

The Ethics of Quality Improvement: Practitioners' Perspectives

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Abstract

Introduction:

Innovation is an essential component of quality improvement (QI) activities that aim to improve the provision of health care. These projects, however, engender ethical and regulatory issues around human subjects' protections. A literature search was conducted to identify issues in the ethical conduct of QI. Findings from the literature search were used to develop questions for semistructured interviews with actual QI practitioners regarding the ethical conduct of QI projects.

Methods and Participants:

This exploratory project reviewed electronic databases to collect 125 relevant articles and develop semistructured interview questions. Using a snowball sampling method, the author conducted guided interviews with QI practitioners until a broad perspective and recurrent themes emerged. The 23 interviewees had significant experience directing QI projects and represented clinically and academically oriented practice settings across the United States. The author compared findings from the literature review with interviewees' perspectives.

Results:

Participants' perspectives differed most from the literature in beliefs about the risk/harm potential for patients, an ethical obligation to conduct QI activities, the requirement for an opt-out rather than opt-in informed consent approach, and the value of an administrative review rather than IRB review of QI projects. Participants outlined essential characteristics of QI including an institutional focus, timely results, requirements that study results feed into changes in care, and emphasis on easily measured but not statistically significant results.

Conclusion:

Unlike the literature, QI practitioners believe in a low harm potential for most QI activities and an ethical obligation to conduct QI. The ethical practice of QI can be enhanced through administrative review of QI projects and informing patients in the care setting about QI projects.

Key Words: Quality Improvement, Ethics, Research Ethics, Human Subjects Protections, IRBs

Introduction

Quality improvement (QI) is a technique for encouraging innovation in many fields. In health care, QI projects vary widely with respect to project size, design, method, health care setting, and resource use, but all have the goal of improving the health care system's ability to provide high-quality, high-value health care (Huycke and All, 2000). These projects, however, may not adequately protect patient and clinician participants from harm (Casarett, Karlawish, and Sugarman, 2000). Human subjects' involvement in federally funded or supported biomedical research in the United States is regulated by the "Common Rule" (Pritchard, 2001), which defines what research is, directs

what Institutional Review Boards (IRBs) should examine, and outlines the role of informed consent in research. No similar state, federal, international, or commonly accepted definition regulates the practice of QI to protect human subjects. Methods used to enhance the validity and generalizability of QI project findings—such as multi-site projects, prospective interventions, and comparison groups—have striking similarities to research, and therefore bump up against blurred definitional boundaries between QI and research (with its related regulatory requirements).

In 1979, the Belmont Report undertook a significant effort to distinguish research from therapeutic practice, (London and Klerman, 1979; Campbell and Cecil, 1979; Gallant, 1979; Goldiamond, 1979; Levine, 1979; Robertson, 1979; Sabiston, 1979; Tropp, 1979) but few recent papers discuss these issues in the context of the current healthcare system or attempt to demarcate research from QI. While a few papers have asked journal editors, QI directors, IRB chairs or university faculty to determine if a sample study should be reviewed by an IRB (Lindenauer, Benjamin, Naglieri-Prescod, and Fitzgerald, 2002) or include informed consent (Ilgen and Bell, 2001), no papers represent the perspectives of QI field practitioners who daily navigate the QI-research boundary line. The purpose of this paper was to explore the perspectives of practitioners engaged in QI projects regarding ethical issues in the conduct of QI, weaving together a literature review with interview findings from a convenience sample of QI practitioners.

Participants and Methods

Literature Review

The author reviewed relevant databases in medicine, nursing, social sciences (including psychology), education, and business including Medline, CINAHL, PsychInfo, ERIC, PAIS, and Health Business Fulltext Elite, for articles related to “ethics”, “methods”, or “sociology” plus any of the terms: “quality,” “quality improvement,” “total quality management,” “performance improvement”, “performance management,” etc. This analysis represents findings from the 85 articles plus relevant references. Relevant references were reviewed and additional articles were culled from source listings, resulting in 125 articles reviewed. The literature review identified a series of key issues that were used to design semistructured interview questions.

Guided Interviews

The author obtained names of potential interviewees from lists of QI professionals maintained by the RAND Center to Improve Care of the Dying and from participants whose title identified them as QI practitioners (e.g. Director of Quality Improvement) at the Institute for Healthcare Improvement’s 2000 National Forum. Potential participants received an e-mail describing the project and inviting participation. Often, recipients passed the invitation e-mail to multiple other recipients. Using this snowball sampling method, interested parties responded directly to the author.

Interviews were conducted via telephone or in-person and transcribed. The author told interviewees that personally identifying characteristics would remain confidential; all information that could identify participants or their facilities was deleted from transcriptions. Tapes were destroyed immediately following transcription.

Interviews lasted on average 45 minutes and occurred in March-June 2001. Participants were asked to describe their QI background and typical QI projects that occurred in their facility. Participants then discussed their views regarding: the essential distinguishing aspects of QI, research,

and clinical practice; risks, harms and benefits of QI; approaches to and guidelines for protecting patients and clinicians from harms in QI participation; methodological, social, or ethical issues in QI and whether they believe in a professional obligation to conduct QI; and informed consent and privacy considerations.

Interviews were analyzed and coded by the author for common themes and recurrent issues around the key issues identified in the literature review using the qualitative research software, NVivo.

Results

Participants

Participants included one in-person and 22 telephone interviews. Participants equally represented the Eastern, Central and Western United States. Interviewees' QI experience and background varied (Note: Not all categories are mutually exclusive). Of the 23 participants, 13 (56.6%) called themselves QI practitioners, 11 (47.8%) considered themselves QI experts or had a title indicating a directorship of QI initiatives. Ten (43.5%) considered themselves outcomes researchers; more of these individuals were affiliated with academic than clinically focused institutions. Eleven (47.8%) came from multi-institutional organizations and 7 (30.4%) were or had at one time been an IRB member.

Table 1 outlines the essential characteristics of QI according to interviewed practitioners. Table 2 outlines similarities and differences between the recent literature and practitioners' perspectives on ethical issues in QI.

Participants' perspectives differed most from the literature with respect to their beliefs about the risk/harm potential for patients, their belief in an ethical obligation to conduct QI activities, the requirement for an opt-out rather than opt-in informed consent approach, and the value of an administrative review as opposed to IRB review of QI projects.

Discussion

Quality Improvement, Quality Assurance, and Clinical Practice

In the literature, routine clinical practice involves uncertainty, "testing," and observation; clinicians make adjustments in routine care to fit the circumstances of their patient's needs (Truog, Robinson, and Randolph, 1999). Over time, repeated patient-specific adjustments can result in major changes in practice and teaching for that clinician. As such, routine clinical activities that adjust care are an acceptable and expected part of clinical practice that can take on elements of an empirical approach (Freedman, Fuks, and WEijer, 1992).

Interview participants recognized this nuance in clinical practice but said that while clinical practice emphasized patient-specific needs, QI was much broader. QI, they said, included "essential characteristics" (See Table 1). Further, they differentiated "quality assurance" (QA) from "quality improvement." As one QI director noted, QA is retrospective record review whereas QI is "prospective and interventional. QA is measuring a particular activity to be sure it is happening within agreed upon parameters while QI goes beyond that to examine different ways of practicing to see what is better with known and accepted modes of treatment."

What Makes QI Different From Research?

Most interviewees clearly distinguished QI from research. One said, “research has to do with underlying mechanisms, while QI has to do with the questioning of process, methods, and outcomes on things you think work in a certain way so as to achieve preferred outcomes.” In their view, research projects are more intensive, have a longer time lag from project initiation to achieving results, and lack a requirement for immediate feedback into the system. Interviewees from smaller practice-oriented institutions felt that QI included minimal interventions, such as taping instant hand sanitizer bottles above patient beds to reduce nosocomial infection rates.

Additionally, participants disallowed randomization and, often, cohort matching for QI projects. They gave a two-step rationale for the distinction. Participants assumed that QI, if it appropriately conducted, would apply only to those interventions with known efficacy, making harm unlikely. If a project met that first criterion, it would be unethical to withhold improvements from patients. In essence, participants rejected the research requirement of clinical equipoise (Freedman, 1987) as a basic assumption of QI.

Participants saw problems with randomization because community members could discover they had received different care. For example, one participant discussed post-operative knee bandaging in which one group received full wraps (standard care) while another got light bandaging (also standard care). The QI department steered the project toward an IRB despite a low likelihood for bodily harm and use of standard care techniques. QI management feared that patients, upon discovery of different care approaches, would equate different care with “poor care.”

Ethical Issues in QI

In the literature, ethical issues around QI include the potential for fiscal incentives to push changes not in the patient’s best interests (Mahler, Veatch, and Sidel, 1982; McGlynn, 1997; Kofke and Rie, 2003) potential patient burdens from data collection (Casarett et al. 2000), patient privacy (Woodward, 1996), and need for a high clinical competence among staff (Lohr, 1997). In the interviews, the important underlying value was patient benefit. As one respondent noted, “if you see a person suffering a symptom, do you just continue if the patient is in a research protocol or do you manage the symptom? I assume that in QI you manage the symptom. While in research, you may have problems because the care is not based on the protocol or because the researcher is supposed to be blinded.”

A QI Director of a large HMO reported concern about using demographic characteristics, like zip code, to select potential QI project participants. “We have had some cancer screening projects where they look for subjects by zip code—such as in low income areas where women are less likely to get mammograms. Some people think we shouldn’t do it that way, but we are obligated to provide care for our members and that is where they live. Picking zip codes for additional intervention is a good quality improvement initiative, but people also could unduly pick out one population.” Fair distribution of QI burden and benefit are bedrock ethics concerns in QI projects.

Most importantly, participants believed it was unethical to provide substandard care. One respondent noted, “No one should be engaged in the practice of...healthcare of another person unless the intent and execution is to do the best that you can. It is unethical to be mediocre.” One author echoes this concern saying providers should be required to inform patients, if QI does not happen at the facility, that they might receive increasingly (but unmeasured) sub-optimal care (Gifford, 2000).

Benefits of QI and the Obligation to Conduct QI

Participants believed QI should be an inherent part of the culture of healthcare. (Berwick, 1996) Further, most respondents believed in a social and/or ethical obligation to conduct QI. Some practitioners thought the obligation stemmed from the Hippocratic Oath while others saw it as a core value of medicine or public health (See also (Gostin, 2001). “There is a social obligation for sure,” said one. “That is just dogmatic, intrinsic to medicine. It is an inherent thing to measure it and try to make it better and understand that what you do now is good, but in 100 years could be total failure.” Here again, the literature is in alignment with practitioner’s views. Some authors note that health care professionals and institutions may have a moral obligation to monitor and respond to identified deficiencies in the health care system (Simon, Unutzer, Young, and Pincus, 2000; Levine, 1996; Levine, 1990) making QI a morally required activity (Bellin and Dubler, 2001). Other participants discussed QI as an obligation of the business of healthcare. “It is a business obligation to improve value for every unit of input. You should get more results and you have that obligation for your clients, patients and investors,” said one. Another added: “If the proportion of the budget for corporations devoted to research and development was the same in medical care as in other businesses, our patients would be much better off.” Respondents universally believed that QI, correctly performed could bring great benefits to patients, clinicians, and the institution.

Harm, Risk and QI

Participants’ generally assessed a low risk from QI. Participants whose definition of QI required activities of known efficacy especially found few risks or harms to discuss. “I am not sure I see much risk. Not to do QI...is risky because you don’t know what you are doing is good either. Doing QI there is always a chance that modification might be better or worse, but you never know unless you try it.” Such individuals strongly believed in institutionalizing a feedback mechanism into the QI process to ensure identification of potential negative outcomes, preferably one that would trigger immediate practice change before actual harm occurred. Bellin and Dubler find a parallel in QA, specifically in retrospective record review. They write that the critical determinant for the work’s non-research status is commitment, prior to data collection, to a corrective plan of action (Bellin and Dubler 2001). They argue that the QI sponsor must have clinical authority to impose recommended changes. One participant even suggested adding a “risk” step in the Plan-Do-Study-Act (PDSA) cycle, a common QI approach. Overall, participants required a functional feedback loop prior to project initiation and generally agreed that the real risk from QI lay in the *absence rather than presence of QI*.

Interviewees also identified potential patient risks. A patient could be harmed by discovering their disease status only after being contacted by QI project staff to participate in enhanced care for that disease. “Social extortion” and patient burden were possible if patients felt compelled to submit to additional assessments or interventions. Interviewees believed that the greatest risk of harm came from privacy considerations around access to sensitive or private health information. Generally, practitioners believed that if no information was disclosed inappropriately, harm was not possible.

Finally, outcomes researchers believed clinicians, more so than patients, needed protection from QI initiatives. As one said,

I have seen studies incentivizing physicians in which the incentives were so strong that they were problematic. ... Sometimes there is so much enthusiasm about one particular medical area or guideline that they push for that one area while taking away from the physician’ judgment to prioritize the patient’s care.

Some projects focusing on clinician performance data were believed to inadequately protect clinician confidentiality. Moreover, some interviewees noted the potential to allocate blame or emphasize individual clinician performance—approaches that can doom a QI endeavor’s effectiveness (Solberg, Mosser, and McDonald, 1997). Generally, though, participants downplayed the risk of QI activities.

Respondents’ modest concern about risk or harm contrasts directly with comments in the literature. Much of the literature examines regulations for protecting human subjects in research projects and extends the underlying ethical considerations to QI practice. Institutions and IRBs confront a paucity of information when considering what patient harms might stem from QI. No general reporting mechanisms track numbers or types of QI projects and associated harms. Few QI activities are reported in the professional literature, often because these efforts deal with local issues that may not be of interest to a broad readership. Research oriented publications commonly reject QI articles because projects lack the methodological rigor of clinical research or, increasingly, because the work was not reviewed by an IRB (Choo, 1998). (Amoroso and Middaugh, 2003; Doyal, 1997; Tobias, 1997) As a result, current reviews of QI focus on the most broad-scale and methodologically rigorous projects—the projects that look most like research (Brett and Grodin, 1991). (Casarett et al. 2000) If interviewees’ views of risk/harm likelihood are based on a fundamentally different perspective of QI than the literature, the literature may be conceptually limited by an emphasis on the research-like aspects of QI projects and a reliance on the research ethics framework to protect human subjects. Nevertheless, the literature may not be completely off base; respondents from research institutions did refer to colleagues naming “research-type” projects as QI, possibly to avoid IRB review. The contrast between the respondents and the literature may also represent a cultural gap between the QI practiced in academic environments vs. non-academic or non-research oriented environments.

The Role of Informed Consent

Interviewees were split over whether patients should receive information about institutional QI projects, though most agreed signed informed consent was unnecessary. Interviewees who considered informing patients about QI generally believed patients should receive information upon admission, including information about potential chart reviews. Some respondents felt that obtaining additional interview data might require informed consent, but through a less rigorous process than that required for research. Participants promoted system “transparency” to engage patients in the health care process and increase patient understanding (Roberts, 2001). (Bellin and Dubler 2001) Most importantly, patients should be allowed to opt out of onerous procedures or data collection. Casarett and colleagues expressed similar ideas. They claim that a QI initiative should be reviewed and regulated as research if it imposes risks or burdens beyond the standard of practice to build generalizable results (Casarett et al. 2000). They point to retrospective data collection from patient records and waiting room satisfaction surveys as possibly burdensome.

Interviewees did not universally agree that such procedures were burdensome or likely to harm patients. Many interviewees conducted QI projects with hospice patients. They noted that IRBs and administrative bodies regularly reject end-of-life care QI projects, believing such patients are too vulnerable and burdened by illness to participate. In the end-of-life care practitioners’ experience, patients often were happy for the opportunity to contribute to the world despite infirmity. Interviewees believed that the hands-off approach harms patients by not allowing improvements or by pushing clinicians to implement clinical innovations without properly measuring the effects. One interviewee cited the common practice of using opiates in suppository form. According to the interviewee, hospice professionals learned through practice that opiates managed pain for terminally

ill patients but swallowing difficulties limited treatment use. In response, clinicians converted the medication into a suppository form without, for the interviewee, proper studies of the risks and potential efficacy of such a change. IRBs and administrators should carefully consider whether additional regulatory review of QI could protect patients or whether it could encourage more unmeasured clinical innovation.

Review of QI, IRBs and Other Administrative Review Possibilities

Interviewees feared the IRB process, regardless of their level of acceptance or rejection of IRB review of QI projects. They felt IRBs lacked the resources and knowledge to judge the merits of QI projects. Further, one noted:

They try to fit the questions into their pre-existing categories and they don't fit well. So, if they are fitting it in the biomedical research category, then they [the IRB] assume you need consent for everything. If they fit it in the non-medical research category, they don't see some areas where you do need more protections. . . . Unfortunately, when they try to apply the same approach to research that studies administrative changes, and has a lower risk, such as implementing an evidence-based guideline, it doesn't always work well.

Most participants agreed with the literature that IRBs are inadequately staffed, unable to perform current tasks (Silverman, Hull, and Sugarman, 2001),(Ilgen and Bell 2001) and lack resources needed to take on an increased workload if projects typically managed as QI were to require IRB review.

Respondents also noted that IRBs' limited flexibility. For instance, time required for IRBs to review protocol changes could significantly hamper the QI process without necessarily providing further protections (See also (Gifford 2000; Cretin et al., 2000).

Some IRB members and practitioners in academic environments believed that researchers are unclear about when a project evolves to the level requiring IRB review. However, evading IRB review, even for a project with minimal harm potential, creates institutional liability risk. Others put it more simply, "Right, wrong or indifferent, our QI doesn't go to the IRB for approval so we don't see it as major issue. Having said that, there is anxiety over whether we can preserve that posture in the context of HIPAA." Participants also noted that new U.S. Privacy Regulations in the Health Insurance Portability and Accountability Act (HIPAA) could move more QI into administrative review (such as by a privacy officer or privacy board), if not IRB review. Interviewees were ambivalent over this prospect:

I guess that I would say with some trepidation, yes. We don't want to increase the workload so that IRBs feel pummeled. But some issues are important. We do QI projects and sometimes...know they will be published. Those things do require oversight, at least a cursory review about what is happening—and the new HIPAA privacy regulations may drive the need for review even harder with respect to confidentiality. But, I am not very happy with what I hear from my academic colleagues. If we haven't gone overboard [with IRB review], we are at risk of doing so and that may hamper not just QI but also research. From what I do understand, for the best of reasons, they [IRBs] have overreached."

Some practitioners and Directors of QI suggested an interim step prior to IRB review. Oral or limited written review of projects, such as from the Quality Improvement Director, could help ensure

some structured examination of the project. Such a review could protect patients, clinicians, and others involved in QI (Casarett et al. 2000). To enable such reviews and/or IRB review of QI, participants hoped for guidance regarding what constitutes QI, what particular human subjects risks could be generated by QI projects, and further support for the moral necessity to perform QI so as to improve healthcare for all patients.

Conclusion

The disjunction between the practitioners' perspectives and the literature may not be the result of fundamentally different definitions of QI or assessments its risk, but instead from the foundation for patient protection from which they begin the analysis. Practitioners generally start from the view that QI is vital to good care—not to continually engage in reviewing and enhancing care harms patients. In contrast, the literature starts with regulations for protecting human research subjects and forces QI practice into this framework. The health care system is poorly served if the research view of QI creates barriers to its continuation. We may be starting to see this complication in recent stoppages of QI projects by the U.S. Office of Human Research Protections (Doezema and Hauswald, 2002; End Stage Renal Disease Networks, 2001). Yet, researchers failing to protect patients or disingenuously using lack of clarity in the QI definition to avoid human subjects regulations may create negative public opinion, more distrust of the health care system, and barriers to ethically sound QI. Given the importance of QI approaches to innovation both within and outside of the public sector, failure to recognize the potential conflicts could also seriously hamper innovation in health care. Conversely, providing information and engaging patients in the QI process—essentially expanding the notion of shared decision making inherent in high quality health care practice to include QI—may enhance the relationship between the patient, the team, and the healthcare system and further support innovation.

Acknowledgments

This paper was supported by AHRQ small conference grant to the RAND Center to Improve Care of the Dying on the Ethics and Epistemology of Quality improvement, Grant # R13HS10961 The author thanks Carolyn Rowe project management support, Chandhana Paka for literature research and Ethel Mitty, Joanne Lynn, Sarah Myers, and Bruce Jennings, and Adam Rogers for editorial support.

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Table 1: Essential Characteristics for Quality Improvement according to Practitioners

- An "institutional focus limited by the philosophy of the institution;"
- Effective or small scale change to ensure minimal harm;
- Follow-up or feedback tied to the entire QI mechanism;
- Timely results, adaptability and flexibility for changing needs and findings;
- Quickly recognized and implemented measurable changes not requiring statistical significance;
- Emphasis on patient related or process level outcomes (e.g. improved staff competency, staff comfort, better service value, or better financial performance);
- Low likelihood of outside funding

Table 2: The Ethical Issues—Literature and Practitioner Perspectives

Issue Area	Literature	Practitioners
Harm or Risk Potential	<ul style="list-style-type: none"> * High degree of unmanaged risk potential * Feedback mechanism may be important 	<ul style="list-style-type: none"> * Focus on known interventions with low risk for harm * Feedback Mechanism required
Ethics Concerns	<ul style="list-style-type: none"> * financial incentives not in patient best interests * measurement burden on patients * privacy concerns * staff clinical competence 	<ul style="list-style-type: none"> * Same as literature plus: * Fairness to participating populations * social extortion * unethical to provide substandard care * patient might learn of condition from QI project
Obligation to Do QI	Potential Ethical Obligation	Absolute Ethical Obligation
Obligation to Do QI Informed Consent	<ul style="list-style-type: none"> * Generally require opt-in as in research 	<ul style="list-style-type: none"> * Opportunity to opt-out but no required opt-in * Transparency of system
Regulation and Administrative Review	<ul style="list-style-type: none"> * IRB review required for a greater scope of QI projects than currently mandated * IRBs lack staffing and resources for current tasks 	<ul style="list-style-type: none"> * Potential for administrative review of QI projects * IRB review too burdensome and fails to appropriately handle minimal risk research * IRBs fail to understand QI and lack flexibility to examine QI