in a hospital might use audit with feedback—a QI strategy with known effectiveness—to show physicians how their prescribing practice compares with an evidence-based guideline. The purpose of using audit with feedback may be to improve the rate at which physicians adhere to a particular prescribing standard or guideline within their setting. In contrast, in QIR, interventions are developed, explored, or tested to determine what works to improve care quality and how QI interventions function under different conditions (Grol and Grimshaw, 1999). What we call "QIR" is also known by other names like knowledge translation (Bhattacharayya and Zwarenstein, 2009) and implementation research (Peters et al., 2013; Shojania and Grimshaw, 2005), for example. Quality improvement practitioners can therefore apply the evidence generated from QIR to select effective QI interventions to change practice in care settings (Shojania and Grimshaw, 2005).

Literature reviews of "what works" to improve quality in healthcare settings indicate that most interventions evaluated for the purposes of QIR have marginal effects in the area of 10% for the study outcome (Grol and Grimshaw, 2003). However, there have been calls for more rigorous intervention evaluation in QIR because evaluations to date have been characterized by problematic design features (Harvey and Wensing, 2003; Ovretveit and Gustafson, 2002; Shojania and Grimshaw, 2005; Wagner et al., 2001). We now describe the nature of these recommendations.

Recommendations for Quality Improvement Research Evaluation

A review of 235 quasi-experimental studies of QIR interventions to increase healthcare professionals' use of evidence-based guidelines found that the quality of the research studies, on the whole, was poor (Grimshaw et al., 2006). Similarly, literature reviews indicate that most QIR studies of CQI are single-site before/after evaluations, a weak design for determining intervention effectiveness (Sales et al., 2012; Shortell et al., 1998). In another review of QIR intervention studies, 30% of studies lacked a comparison group, and only half assessed outcomes using a longitudinal design (Alexander and Hearld, 2009). Another important finding, randomized controlled trials (RCT) were less likely to report improvements than observational studies; the same relationship was identified for single-site versus

multisite designs and for cross-sectional versus longitudinal studies (Alexander and Hearld, 2009; Sales et al., 2012). On the whole, this suggests that observational single-site studies that employ only preintervention and postintervention measures are likely to produce biased estimates of effect. In light of this, recommendations to reduce bias in the conduct of QIR evaluation have been made (see Table 1) (Bhattacharyya et al., 2011; Grol, 2001; Lansisalmi et al., 2006; Wagner et al., 2001).

Study authors have proposed experimental or quasiexperimental designs (Grol, 2001; Lansisalmi et al., 2006) like controlled before-after studies and, where possible, the interrupted time-series design (Bhattacharyya et al., 2011) to reduce bias in QIR. Other methods to handle bias characteristic of the RCT design include randomization, treatment allocation, control groups, and prospective data collection (Bellin and Neveloff Dubler, 2001). In addition to

Table 1. Critiques of Evaluation in Quality Improvement Research and Suggestions for Improvement

Type of research question	Common design elements of prior QIR evaluations	Critique	Design elements suggested to improve QIR (NOT QIP[a]) evaluation
Does the intervention work?	• Single-site design	Not generalizable *(i.e., findings may not reflect what happens in other contexts)*	• Multisite design
	• Observational or cross-sectional designs	Biased *(i.e., report improvement when there may actually be none that can be attributed to the intervention)*	• Experimental (RCT) or quasi-experimental (e.g., controlled before and after) studies
	• Before-after evaluations		• Randomization
	• No comparison group		• Treatment allocation • Control groups • Prospective data collection, longitudinal and interrupted time-series designs
How or why does the intervention work? In what context is the intervention effective or not?	Quantitative studies *(see above)*	Lack of rigorous qualitative study *(i.e., quantitative studies designed to test if an intervention works do not explore mechanisms for how or why it works, and the contextual factors which may affect this)*	In depth study of local context using qualitative or mixed methods like: • Action research • Multiple case studies

[a]We argue in this article that these recommendations were made for QIR and are not appropriate for QIP for reasons of feasibility, ethics, and the aims of QIP.

recommendations to reduce bias, others have described how QIR evaluation can be improved by studying the context and conditions to explain how and why interventions work (Harvey and Wensing, 2003). Research methods, such as action research and multiple case studies, could be used for this purpose, both of which require analysis of rich data collected from in-depth study of a few local settings (Harvey and Wensing, 2003). We do not dispute the value of these recommendations to reduce bias or enhance the in-depth study of local settings for the purposes of QIR; instead, we argue that these suggestions are neither appropriate nor meaningful for application in QIP.

Why Quality Improvement Research Demands a Distinct Evaluative Approach

Although QIP is not research, neither is it strictly clinical care, so it can be difficult to distinguish QIP from QIR (Casarett et al., 2000). Further, QIP often shares some characteristics with QIR including the use of large electronic databases of patient records, application of statistics, and following of patient cohorts to monitor outcomes before and after QI interventions (Bellin and Neveloff Dubler, 2001). Despite these similarities, paying attention to feasibility, ethics, and the aims of practice versus research can help to distinguish QIP from QIR (see Table 2), a distinction critical to making recommendations to improve evaluation of QIP.

Feasibility and Ethics

One review identified that many published QI articles were unfunded evaluations reporting findings from "an administratively or clinically mandated change in an organizational practice" (Alexander and Hearld, 2009, p. 249). The lack of external (i.e., grant) funding coupled with project initiation within the practice environment suggests that at least some of these studies were evaluations of QIP, not QIR. Limited funding is certainly a feature of QIP: results from a survey of 102 QI practitioners in the United States indicated that less than 15% of QIP initiatives were supported by external funds

Table 2. Quality Improvement Research Compared to Quality Improvement Practice

	Quality improvement research	Quality improvement practice
Aims	Understand why & how interventions work in different contexts	Improve patient care and outcomes in a local context; monitor the health of patients and system
QI interventions	Tested, explored, examined	Selected, applied and revised to fit local needs
Evaluation approach	Time intensive; require statistical *(e.g., time-series analysis)* or methodological *(e.g., RCT, in-depth case study)* expertise	Less time intensive; requires knowledge of basic statistics *(e.g., audit of care outcomes from medical record)* and clear documentation of QI practitioner process *(e.g., describe "lessons learnt")*
Project lead	An expert in research methods *(e.g., implementation scientist)*	An expert in the local context *(e.g., clinical practice leader)*
Funding	External grant funds, obtained following competitive peer-review	Unfunded or money allocated to improvement projects by the system
Ethics	Required	Not Required
	Methods *(e.g., to reduce bias or increase generalizability)* may burden participant and are not part of clinical care; QI intervention may or may not benefit participants directly	Evaluation of outcomes is part of usual clinical care; there is good reason to believe that the QI intervention will directly benefit the patient

(Taylor et al., 2010). Resource limitations have implications for QIP because inadequate time, money, or personnel can limit the availability of individuals with the expertise to carefully design the evaluation or the use of control groups, for example (Alexander and Hearld, 2009). Thus, recommendations for QIP evaluation must balance the need for rigor with a consideration for feasibility (Straus et al., 2009); the evaluation plan should consider logistics and be practical to conduct (Sidani and Braden, 2011).

In addition to feasibility, ethics must be considered. It is ethically problematic to conduct a QIP intervention evaluation that has key features of QIR without first obtaining ethical review by an independent ethics committee (Taylor et al., 2010). If there are additional burdens imposed on patients in order to make the information generalizable (e.g., including a larger sample or multiple sites) or if there is no direct benefit to the patient involved in the intervention, then the activity will most likely be viewed as QIR and not QIP (Casarett et al., 2000). Design features that reduce bias like randomization, treatment allocation, control groups, and prospective data collection also signify an activity as QIR instead of QIP and thus in need of ethics approval (Bellin and Neveloff Dubler, 2001). Other research methods aimed at reducing bias (e.g., time-series analysis) or understanding how and why interventions work (e.g., multiple case study) remain time intensive and would likely require both ethics review and personnel with the appropriate methodological expertise to ensure rigorous application.

The aforementioned recommendations are appropriate for the particular purpose of QIR: to rigorously assess whether, how, or why a particular QI intervention affects patient outcomes. Given that for reasons of feasibility and ethics, these recommendations are inappropriate for QIP, does that mean that QIP evaluations can only produce weak evidence? We do not think so. Instead, we suggest that feasible, ethical evaluations of QIP interventions can produce a distinct form of evidence that adds value to the knowledge base *by providing answers to the questions posed in QIP*. We argue that QIP evaluators should aim to produce evidence that does not replicate, but instead *complements*, the findings from QIR: evidence about the process of using QI interventions in practice and the health of patients and systems in the presence of different QI interventions. Before making any recommendations for the evaluation of interventions in QIP, we must first articulate the evaluative questions aligned with QIP's aims.

Evaluative Questions and the Aims of Quality Improvement Practice

In contrast to QIR, whether, how, and why the QI intervention is driving the observed differences in patient outcomes are not the primary questions asked during the evaluation of an intervention in QIP. A fundamental difference between QIR and QIP is that the QI practitioner focuses on the care, health, and well being of patients within a particular context, whereas the QI researcher focuses on understanding the QI intervention, the drivers of the intervention effect if any, and whether or not participation in the intervention has lead to improved patient outcomes (Bellin and Neveloff Dubler, 2001; Casarett et al., 2000). To be clear, QI practitioners *can* explore whether a QI intervention conducted for the purpose of QIP has an important impact on patients in their local setting (Rowe et al., 2005), for example by auditing care outcomes (Harvey and Wensing, 2003; Solberg et al., 1997). However, in contrast to QIR (where use of a control group is recommended), in QIP the same patients whose information is audited should be *directly* influenced by the QI intervention that the practitioner has put in place (Bellin and Neveloff Dubler, 2001; Casarett et al., 2000). Testing whether the QI intervention is directly responsible for any observed change to audited patient outcomes is not the main focus of the QI practitioner.

Quality improvement practitioners may also aim to improve local understanding of their context, examine issues that arise and effective resolutions during the QI intervention phase, and compare the process and outcomes of small local projects and the lessons that were learnt (Harvey and Wensing, 2003). However, in all of these situations, the QIP focus remains *on the health and care of a group of patients* in a particular setting who receive a QI intervention (vs. the QIR focus on understanding the *intervention*). This is analogous to the clinicians' focus on the health of the patient who receives a drug (vs. a researcher's focus on understanding the effects of a drug), a comparison that we now explore with a case example.

Case Example: Aims of the QI Practice Team as Analogous to the Clinician's. After assessing a patient, a physician prescribed a drug that a nurse administered. Even though previous research tested the drug, its effects on *this* patient remained uncertain, so the physician and nurse monitored the patient for intolerable side effects, improved health, and stabilization. However, they did not establish whether the effects they observed in the patient were the direct result of the prescribed drug, conduct in-depth study of the conditions under which the drug worked, or explore mechanisms for why it worked in this patient but not in others. Instead, the healthcare professionals, based on their knowledge, assumed that some combination of the drug as well as other interventions (proper nutrition and sleep, for example) were responsible for stabilizing the patient. Their priority was not to study the drug, but to assess the patient and ensure that he or she remained as well as could be expected. The evidence that their work generated was primarily about the health status of and side effects experienced by the patient, not about whether, how, or why that drug caused those effects.

We can now substitute the QI team for the physician and nurse, and the QI intervention for the drug treatment. In this case, the QI team working in one hospital put a QI intervention such as audit and feedback in place to improve care for inpatients on several units. Following this, they monitored select outcomes for those patients affected by the intervention to determine whether these outcomes improved or stabilized. In addition, the QI team wanted to ensure that neither the patients nor the system suffered hardship (analogous to side effects). To assess this, they evaluated the required effort to implement the QI intervention as well as other outcomes to assess for unintended consequences. The evaluation conducted for QIP generated ***evidence about the system and quality of care in the presence of the intervention.*** This evidence is different from and complementary to the QIR evidence that seeks to attribute particular outcomes to a QI intervention.

How Evidence From Quality Improvement Practice Can Inform the Quality Improvement Knowledge Base

Recent discourse on what counts as "good evidence" to inform patient care help support an understanding of how QIP and QIR can generate evidence forms that are distinct but complementary and of equal value (Dopson and Fitzgerald, 2005; Greenhalgh and Wieringa, 2011; Rycroft-Malone et al., 2004; Upshur, 2005). In the early calls for evidence-based practice, "best practice" was assumed to reflect the findings from (primarily quantitative) research and this stimulated considerable debate because it excluded and devalued other important forms of evidence (Bluhm, 2005; Charlton, 1997; Dickinson, 1998; Estabrooks, 1998; Rapheal, 2000; Rycroft-Malone et al., 2004). One way to address this has been to differentiate between evidence derived from research and that which is practice-based or experiential (Graham et al., 2006). This is more radical than conducting research which connects with the needs of practice (Glasgow, 2013; Martin et al., 2013), and instead considers the potential contribution of evidence generated not from

research that reflects practice priorities, but directly from the everyday practices of QI teams. In this schema, research is one form of knowledge that is used in concert with other types of knowledge, including patient preference and clinical expertise (Estabrooks, 1998; Haynes and Haines, 1998; Sackett et al., 1996), the appropriate combination of which remains open to question, debate, and further research.

Heuristic knowledge—the things we know based on clinical problem solving and discovering what works in certain situations—is both important and challenging to capture (Cornelissen et al., 2011). Undertaking more formal efforts to codify clinical expertise and placing experiential knowledge in a space that is open to critique could eventually move some aspects of experiential knowledge from the nonpropositional (i.e., informal, implicit, practice-based) to the propositional realm (i.e., formal, explicit, generalizable) (Rycroft-Malone et al., 2004; Titchen and Ersser, 2001). In the case of QI practice, this is an argument for publishing and disseminating heuristic knowledge gleaned from local QI efforts (Harvey and Wensing, 2003) and for evaluating the strength of the evidence base of heuristic knowledge according to its *own* criteria and logic. In other words, this supports the need to value, publish, and learn from the findings of QIP.

In an evidence schema that values distinct forms of knowledge, findings from QIP would be exposed to critique according to standards for quality that fit with the types of questions that QIP evaluations aim to answer. Published reports of QIP evaluations could fill knowledge gaps about feasibility, fidelity and cost of QI interventions, appropriate benchmarks for particular health outcomes in different settings, and salient contextual issues to consider during implementation of QI projects (Harvey and Wensing, 2003). For example, QIP evaluation evidence could describe the rates that QI interventions are attempted and completed as planned in a practice setting, and QI teams could document the factors that affected their ability to apply a QI intervention in their context. Such questions about the real-world experiences of teams who apply QI interventions are very different from QIR.

Approaches to addressing sustainability could also be explored by the QI team, documented, and disseminated (Harvey and Wensing, 2003). Indeed, it would be interesting to see whether there was a need to sustain a particular QI project at all, in order to maintain desired patient outcomes, measured over time according to information obtained via aggregated, standardized, and available patient assessments, such as the Resident Assessment Instrument data used internationally in long-term care facility settings (Hirdes et al., 2011).

Conclusion

Rather than labeling the evidence from QIP evaluations as "weak" according to the criteria for rigorous evaluative design for QIR, a more productive line of inquiry would be to ask: what are all learning, given the distinct evidence generated from each of QIP and QIR? (Berwick, 2008, p. 1,184). Rigorous intervention evaluations in QIP should attend to feasibility, ethics, and the questions relevant to QIP. Development of clear and appropriate standards for appraising the rigor of intervention evaluation and reporting in QIP is needed. Such standards would be used to appropriately appraise the unique evidence that can be gleaned from experience, supporting QI practitioners to contribute equally, but differently given their unique skill-sets and perspectives, to the development of QI knowledge. We agree with Rubenstein et al. (2008) that there are diverse perspectives and approaches necessary to advance the QI knowledge base, but advancements will not be realized unless these diverse perspectives can come together in complementary ways. By using an expanded notion of evidence, both QIP and QIR can contribute in value-added ways to what is known about healthcare quality improvement.

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Core CPHQ Examination Content Area

IV. [**Domain** #3 Performance Measurement and Improvement]

Learning Objectives

1. Define and differentiate the aims of quality improvement practice and quality improvement research.
2. Summarize why it is problematic to apply standards recommended for the evaluation of quality improvement research directly to quality improvement practice.
3. Describe how evidence generated from evaluations of quality improvement practice could complement that produced by research.

Questions

1. Continuous quality improvement:

a. is a discrete intervention used by clinicians to improve care.
b. relies primarily on qualitative data to evaluate outcomes.
c. uses discrete quality improvement interventions to improve care.
d. is the same as research when it uses statistics to evaluate outcomes.

2. A feature that distinguishes quality improvement practice (QIP) from research is QIP's focus on:

a. local care and patient well-being.
b. in-depth study of implementation conditions.
c. continuous quality improvement.
d. statistics and clinical administrative data.

3. A feature that distinguishes quality improvement research (QIR) from practice is QIR's focus on:

a. effectiveness instead of the context and process of implementation.
b. discrete improvement approaches like audit and feedback.
c. assessing and contextualizing the intervention impact.
d. statistics and large data sets.

4. Quality improvement interventions are:

a. not used in research, because they cannot be assessed scientifically.
b. used and evaluated in both research and practice.
c. not used in practice, because they need to be assessed scientifically.
d. used in research and practice, but only evaluated by researchers.

5. Clinicians can use the findings from randomized controlled trials of quality improvement interventions to

a. decide which interventions are most likely to be effective to improve outcomes in their setting.
b. identify processes necessary to implement an improvement practice in their setting.
c. understand the barriers and facilitators to implementing an improvement practice in their setting.
d. predict how health care providers in their setting might react to a type of quality improvement intervention.

6. Of the options below, the research design that reflects the least biased and most generalizable approach to test the effectiveness of a quality improvement intervention to improve patient outcomes would be:

a. the multisite time-series design, using data collected from three time points over 12 months to understand outcomes.
b. the multisite before-after design, using clinical administrative/assessment data to understand outcomes.
c. the single-site controlled before-after design, using data collected by the researchers to understand outcomes.
d. the multisite time-series design, using clinical administrative/assessment data from 24 time points over 12 months to understand outcomes.

7. To evaluate an intervention aimed at reducing the rate of falls on a long-term care unit, which activity should be possible without independent ethics approval?:
a. Interviewing and comparing responses from patients on units that received and did not receive the intervention about their general experiences of receiving nursing care.
b. Assessing the rate of falls before and after the intervention by collecting data from patients on the unit that received the intervention using surveys, interviews, and observation.
c. Interviewing patients from the unit that received the intervention about their general experiences of being cared for on that unit.
d. Assessing the rate of falls before and after the intervention using data from routinely collected weekly clinical assessments from units that received the intervention.
8. In a contemporary view of evidence, "best practice" knowledge is derived from:
a. randomized controlled trials, qualitative studies, and patient preference.
b. process and outcome research, patient preference, and clinical expertise.
c. quantitative meta-analysis, clinical expertise, and patient preference.
d. randomized controlled trials, qualitative studies, and clinical expertise.
9. Codifying heuristic knowledge is important so that it can be:
a. modified to reflect evidence-based practice.
b. used instead of the findings from research.
c. made explicit and critiqued.
d. studied using qualitative methods.
10. A rigorous evaluation of quality improvement practice would:
a. describe intervention feasibility and sustainability.
b. include a control group.
c. require an independent ethics review.
d. study patient experience using in-depth interviews.