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The Views of Quality Improvement Professionals and Comparative Effectiveness Researchers on Ethics, IRBs, and Oversight

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Abstract

Recently, there have been increasing numbers of activities labeled as either *quality improvement* (QI) or *comparative effectiveness research* (CER), both of which are designed to learn what works and what does not in routine clinical care settings. These activities can create confusion for researchers, Institutional Review Board members, and other stakeholders as they try to determine which activities or components of activities constitute clinical practices and which constitute clinical research requiring ethical oversight and informed consent. We conducted a series of semi-structured focus groups with QI and CER professionals to understand their experiences and views of the ethical and regulatory challenges that exist as well as the formal or informal practices and criteria they and their institutions use to address these issues. We found that most participants have experienced challenges related to the ethical oversight of QI and CER activities, and many believe that current regulatory criteria for distinguishing clinical practice from clinical research requiring ethical oversight are confusing. Instead, many participants described other criteria that they believe are more ethically appropriate. Many also described developing formal or informal practices at their institutions to navigate which activities require ethical oversight. However, these local solutions do not completely resolve the issues caused by the blurring of clinical practice and clinical research, raising the question of whether more foundational regulatory changes are needed.

Keywords

qualitative methods, focus groups, bioethics, research ethics committee, IRB review, informed consent

In recent years, there have been increased efforts to learn more about what works and does not work in clinical care. Some such efforts are conducted under the label of quality improvement (QI), others under the label of comparative effectiveness research (CER). Quality improvement activities have been defined as "systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings" (Lynn et al., 2007, p. 667). Comparative effectiveness research has been defined as "the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in 'real world' settings" (U.S. Department of Health and Human Services [U.S. HHS], 2009a, p. 5). As their definitions suggest, these data gathering activities generate new information intended to improve the quality and efficiency of health care (Institute of Medicine [IOM], 2001; Tunis, Stryer, & Clancy, 2003).

However, these activities often create confusion about when they constitute research and when they require ethical oversight and of what sort. Current human subjects research regulations (U.S. HHS, 2009b) rely on being able to draw a sharp boundary between clinical research and clinical practice[1] (Beauchamp & Saghai, 2012). This is no easy task, especially for QI projects, which sometimes use interventions and systematic methods that challenge whether the activity is research or practice. In addition, CER projects that compare approved interventions in the context of usual care settings raise questions about which aspects of the study are practice and which are research. Activities labeled clinical research must be submitted to an Institutional Review Board (IRB) for review, while clinical care need not. When clinical research and clinical practice are tightly integrated, medical

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(1)	Have there been any [CER or QI] projects with which you were involved, or of which you are aware, where there were questions about whether the activity was practice or whether it was research? And perhaps related, about whether the project needed IRB review of any sort?
(2)	If you have been involved in any [CER or QI] projects that did NOT go to an IRB – what types of oversight, if any, did they receive? Would you call any of that *ethics* oversight?
(3)	For projects that *did* go to an IRB, what have been your experiences? (a) What aspects of a study's design caused difficulties or bottlenecks in the review, or raised questions from the IRB? Was there anything specific to [CER or QI] that perhaps caused bottlenecks for IRB review? (b) Are there any new or tough ethics issues you think emerge in [CER or QI], whether or not these were flagged by an IRB? (c) For projects that did go to an IRB, were there projects where it seemed informed consent was not necessary or where questions about how to handle consent were raised in IRB reviews?
(4)	Are there any projects in which you were involved, or that you considered, that were never conducted because of ethics oversight issues? Have there been any studies you did not do because the ethics oversight would have been too problematic or complicated?
(5)	Are there any strategies or solutions identified in your projects or in conjunction with your IRB or institution that you think might be helpful examples for others in the field?

Figure 1. Questions asked during the focus groups with QI professionals and comparative effectiveness researchers.
Note. CER = comparative effectiveness research; QI = quality improvement; IRB = Institutional Review Board.

professionals, researchers, and institutional ethics oversight bodies may be uncertain whether particular projects require oversight, as well as whether informed consent is needed, and if so, from whom. Concerns have been expressed that this ambiguity results in significant burdens for those working in the fields of QI and CER as well as for their institutions (Selker et al., 2011), with potential additional costs associated with delays as well; the objective of both protecting patients and accelerating improvements in care likely could be addressed by clarifying the underlying confusion.

Despite a growing literature describing the challenges in navigating the "blurred boundaries" between research and clinical practice (Baily, Bottrell, Lynn, & Jennings, 2006; Bellin & Dubler, 2001; Casarett, Karlawish, & Sugarman, 2000; ; Kass, Faden, & Tunis, 2012; Kass et al., 2008; Largent, Joffe, & Miller, 2011; Lo & Groman, 2003; Lynn, 2004; Selker et al., 2011), there is little empirical information documenting the nature and specific types of challenges quality professionals and comparative effectiveness (CE) researchers face. In this article, we provide relevant insights from four focus groups with professionals experienced in the fields of QI and CER. Our aim in this exploratory study was to understand how professionals working in the fields of QI and CER experience and understand ethical and regulatory challenges; we also wanted to learn what formal or informal practices and criteria they and their institutions use to address these issues.

Method

Approach

We conducted four semi-structured focus groups between May 2010 and November 2010. Focus groups are useful for exploring a range of views about a particular topic. Qualitative approaches are often undertaken when little descriptive information exists on a topic (Taylor, Hull, & Kass, 2010).

Focus Group Composition and Recruitment

Two focus groups targeted individuals with experience designing, conducting, overseeing, or funding CER, and two targeted individuals with similar types of experience in QI projects in the United States. Due to scheduling challenges, one CER focus group and one QI focus group were conducted by phone whereas the other two groups were conducted in-person in Baltimore, MD.

To recruit individuals for the groups, investigators familiar with the fields of CER and QI identified experienced individuals in their fields. Attempts were made to include professionals with different clinical and technical backgrounds, from different types of institutions, and from different regions. Letters of invitation were sent to potential participants, co-signed by the investigator with experience in either QI or CER. Follow-up arrangements were made by email or telephone. This project was classified as not human subjects research by the Johns Hopkins Bloomberg School of Public Health IRB.

Description of the Focus Group

Focus group discussions were moderated by two members of the study team (N.K. plus either P.P. [for QI groups] or S.T. [for CER groups]) and audio recorded.

A focus group guide was developed by one member of the study team (N.K.) and reviewed by the other members (Figure 1). Participants were asked whether they had been

involved in activities where questions were raised regarding whether the activity was research, whether it required IRB review or some other form of oversight, about experiences with IRB review and consent, and about solutions they or their institutions had devised. All question types were asked in each focus group, although questions were not always asked in the same way or in the same order. The moderator allowed for significant flexibility in how the discussion proceeded. Participants were asked to provide details about examples or experiences raised.

Analysis

Audio recordings were transcribed, and a study team member verified each transcript against recordings, correcting any mistakes. One study team member (D.W.) reviewed all transcripts and developed a coding scheme. Codes were developed that corresponded both to the questions asked of focus group members and to new ideas raised by focus group members themselves. Text corresponding to each code was then analyzed to discern how often it was mentioned, what types of comments were made, and whether comments differed between groups comprised of QI professionals and groups comprised of CE researchers. All transcripts were independently coded by two coders (D.W. and Y.S.), discussing and resolving discrepancies after each transcript was coded.

Tables were created, organized by code, with all relevant text segments included under each code, and then summaries were created of key findings for each code; these were used to draw conclusions relevant to each theme or question. At each step of the coding process, the two coders (D.W. and Y.S.) met with a member of the study team (N.K.) to discuss the coding scheme and key themes emerging from the transcripts.

Results

Participants

We conducted four focus groups, and each lasted approximately 2 hr. A total of 53 individuals were invited to participate. Twenty participants ended up participating in the four groups (15 males and 5 females; at least 1 female was in each group). Each group had 3 to 9 participants. Participants came from three federal agencies, five academic medical centers, two independent non-profit health systems, two specialty cancer centers, one pharmaceutical company, two consumer advocacy organizations, and two organizations that represent institutions. Participants came from varied regions of the United States, including Atlanta, GA; Baltimore, MD; Boston, MA; Chicago, IL; Durham, NC; New York, NY; Salt Lake City, UT; San Francisco, CA; Seattle, WA; and Washington, DC.

We group our results into four broad themes that emerged through our analysis:

1. the nature and severity of challenges created by the blurring of research and practice,
2. challenges created for institutional oversight bodies as a result of the blurring of research and practice,
3. the criteria respondents used or think should be used to determine when a project needs ethical oversight and/or requires informed consent, and
4. the models of institutional policy that have been developed to address issues created by the blurring of research and practice.

Nature and Severity of Challenges Related to Difficulties Distinguishing Research and Practice

Participants in all four focus groups discussed ethical and regulatory challenges when collecting QI or CER data, describing challenges in general terms and by providing specific examples. Twelve participants provided 36 examples where challenges existed in determining whether their QI or CER activity constituted research or practice, which some further noted created barriers or delays in implementing projects.

Describing the problem generally, one CE researcher stated,

> If you want to have true learning systems where you put all these pieces in there together, you're going to have to have some pieces that clearly are research, and it's going to have to fall within all of the research expectations and you're going to have to have some pieces that are clearly quality and should really fall outside of those research expectations. But there's a lot of gray zone in-between, and how you deal with that can't be decided by one PI [principal investigator] and really sort of needs to be thought through. (C2, P3)[2]

Many of the specific examples provided described activities designed to systematically implement and assess the impact of evidence-based practices or guidelines on patient outcomes, or investigate the barriers to the adoption of best practices. One QI professional described a perinatal project to improve quality where the hospital had had some malpractice claims. The participant described the project as involving the implementation of a training program for health care professionals that was based on accepted clinical guidelines. The participant described,

> [s]o I guess, in a sense, there was a hypothesis. There was no statistical plan . . . It was a purely quality initiative. Not with any attempt to generalize this . . . But at the end of the day, even without a statistical plan, the results were striking and the reduction in our claims and our dollars paid out were striking. And it did get published, and it probably did influence other people even though that was an unintended consequence. So I think you do have a hybrid. (Q1, P7)[3]

Similar examples were raised by other QI professionals of activities evaluating software to improve physician shift changes, implementing a new electronic medical record tool for their hospital, and introducing an environmental care checklist to prevent suicide, all of which had elements of both research and practice.

One participant from a CER focus group mentioned designing a project with colleagues to improve the use of an evidence-based drug to boost white blood cells for cancer patients. The team wanted to implement a project where clinics are randomized to either "automatic order entry according to guidelines" or usual care. The participant said, "It's been a conundrum . . . whether that's a quality improvement issue or whether that's actually research" (C2, P5).

Another CE researcher mentioned that a network of clinics "developed an electronic patient-reported outcomes monitoring system as a way of initially trying to understand and monitor patient-recorded concerns about toxicity." The participant described that

> [d]uring the development of that [system], we would take the system in and out of the clinic as we would kind of get things up and running, and it started to irritate the physicians because they would get used to having it in their clinic as a part of practice . . . So they went to the hospital and said you need to make this a standard part of what we do, so now it's a standard part of every single one of our clinical visits . . . but it's also still the research data set that we were developing and it is still being populated as the research data set. So . . . it was very blurry as to when it shifted from being a research activity to a clinical [one]. (C2, P3)

And yet a QI professional gave an example of a retrospective project designed to determine whether physicians from several university hospitals were complying with a set of bundled care guidelines: "We found we actually had some potentially publishable results, but none of the folks from the multi-center group, nor any of the editors ever said, 'Gee, you know, what about an IRB?'" (Q1, P2).

IRB oversight. When describing interactions with IRBs around their QI and CER projects, many focus group participants described variations in how IRBs interpret oversight requirements, delays in IRB review, and confusion over when informed consent was needed and from whom; several participants also described examples of positive interactions with their IRBs.

Three QI professionals and three CE researchers provided examples of IRBs drawing inconsistent conclusions about projects. Examples included IRBs differing from one another in whether specific projects required IRB review and whether informed consent was required from research participants. One QI professional concluded,

> If you leave [the decision about what counts as research versus practice] to . . .all of the local IRBs, you get a thousand different opinions . . . And maybe that's okay. That's sort of the nature of our society . . . But it will hamper our efforts to learn from our health care system if we don't have, I would think, some sort of national standards [about what requires review]. (Q1, P6)

One QI professional and two CE researchers felt that delays in IRB review for projects in the "gray zone" resulted from the fact that these projects differ in notable ways from the types of projects that IRBs are accustomed to reviewing. The QI professional noted that many QI protocols constantly evolve depending on the outcomes collected, and IRBs are generally not trained to oversee these sorts of evolving protocols (Q1, P1). A CE researcher similarly stated, "If you're doing something out of the box it just makes IRBs go crazy" (C2, P5). This researcher elaborated that the IRB process has resulted in delays for several of his projects including one that took 2 years for IRB review and approval; he now writes a staff person into each grant proposal to manage regulatory issues (C2, P5).

Informed consent. Participants from all four focus groups discussed situations in which they were required to get informed consent but where they believed obtaining consent was inappropriate. One QI professional discussed an activity designed "to study the effects of clinical alerts on reducing the use of inappropriate medications in the elderly." He explained,

> We randomized the physicians to receiving [the clinical alerts] or not, and we put it through the IRB, and we ended up having to offer the physicians an opportunity to opt out of it. But, arguably, it's not terribly different than what's going on, and I would say in some ways the risks of this are lower because we're actually taking something that there's some consensus about what to do. (Q1, P6)

A CE researcher similarly questioned whether consent is needed to be obtained from patients for an intervention to improve shared decision making, an intervention that he believed would eventually become the clinical standard:

> So the patient comes in. You know what the chief complaint is. Let's say it's back pain, and let's say you have a state-of-the-art protocol that's designed for really fostering shared decision-making when you're getting data from the patient and the whole intent is to infuse that encounter with a lot more guidance information versus usual care. That, I think is going to become a common norm where we can learn real time, where there's something that we think and believe is the best guideline [for] care possible. It has to be at least as good as usual care. Does that get done with consent or not? (C1, P1)

Criteria Used to Distinguish Research From Practice

Participants in all four focus groups discussed different criteria that they believe are currently used or believe should be used to distinguish research activities requiring oversight from activities that do not require institutional ethics oversight. Participants discussed criteria they find confusing and criteria they find useful.

Intent to produce generalizable knowledge or to publish. Intent to produce generalizable knowledge or to publish was the most prominent criterion participants mentioned as being used to distinguish research requiring oversight from practice. We group these two together as both rely on the notion of prior intention, and several participants seemed to use "intent to publish" as a proxy for intention to generalize findings beyond the environment where the activity was being conducted. Intent was discussed by 10 participants from three focus groups, with most participants believing it was not an appropriate criterion for deciding whether an activity requires oversight. Two QI professionals specifically said it is an inappropriate criterion because of the difficulty telling what someone's intentions are. One stated, "Trying to understand somebody's intent is basically a standard that one can't judge by. You don't know what somebody's intent is . . . It seems to me you have to use other criteria that are measurable" (Q1, P5).

Intent to produce generalizable knowledge was discussed at length by four QI professionals in the same group who agreed it was difficult to anticipate what would be of interest only locally from what is potentially generalizable. One said,

> They [the IRB] always harp on . . . the generalizability issue . . . That's very tough. I mean we say, "Well, you know, we are doing something that's very unique to this situation. You know, at that time we weren't aware of anyone else who's doing exactly this thing." So it's not generalizable in that sense, but it's going to be of interest to people. I mean even though we can't say it's generalizable, other people are going to look at this and make interpretations, and it's probably going to influence what they do. They may try to reproduce it, and it might become generalizable over time. It's almost like this is not a static thing. (Q1, P3)

Several respondents were troubled with the use of intent to publish as a criterion. One CER professional mentioned that although his institution uses this criterion for determining what needs oversight, he finds it to be confusing (C1, P1), and two different participants (one QI professional and one CER professional) commented that results of activities can still be published even if the activity was not reviewed by the IRB (Q1, P7; C1, P2). In addition, two QI professionals and one CER professional mentioned that it is not possible to know up front if an activity's results are going to be worthy of publication (Q1, P2 and P8; Q2, P2). However, despite participants finding this criterion illogical, one QI professional explained that many people at his institution submit QI projects to the IRB expressly because they are concerned they will not be able to publish results if they do not get IRB approval (Q1, P7).

Risk of harm. There was generally a more positive response to using risk of harm as a criterion. Participants in three groups (four QI professionals and two CE researchers) commented that the level of uncertainty about risk of harm to participants is a valuable criterion for determining which activities require oversight. One CE researcher commented, "Well, I guess for the study I'm thinking about I think it should go to an IRB because it is involving a drug that has risks and a condition that has risks" (C2, P5). Two QI professionals, however, specifically said risk of harm was appropriate for determining what should have oversight but *not* for distinguishing what should be labeled research versus routine clinical practice. One stated,

> To me, it gets back to . . . risk . . . the question is protecting patients, and whether it's QI or research is something that people can debate until the bars close, and no one will ever agree. So if you can agree that patients need to be protected, then you need to have some kind of mechanism for deciding. (Q1, P6)

Two QI professionals specifically commented that when evaluating risk to help determine whether an activity needs oversight, it is important to consider whether the activity puts people at additional risk of harm compared with standard clinical practice (Q1, P5; Q2, P2).

Adopting a different perspective, one QI professional commented that because any activity has the potential to increase risk and because the investigator is not in the best position to assess risk, all activities should receive some form of oversight. To illustrate his point, he described an example of a QI activity that did not receive oversight and that was

> designed to get . . . computers to the bedside, and we were doing all this great testing of devices. The head of infection control said, "What the hell are you guys doing? You don't have these keyboards protected properly. You're creating all this new risk." And perhaps if somebody had asked us to sort of submit those plans for a little bit more scrutiny [that risk would have been identified sooner]. (Q1, P6)

Two CE researchers also mentioned the risk of activities using identifiable health information, in which case they believed oversight should be required (C1, P1; C1, P2).

Two QI professionals from the same focus group raised a different kind of consideration, using a different sense of risk. These respondents emphasized the importance of comparing the risk of conducting QI activities with the risk to patients as a whole of the status quo or of not doing anything, noting that research can help to address quality and safety problems that exist in clinical medicine today (Q1, P4 and P8).

Manipulation of medical care for reasons not relevant to patients' best interests. Two QI professionals from different focus groups commented that anytime an activity requires that something be done to a patient because it is necessary for the activity, rather than because it is in the best interests of the patient, the activity should be considered research requiring ethical oversight. One argued that an activity constitutes research "where some other end or goal was coming before the best result for this particular patient" (Q2, P2). The other stated that if those involved in an activity,

> do something not because right now [they] think it's the best thing for the patient . . . but because [they are] committed to collecting the data and [they're] going to continue to do things in the way that the data needs to be done [that activity needs to be overseen by an ethics oversight body]. (Q1, P1)

Related, two CE researchers and one QI professional discussed randomization. The QI professional, who had said oversight was needed when an activity's goals come before the best interests of patients, also stated, "if you randomize, it's IRB" (Q2, P2), later clarifying that he meant individual patient-level randomization, not cluster randomization. However, the two CE researchers questioned randomization as a criterion because there is so much random variation in routine clinical care. One commented that some doctors prefer one intervention over another "without any level of evidence" (C1, P2) whereas the other suggested that randomizing patients does not necessarily increase risk to patients: "Which is more harmful, randomizing where there's clinical equipoise or just letting it happen as it does, haphazardly, or in ways that we just don't understand the motivation for?" (C1, P1).

Experimental or non-standard approaches. Three QI professionals from different focus groups and one CE researcher mentioned that if an activity involves new or experimental interventions or if the intervention provided "drifts away from established best practices" (Q1, P2), that activity should be considered research requiring ethical oversight. One CE researcher commented, "If there's an experimental intervention and if this is new treatments, this is observing something that is particularly sensitive information that you otherwise wouldn't get, that clearly belongs over there in the research box" (C2, P3). One QI professional similarly stated,

> To me, the degree to which it starts to verge from recommended practice . . . You know, once you're starting to test new ideas about things that improve human biology and human response to disease or—to me, it starts to smell more like science and discovery. (Q1, P6)

Models of Institutional Policy and Informal Practices for Oversight and Informed Consent for QI and CER Activities

There was discussion in each focus group about different approaches, agreements, or formal or informal practices that are used by individuals and/or their institutions to provide oversight for, or determine when oversight is needed for, QI and CER activities. In addition, a few participants discussed several different models of informed consent that are used within their institution. While some participants discussed challenges or delays in oversight questions, no participants described abandoning an activity for these reasons. Rather, several participants have worked with their IRBs or their institutions to identify solutions for resolving oversight questions.

Two CE researchers explicitly stated that all CER in which they are involved is first reviewed by the IRB. One noted, "For the stuff that I'm doing . . . everything goes to the IRB" (C1, P2). The other similarly said, "We put everything through our IRB" (C2, P5). This same CE researcher suggested it would be useful if there were reciprocity among IRBs when conducting multi-center CER studies:

> Comparative effectiveness research by nature is going to be . . . almost always multi-institutional. And to have to go through IRB procedures at all those different places that touch the data is just extraordinarily inefficient. So to me, I would like to see a world where IRBs as a rule agree to cede their authority to a single IRB which would oversee a project that involves multiple groups. (C2, P5)

A different CE researcher described having worked out with his IRB an arrangement whereby he, as an individual investigator, has received a broad IRB waiver to conduct a specific type of retrospective observational CER design that relies on routinely collected information about patients from outside his institution:

> I have a waiver for all of my research actually because I don't touch human subjects directly. So that's actually how . . . we dealt with this . . . So like all of our work, you know, Medicare, any other sort of data sets, even acquiring clinical trial data

> from other institutions, some of the multi-center studies where there's been IRB approval at that site, and then we reprocess the data or do meta-analysis . . . All that stuff, it's all under a waiver . . . our institutional view on this actually is that our IRB largely exists to protect our patients. And so, because almost everything I do involves data from other institutions, they don't feel that they actually have much of a domain in that. (C2, P1)

The models of oversight discussed by QI professionals were more diverse. Several participants discussed models where all QI projects were reviewed before being implemented, but not necessarily by a group or individual with an ethics charge. One QI professional commented that QI projects are reviewed at his institution by a quality council:

> I think that the way our institution, and I suspect most institutions, handle this is at the level of senior leadership communication and discussion. And at our institution there's weekly . . . Quality Council—and that's where all the vice presidents and department chairs review stuff that's happening, and that involves also reviewing . . . the hospital quality improvement . . . And I think if there is any oversight of these kinds of activities, it's happening at that kind of forum. (Q1, P6)

Another QI professional commented that all QI activities at her institution are approved by those in charge of health systems management (Q1, P8).

A different QI professional commented that at his institution, many QI activities receive oversight by the IRB even though they do not necessarily require IRB oversight:

> Protocols get sent to the IRB here at [academic institution] that are strictly quality improvement but people are submitting them under the guise of research because of—they think, I guess, it strengthens their proposal to be approved by the IRB or whatever. But we get many, many projects here that are not research that are submitted to our IRB. (Q1, P7)

A QI professional in a different focus group commented that there is a separate study section of the IRB responsible for overseeing QI activities: "Our IRB kind of understands this work and has a separate study section set aside for this, and we have a bunch of different little working groups that do different sorts of research protocols" (Q2, P3). Another QI professional discussed—similar to a strategy raised by a CE researcher above—that his institution is considering granting broad IRB approval for certain types of QI activities:

> What we're working at the IRB to do . . . is to create a kind of omnibus QI . . . IRB approval, which covers a range of our usual QI activities. It specifies the data we'll be collecting, and then every year we'll put on our renewals what the projects we're going to be evaluating this year are, using those data. And we talked more about our controls, I guess, you know, kind of our data safety monitoring and how are we monitoring for adverse and beneficial effects, and that's a work in progress. (Q2, P3)

One QI professional described a process where IRB liaisons have the responsibility of determining whether IRB oversight is required for a given activity:

> We have IRB liaisons at each of our centers, and that's our usual point of contact. And that person usually helps us make—and has the power to make the determination: Research, non-research. I think they can also make the exempt, non-exempt. So it gets stopped there. There are things that wouldn't go to the IRB because this person says this is clearly not [research]. (Q1, P3)

In addition, two QI professionals also described checklists being used to determine whether a project requires IRB oversight. One commented, "[t]here's often a lot of uncertainty about does this need the IRB at all, and our IRB is pretty good about working with you to screen a project using a checklist" (Q2, P3). The other commented that his institution has "a series of questions we ask—that you run the series of questions, you decide if it goes to an IRB. It gives the answer. And we actually have it built into our website where people cue up projects" (Q2, P2).

Several QI and CER participants mentioned how helpful it was to have ongoing discussions with their IRB chairs about appropriate oversight of QI or CER activities. One QI professional said, "We've been working with them [the IRB] for years. Whenever there's turnover, we have to kind of re-educate the new people that are on the committee" (Q2, P3). Another QI professional remarked,

> We try to put the chairs through training around what we're doing and why we're doing it and lay out some pretty good background. We've been able to put some policies in place to make it functional that people are comfortable with, so it runs pretty smoothly for us. (Q2, P2)

A CE researcher similarly discussed working with his IRB regarding oversight of retrospective observational CER studies: "We trained our IRB over the last 10, 15 years to understand that type of research because [the IRB] comes from the classical randomized trials paradigm, and by now they very well understand this type of research" (C1, P2). And another CE researcher mentioned meeting with the IRB chairs to discuss appropriate conduct of CE activities. This individual commented that her IRB is very CER savvy and when the IRB has issues with one of her protocols,

> [t]he IRB Chair usually calls me, and he will . . . say, "I think we need to talk about this." And that's been helpful because . . . it becomes a conversation and we kind of work our way through. So in other words, he doesn't see the end product not doing the research, but what's a practical way forward and that this is meaningful. (C1, P3)

A QI professional also stated that there is reciprocity among all IRBs in his health care system and suggested that developing reciprocity among IRBs at other institutions outside of his health care system "would be an incredible win" (Q2, P3).

Finally, two different QI professionals described a practical solution whereby, they said, QI professionals will often avoid labeling a project as research. One stated,

> We never call it research. We have like research centers, but we call them centers of inquiry. If we send out a form for people to fill out, we call it a questionnaire, not a survey because a survey has a certain feel of epidemiology to it. A questionnaire doesn't, you know. [We have created] little work-arounds like that to get things done. (Q1, P8)

Models of informed consent. The topic of models of consent came up only twice in our discussions. One QI professional commented that at his institution, providers must participate in QI activities as a condition of their employment:

> Our primary responsibility is to our patients, and we think that we have both a legal obligation and a core institutional [obligation] to do quality assurance, and so there is no question that if you're employed or working here, that we get to oversee your quality of care. And I think that any institution that's struggling with that relative to employees needs to examine their morals. (Q2, P2)

In addition, one CE researcher gave examples of three different models of informed consent. The first was for physician-targeted interventions:

> One of our trials, for example, we have a physician information activity to get up to speed with diagnosis of a certain condition, how to treat this, and, of course, the unit of randomization then is the physician and the physician's practice, so we get the informed consent, obviously, of that physician, right? And it's at that setting actually I don't think you need informed consent of the individual patients. (C1, P2)

This same individual continued that for large retrospective observational studies, the IRB often grants waivers of informed consent:

> We work with tens of thousands of patients mostly in our studies, and we say the rationale why we can't ask for informed consent from the study subjects is that it's impossible to contact them in retrospect and contact them in such large numbers, and we need those large numbers in order to carry out the research . . . And to this day, in a hundred percent of the cases, we were successful in making our case that the research benefit outweighs the minimum to no risks to the individuals, to study participants. (C1, P2)

The last example provided by this CE researcher was an opt-out approach used when enrolling patients in a randomized controlled trial (RCT). He explained that the institution and the insurance company worked together to identify patients with a certain health condition. When patients experienced the condition, an automatic alert was triggered,

> and we check whether they [the patients] fit the eligibility criteria, and then we enroll these patients identified in the claims databases into a randomized trial, and the intervention is that you get all medication for free versus the usual cost-sharing activity. And the individual patients get notified that they can opt out. (C1, P2).

The participant elaborated that the IRB was originally reluctant to approve this opt-out approach but ultimately did so.

Discussion

This is one of the first projects of which we are aware to collect detailed information about the experiences of QI and CER professionals with regard to ethical oversight and consent.[4] Three key themes emerged: (a) most participants, across both QI and CER, described challenging experiences and confusing criteria regarding QI and CER activities and ethical oversight; (b) participants identified other criteria that do not appear in current human subjects regulations that they believe would be more appropriate; and (c) many participants described working with their institutions and particularly their IRBs to develop local solutions to navigate which activities require oversight.

That both QI and CER participants so readily and uniformly provided examples of challenging, inconsistent, or delayed reviews of what they often considered to be low-risk QI or CER activities provides empirical support for the challenges related to ethics, QI, and CER described more generally in the literature (Baily et al., 2006; Bellin & Dubler, 2001; Casarett et al., 2000; Kass et al., 2012; Largent et al., 2011; Lo & Groman, 2003; Lynn, 2004; Selker et al., 2011). One highly publicized such example was "an evidence-based safety initiative" implemented by Peter Pronovost and colleagues to reduce catheter associated infections in intensive care units across the state of Michigan (Kass et al., 2008; Pronovost et al., 2006). Although the IRB at the investigator's institution

determined the activity was exempt, requiring no further oversight or informed consent, the Office for Human Research Protections (OHRP; 2007) later disagreed, concluding the project was not exempt and that "JHU failed to ensure that the requirements for obtaining and documenting the legally effective informed consent of the subjects or the subjects' legally authorized representative . . . were satisfied."

More recently, several scholars engaged in low-risk CER activities have argued these activities blur "the line between the two often distinct paradigms of clinical care and clinical research . . . [and] challenge institutional review boards to carefully consider the definitions of 'engaged in research' and the requirements related to informed consent" (D'Avolio et al., 2012, p. e175). Related, Selker and colleagues (2011) questioned the necessity of IRB oversight for low-risk QI and effectiveness activities given their importance to normal health care operations.

The Common Rule suggests two criteria that are necessary and jointly sufficient to distinguish research activities from practice: (a) the intent to contribute to or generate generalizable knowledge and (b) the systematic implementation of interventions and the collection of data. These criteria, along with regulatory definitions of what counts as a human subject, significantly define what types of research require oversight according to the Common Rule. Interestingly, only one participant, a QI professional, mentioned the second criterion. And of note, while many participants discussed the first, they generally concluded that intent to produce generalizable knowledge or the related intent to publish were not useful criteria for distinguishing what activities should be subject to IRB oversight. Although some participants stated their local IRBs relied on these criteria, most participants felt they were conceptually confusing and ethically inappropriate. Some stated it may be hard to know, early in an activity, whether the results will be worth publishing. Others mentioned it is conceptually hard to distinguish local learning from learning generalizable to other situations as generalizability is a matter of degree. Scholars similarly have argued that it is difficult to ascertain intent (Casarett et al., 2000; Kofke & Rie, 2003) and that generalizability is not a binary concept, but falls along a spectrum (Kass et al., 2013). Indeed, some suggest eliminating the intent to produce generalizable knowledge criterion from determinations about oversight (Selker et al., 2011).

Instead, many participants suggested that considering the risk of harm to participants in a QI or CER activity makes more sense when determining what should be subject to ethical oversight, a view consistent with recommendations in the literature (Lo & Groman, 2003; Selker et al., 2011). Other criteria that several participants felt were relevant included whether a QI or CER activity implements an experimental intervention, diverges from best practices, or involves procedures that benefit only the learning activity and not the patients affected, views that also have been voiced previously in the literature (Casarett et al., 2000; Faden, Kass, Whicher, Stewart, & Tunis, 2013; Largent et al., 2011; Lynn et al., 2007). While one individual noted that randomization of patients automatically triggers the need, in his experience, for oversight and consent, a few noted that randomizing patients to interventions does not always increase risk and thus should not necessarily be sufficient cause alone for ethical oversight without additional scrutiny of what is being randomized. Again, this is consistent with views expressed in the peer reviewed literature (Faden, Beauchamp, & Kass, 2014; Truog, Robinson, Randolph, & Morris, 1999).

Across focus groups, participants described solutions that they, with their institutions, have established for navigating the challenges created by the blurring of research and practice. Solutions discussed were responsive to existing regulations and most aimed to provide guidance on which activities must be reviewed by an IRB. Examples included IRB liaisons or checklists for determining when activities needed to go to an IRB and broad IRB approval for certain types of low-risk, records review CER. Several participants also mentioned meeting with or "educating" their local IRB about QI and CER methods so that the IRB was more familiar with these types of activities. In addition, several QI professionals described QI activities being overseen by groups that do not necessarily have an ethics charge. This approach is consistent with the results of a study conducted by Taylor, Pronovost, Faden, Kass, and Sugarman (2010) who found that QI initiatives are routinely reviewed by various internal mechanisms but rarely through an IRB. Finally, several QI professionals mentioned avoiding calling a project research because using the label of research triggers the need for institutional oversight and possibly informed consent.

These findings might be read in two different ways. They might seem troubling if one considers that in many institutions, the individuals designing and implementing the QI activities are left with the responsibility of determining whether the activity constitutes research requiring IRB oversight. The IRB apparatus was in fact built to avoid this type of self-regulation. For example, we heard from one QI professional that he and his colleagues under-estimated the level of risk involved with the implementation of a QI activity. One topic that deserves further consideration is who should ultimately be responsible for making the decision regarding which learning activities require ethical oversight and which do not.

However, the same findings might be read differently. Professionals engaged in QI or CER activities do not subvert the rationale for independent ethical oversight of some activities. Indeed, many of our respondents—and scholars in the literature—voiced a precise opinion about the criterion that they believed should trigger oversight and its

extent, namely, the degree of additional risk or burden imposed on participants by the activity, beyond the level that they would have experienced in their usual care. The problem arises because what constitutes research, as defined by current regulations, is conceptually unclear. The same activity can be reasonably viewed as *either* research requiring oversight or QI not requiring oversight.

As the comments of our participants so clearly illustrate, navigating what is required from both an ethics and a regulatory perspective in the blurry terrain of QI and CER is often challenging. Several groups of experts suggested ways to mitigate these challenges in the context of the current regulatory environment. For example, one group has proposed that for QI in particular, projects are more likely to constitute research that should be subject to IRB oversight if they involve (a) randomization, (b) testing of experimental interventions, (c) involvement of researchers who do not have a commitment to the organization where the research is being conducted, (d) outside funding by an institution that has commercial interests in the results, and (e) non-continuous feedback of data (Baily et al., 2006). Another set of scholars suggested sending activities to an IRB when "the majority of patients involved [in those activities] are not expected to benefit directly from the knowledge to be gained," and those activities pose additional risks and burdens to patients beyond those the patients would have encountered absent the activity (Casarett et al., 2000). A more recent article also suggested risk-based assessment, whereby the need for ethical oversight is entirely indexed to the level of risk imposed by the study on the participants (Selker et al., 2011).

A more fundamental question is whether changes in current regulatory requirements are warranted, and if so, whether those changes should be introduced through exemptions for QI and CER activities, a redefinition of research, or innovations as to the criteria used to determine the nature and extent of oversight. An advanced notice of proposed rulemaking suggested in 2011 that modifications to federal human subjects regulations might be made (U.S. HHS, 2011), some of which may be helpful to QI and CER, but as yet no further action in the direction of rulemaking has been announced. Although many suggest regulatory changes that remain faithful to the distinction between research and clinical care, a group of scholars has recently put forward a new framework that does not rely on this distinction to determine which activities require oversight. Moreover, unlike other alternative models proposed, this framework does not rely on a single criterion (such as risk) for determining needs for oversight or consent. Rather, a series of ethical obligations are outlined that together would determine the degree of oversight or consent required for any given activity (Faden et al., 2013).

There were several limitations to this study. First, we conducted only four focus groups, with a total of 20 QI and CER professionals. Second, participants were purposely selected to be thought leaders in their respective fields. The experiences and views of thought leaders may not be representative of others doing QI or CER, and, as we had only 20 participants, even of other thought leaders. Third, group discussions were limited to 2 hr, which may not have been sufficient time for some thoughts or themes to emerge, particularly in larger groups.

Nevertheless, the views put forward by these participants are consistent with what has been reported in the literature anecdotally. In both QI and CER, it can be difficult to determine which activities require IRB oversight and consent and which do not. Moreover, even where local solutions emerge that help QI and CER professionals work around these difficulties, the solutions—while important testaments to the commitments of IRBs and investigators to work together toward reasonable, pragmatic solutions—are not necessarily ethically coherent or satisfying given the inconsistencies that many appreciate still often exist. Moreover, these local solutions may impart risks to patients, organizations, or society, potentially stalling learning and the sharing of information. Given the enormous new investment in both QI and CE work in recent years (American Recovery and Reinvestment Act of 2009; Centers for Medicare & Medicaid Services [CMS], n.d.; McCurdy, 2011; Patient Protection and Affordable Care Act of 2010), better way forward must be found. Those active in the field are clear that solutions are needed beyond simply finding ways to call activities by different names. Addressing these issues will require revisiting the definitions used in current regulations and developing clearer guidance regarding which features of QI and CER activities trigger the need for ethical oversight and informed consent.

Best Practices

Working within the current regulatory requirements, the participants in this study suggested it was helpful to meet with one's IRB to explain the nature of QI or CER activities and to arrive at solutions together. Specific solutions have included developing IRB checklists or IRB's granting broad approval for a certain type of study. For QI, participants also discussed that these activities are sometimes overseen by a group without an ethics charge. Given the limited sample size of this study, other useful practices likely have been achieved by other institutions as well. In the short term, CER and QI professionals might consider discussing these options with officials at their institutions.

Research and Policy Agenda

A clear finding from this study is that many QI and CER professionals find current Common Rule criteria confusing and not always synonymous with what they think matters

most ethically. These respondents believed that risk should be given greater weight in determining the degree of oversight an activity should receive; future work should determine whether others share this view, as well as any alternative criteria that other respondents believe are important. Furthermore, research should increasingly test alternative structures and approaches to oversight and begin to evaluate and share such experiences.

Educational Implications

The findings of this article would likely be most effectively taught to ethicists, policy makers, and other relevant stakeholders by generating a series of examples of QI and CER activities that involve both components of usual clinical practice and clinical research. Several such examples are provided in the "Results" and "Discussion" sections of this article. Discussing these examples is useful in illustrating the challenges faced, from a practical perspective, in determining which activities or components of activities constitute research requiring ethical oversight and informed consent, under current regulatory requirements, for QI and CER activities.

Authors' Note

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Notes

1. By clinical practice, we mean activities related to treatment of medical conditions, billing, and other activities that are necessary to the normal functioning of a health care institution and that have traditionally fallen outside of the regulations of human subjects research.
2. The letter "C" indicates that the quote is from a CE researcher. The number "2" indicates that this quote was said during the second of the two focus groups with CE researchers. Within each focus group, participants were assigned a unique number. "P" stands for participant and the number following it indicates that the quote was said by inidividual 3 within that group.
3. The letter "Q" indicates that the quote is from a QI professional. The number "1" indicates that this quote was said during the first of the two focus groups with QI professionals. Within each focus group, participants were assigned a unique number. "P" stands for participant and the number following it indicates that the quote was said by individual 7 within that group.
4. With the exception of an exploratory project conducted by Melissa Bottrell in 2003 titled "The Ethics of Quality Improvement: Practitioners' Perspectives." This project was commissioned by the Epistemology and Ethics of Quality Improvement Project at the RAND Center to Improve Care of the Dying. Additional information can be retrieved from http://www.innovation.cc/peer-reviewed/bottrell-ethics.pdf

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