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Patient-Centered Outcomes Research: Stakeholder Perspectives and Ethical and Regulatory Oversight Issues

Emily A. Largent, J.D., Ph.D.,
Research Associate, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School

Joel S. Weissman, Ph.D.,
Center for Surgery and Public Health, Brigham and Women's Hospital

Avni Gupta, BDS, M.P.H.,
Center for Surgery and Public Health, Brigham and Women's Hospital

Melissa Abraham, Ph.D., M.Sc. [Assistant Professor],
Harvard Medical School, Department of Psychiatry, Massachusetts General Hospital and Faculty Associate Center for Bioethics, Harvard Medical School

Ronen Rozenblum, Ph.D., M.P.H. [Director],
Unit for Innovative Healthcare Practice and Technology, Brigham and Women's Hospital Harvard Medical School

Holly Fernandez Lynch, J.D., M.Bioethics [Executive Director], and
Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School Faculty, Center for Bioethics, Harvard Medical School

I. Glenn Cohen, J.D. [Professor]
Harvard Law School, Faculty Director, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Harvard Law School

Over the past decade, increasing emphasis has been placed on both patient-centered care and patient engagement.[1] A growing body of evidence suggests that meaningful involvement of patients in their own care can lead to greater patient satisfaction, improved clinical outcomes, enhanced efficiency of healthcare services, and even reduced costs.[2] As a result, patient-centered care is now recognized as an essential feature of a high-quality healthcare system. Patient-centered outcomes research (PCOR) "is the bridge between facilitating patient-centered healthcare interactions at an individual level and creating a more patient-centered healthcare system."[3]

The Patient-Centered Outcomes Research Institute (PCORI), the leading research institute in the United States for PCOR, defines PCOR as research that "helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options."[4] Further, PCORI explains that "the definition of PCOR includes many components" of comparative effectiveness research (CER).[5] To achieve the aims of PCOR, PCORI shifts the familiar clinical research paradigm, in which investigators choose which questions to ask and how, and requires that the research proposals it funds include patients and other stakeholders at *every step* of the research

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process—"from proposal development to research design and dissemination of the study results."[6] The underlying belief is that research meaningfully informed by the patient perspective is more likely to be used to inform patient decision-making and, in the end, to improve patient outcomes.[7] As of early 2017, PCORI had awarded approximately $1.66 billion dollars, funding more than 580 projects.[8]

The proliferation of PCOR studies—whether funded by PCORI or others—has resulted in calls from various stakeholders, including investigators and institutional review boards (IRBs), to address technical and methodological challenges as well as "to examine ethical and regulatory oversight" mechanisms.[9] Such examination is important, as ethical and regulatory challenges could erect barriers to PCORI's major initiatives to generate data needed to improve patient care.[10] Although anecdotal evidence suggests that investigators and IRBs have found oversight of PCOR to be particularly burdensome, no one has yet performed the rigorous investigation needed to answer two key questions: (1) what are the main ethical and regulatory oversight challenges for PCOR, and (2) are those oversight challenges substantively new or different as compared to those arising in other types of research (therefore demanding new approaches), or are they simply familiar issues playing out in a new context (therefore satisfactorily addressed within existing ethical and regulatory frameworks)?

PCORI funded our multi-year mixed-methods project, the Patient Centered Outcomes Research Oversight Study (PCOROS), to begin systematically answering these two crucial questions. The qualitative data gathering effort described herein was primarily intended to inform a national survey of IRB chairpersons, which is currently in the field. These qualitative and quantitative efforts, in combination with a literature review, will ultimately form the basis for recommendations to facilitate appropriate ethical and regulatory oversight of PCOR, as well as inform a policy conference.

The objective of this article is to present our qualitative findings. Our preliminary data suggest that familiarity with PCOR is incomplete and that while oversight challenges do arise, existing frameworks are likely adequate to address them. Additionally, our data raise a critical issue: for all the emphasis placed on patient engagement, and for all the resources PCORI devotes to it, very few investigators reported that patient-centeredness was having any substantive impact on their studies.

METHODS

Our qualitative research, which was exploratory in nature and sought to generate novel insights into ethical and regulatory oversight of PCOR studies, combined multiple methods: institutional case studies, individual interviews, and focus groups. We utilized these three qualitative methods in diverse settings and contexts in order to capitalize on the strengths of each, to triangulate our findings, and ultimately, to generate stronger data.

A semi-structured interview guide was developed based on expert opinion, input from the PCOROS Stakeholder Advisory Panel (comprised of IRB members, investigators, research ethicists, and patient and family advisors), and a review of the literature. Having a master

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guide, tailored in limited ways as appropriate, ensured consistency in the questions asked across each of the respective data-gathering contexts. Because our focus was on policy rather than individual behaviors, the questions always covered the same four domains: (1) how to define PCOR; (2) what, if any, ethical and regulatory oversight challenges arise in relation to PCOR and to what extent these challenges are perceived as novel; (3) how, if at all, oversight challenges are currently being addressed and how they should be addressed in the future; and (4) general demographic information. Interview guides are available from the authors upon request.

Our primary mode of data collection was the institutional case study. Case studies are an "investigation of a specific, unique system with patterned behavior, dynamic properties, and defined features."[11] We used purposive sampling to select three organizations with experience conducting a range of PCOR studies: a research-intensive medical school, a school of public health, and an independent hospital system. The principal investigator (PI) and at least two additional members of the PCOROS research team visited each site between March 2016 and May 2016. At each organization, we conducted a series of face-to-face interviews, which are known to result in greater detail and elaboration as compared to telephone interviews, to draw lessons about research oversight that could in turn be transferred to a larger group of cases. The interviews granted us an understanding of PCOR oversight from multiple perspectives—such as IRB members and investigators, as well as project managers, research nurses, and high-level administrators; afforded us opportunities to examine the content and effects of institutional policies and structures on oversight; and allowed for a deeper exploration of the research and oversight culture of the organizations.

In addition to the case studies, we conducted 13 individual interviews between November 2015 and March 2016. We utilized snowball sampling, a technique that supplements purposive sampling by asking interviewees to identify other information-rich informants.[12] Interviewing began with members of the PCOROS Stakeholder Advisory Panel, who were chosen in the first instance because they are nationally recognized leaders in the field, and we made additional contacts based on their recommendations. In this way, we gained expert opinions external to the three organizations that comprised our case studies. At least one, and typically two, members of the research team participated in each individual interview. Interviews were telephonic and generally lasted between 30 minutes and one hour.

Finally, we conducted six focus groups between November 2015 and July 2016: two in-person with IRB members and chairs recruited from among attendees at the 2015 Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research Conference; two online with PCOR investigators recruited from among PCORI-funded investigators and authors of published articles reporting use of PCOR methods; and two—one online and one in-person—with patient and family advisors recruited via hospitals' Patient and Family Advisory Councils and PCORI-funded investigators. Focus groups are often, as here, used in combination with individual interviews because, whereas individual interviews offer depth, focus groups offer breadth.[13] Participants were chosen to ensure geographic, institutional, gender, and professional background diversity. Each focus group included between 7 and 10 participants and was co-facilitated by the PI and at least one other member of the PCOROS research team.

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Our combination of qualitative research strategies permitted us to gain insight from a relatively wide range of individuals, to elicit multiple experiences and perspectives, and to add depth to our findings. In all, we spoke with more than 100 individuals engaged in various aspects of PCOR (see Table 1). All participants granted their informed consent verbally and were assured confidentiality. The study was deemed exempt by the Partners Healthcare IRB (#2015P001946/BWH).

A rigorous approach can help to ensure the reliable discovery of emergent themes from qualitative data. To ensure the quality of the data and its interpretation, our analysis generally followed the multi-step, iterative process described by Miles and Huberman.[14] The first step was familiarization, in which a review of the material was undertaken to intellectually immerse ourselves in the data and to begin to list key ideas, emphasizing the four domains from our interview guides. Two members of the research team analyzed the notes and verbatim transcripts from each of the case studies, individual interviews, and focus groups to develop and summarize cross-cutting themes—that is, common responses mentioned by multiple respondents across data collection modes—until no new themes emerged. Because we were interested in a thematic and policy analysis more than individual behavior or the development of grounded theory, we were able to perform the coding manually. Team meetings were held to reach consensus on main themes from the data. Relevant quotations from respondents explaining or elaborating on a theme or sub-theme were noted and keyed to a separate file of quotations.

RESULTS

Five main themes emerged from our work (see Table 2). Hereafter, “respondents” will be used to refer collectively to case-study participants, individual interviewees, and focus group participants, as distinctions are most helpfully drawn between their PCOR-associated roles rather than between the data-gathering contexts.

THEME 1. Respondents emphasized the patient perspective in their definitions of PCOR, but many remain uncertain about what exactly PCOR is and what methods are entailed.

When asked to define PCOR, most respondents emphasized the importance of the patient perspective. For example, one investigator explained, “‘Patient-centered’ means actively incorporating the patient voice in everything that we do.” And an IRB member explained, “I think this is focused on primarily doing things that are of importance to patients and not rhetoric . . . having patients participate.” Others described PCOR in terms of patients but had a slightly narrower focus; for example, multiple respondents included “patient-reported outcomes” in their definitions.

As a group, investigators—particularly those with PCORI-funding—had the easiest time defining PCOR and seemed most confident in their definitions. Investigators were also most likely to discuss PCOR methods, such as CER, and also to know about PCORI-funded Clinical Data Research Networks (CDRNs), which aim to collect clinical information on at least 1,000,000 patients, and Patient-Powered Research Networks (PPRNs), which aim to enroll more than 50,000 patients for common conditions.[15] By comparison, IRB members were generally less confident when defining PCOR. A number of IRB members, for

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instance, defined PCOR as studies that are “PCORI-funded” or explained that “[t]o me, [PCOR] meant the same as PCORI.” Others admitted that they weren’t “familiar with [PCOR]” or said, “I don’t know. I don’t know.” Notably, few of the IRB members defined PCOR in terms of methods that might be used.

THEME 2. Respondents identified widespread engagement of patients in non-traditional roles as the one novel aspect of PCOR from an ethical and regulatory oversight perspective.

Although respondents were given the opportunity to indicate that PCOR involves *no* new ethical or regulatory oversight challenges, they repeatedly identified the widespread involvement of patients in non-traditional roles—that is, in roles other than the traditional role of human subject—as a novel issue. Few felt that there were any other novel ethical or regulatory oversight challenges.

Respondents described various non-traditional roles that can be assumed by patients engaged in PCOR. According to both patients and investigators, patients are most often engaged as “advisors” or “consultants.” In these roles, patient responsibilities may include providing insight into their lived experience, reviewing survey instruments, and commenting on recruitment materials. In some instances, patients are engaged to help with recruitment, community engagement, and dissemination of results. Only rarely were patient collaborators described as “co-investigators” with responsibilities such as data collection and data analysis.

Respondents had highly disparate views on whether and to what extent patients in non-traditional roles need to be protected by IRBs. “Some IRBs,” one patient advisor said, “see that someone has the ‘p-word’ [patient] next to their name and [conclude they have] to be protected . . . I think that’s ridiculous.” Some IRB members shared the opinion that traditional subject protections are inappropriate in this context, as patients in non-traditional roles are not objects of study. Other IRB members, however, felt that despite occupying non-traditional roles, these individuals should be treated like traditional research participants because they are likely being asked to share personal experiences with the research team. These IRB members believed that patients in non-traditional roles should, for example, provide informed consent even when not technically serving as “subjects” under the federal regulations. A third group of IRB members identified the problem but described feeling conflicted about how best to proceed.

Several respondents reported contentious relationships between patients in non-traditional roles and IRBs. In these instances, patients in non-traditional roles perceived the IRB as a barrier to conducting the research that was important to them, rather than as a source of protection. This dynamic was reported by a variety of stakeholders. For example, one investigator described how delays perceived to be caused by IRB review “turn[ed] patients [in non-traditional roles] off” to participating in her research. Another investigator related how the patient organization with which she was working deemed the IRB to be “interfering” and found IRB review “too burdensome [and] complicated;” this contributed to the ultimate demise of the patient organization-investigator collaboration. One patient lamented, “From what I can tell, patients are willing to take on more risk than the IRB

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would approve. . . . Going through the traditional IRB process isn't going to gain anything but [will] dilute my efforts and energy." Although some respondents suggested that more education is needed so that patients in non-traditional roles will understand the importance of IRB oversight, a point discussed further below, a handful of others suggested that having patients embedded in the research team should lead to a reassessment of the necessity of some traditional elements of ethical and regulatory oversight.

A few respondents indicated that when patients are engaged in non-traditional roles it is not the patient but the *institution* that needs to be protected. More generally, there were questions about whether the IRB could or should require patients in non-traditional roles to be considered formal study staff, and therefore undergo training in research ethics and regulation, privacy training, or even TB testing if interacting with other patients or coming on-site to a hospital. In some instances, these were described as human resource requirements, not IRB requirements. Respondents reported highly variable practices around training and "onboarding" of patients in non-traditional roles.

THEME 3: Respondents perceived many barriers to the meaningful engagement of patients in non-traditional roles but did not widely view lack of meaningful engagement as a problem for IRBs to resolve.

Although most patient and family advisors reported that they were meaningfully engaged in their own PCOR studies, several respondents—a group including patient and family advisors, patient engagement advocates, and investigators—perceived patient involvement in PCOR as no more than "checking a box" because "[the investigator] needed someone to get funded." Further, only a handful of investigators reported that patient involvement had, in their personal experience, been a true partnership or resulted in substantive changes to their studies.

Respondents identified various barriers to meaningful engagement of patients in non-traditional roles. Most often, they cited what one respondent deemed "cultural barriers." That is, patients were insufficiently steeped in research culture—lacking knowledge about the purpose of IRB review, research methods, or the medical jargon and research-specific acronyms investigators bandied about—to contribute meaningfully to a study. Many respondents asserted the importance of having training for patients in non-traditional roles—both in research methods and the ethics of human subjects research. Such training, they felt, would "level the playing field" between investigators and patients and enable patients in non-traditional roles to make more substantive contributions. Yet, some expressed caution and worried that such training could turn patients into "insiders," thereby losing the unique (i.e., non-researcher) perspective that is a key feature of PCOR.

In a similar vein, some investigators and patient and family advisors raised concerns that patients chosen to act in non-traditional roles are more likely to be a vocal and well-educated minority—and, therefore, not necessarily representative of the larger community of patients. In several instances, researchers reported reaching out to advocacy organizations, some of which were supported by industry, to catalyze collaborations.[16] Select respondents noted that this may lead to a kind of conflict of interest related to "capture": through their association with and training by an advocacy organization, the patient may represent that

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organization's views, which can differ from those of the "typical" patient on whom the study is focused.

Patients and investigators also discussed the perceived inadequacies of compensation for patients assuming non-traditional roles. While some were of the opinion that these patients should be compensated comparably to investigators in order to demonstrate that the groups' respective contributions to PCOR are equally valued, the norm around compensation appears to be small payments made on a per-meeting basis. In the vast majority of cases, respondents reported that their institution's IRB did not review offers of payment made to patients in non-traditional roles, though a few said that such offers should be reviewed for the possibility of coercion and undue influence.

Generally, respondents felt that it was the role of investigators and funders to ensure that patients were more meaningfully engaged in PCOR and that this—while extremely important—was not a regulatory or ethical oversight issue within the purview of the IRB. Nevertheless, many respondents stated that additional guidance around patient-engagement would be welcomed, not only to inform their own decisions but also to provide a standardized approach within and between institutions.

THEME 4: Respondents reported that, although the ethical and regulatory oversight issues associated with PCOR are largely familiar, PCOR oversight is nevertheless relatively challenging as compared with traditional clinical research.

With the exception of engagement of patients in non-traditional roles, discussed above, the general consensus among respondents was that PCOR does not present novel ethical or regulatory oversight challenges. Even so, respondents characterized oversight of PCOR as relatively more burdensome than oversight of traditional clinical research and described significant investments of time and energy in securing IRB approval. When pressed, respondents had three main explanations for this.

First, PCOR occurs on a scale that presents oversight challenges. For example, one respondent explained, "I don't think [PCOR is] a unique issue, but it potentially brings up a unique perspective" on issues like waiver of informed consent because PCOR is more likely than traditional clinical studies to involve large numbers of patients. As mentioned above, PCORI-funded CDRNs aim to include at least 1,000,000 patients, and PPRNs aim to include at least 50,000. One investigator described spending many months "mud wrestling with the IRB" about appropriate recruitment strategies and consent procedures for a large study of this kind.

Second, PCOR studies are often conducted at multiple sites, which can lead to variations in IRB review. An investigator described a study that was approved in 2 days at one site but took 3 months to be approved at another. While respondents recognized that variability and delays in IRB review are not themselves unusual, they described them as particularly frustrating for both IRBs and investigators in light of the deadline-driven schedule of PCORI-funded contracts.[1]

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Third, the growth in PCOR has corresponded with growth in new technologies, and ethical and regulatory oversight challenges related to these technologies have not yet been satisfactorily resolved. One respondent explained, "I think . . . the rise in PCOR coincides with a lot of other trends." She pointed to the use of social media and mobile health (mHealth) (i.e., "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices"). [17] Although respondents noted that both social media and mHealth are being used in many different kinds of research, they identified these technologies as a particularly common source of oversight challenges in PCOR. Investigators were excited about the opportunities presented by social media and mHealth for advertising to and recruiting research participants, gathering data, and disseminating research results. In fact, many felt that such technologies made PCOR possible—how else, for example, could you find 1,000,000 patients? IRB members were, by comparison, more reserved. In particular, they worried about the rapidly changing technological landscape and discussed the complexities of maintaining sufficiently current knowledge to keep abreast of possible ethical and regulatory oversight issues. One IRB chair described his "resignation that we're never going to understand it." Other IRB members explained that they rely on investigators to explain new technology to them while also recognizing the bind this placed them in. IRB members and high-level administrators raised concerns about data ownership and security, as well as privacy and confidentiality.

THEME 5: Respondents explained that IRBs and institutions are still identifying best practices for ethical and regulatory oversight of PCOR.

Despite a lack of consensus among respondents that PCOR demands special oversight given that many of the ethical and regulatory oversight issues are familiar ones, some IRBs have begun to develop policies on how best to proceed with PCOR studies, both in an effort to improve the efficiency of oversight for these projects and to ensure that research is conducted in an ethical manner. These efforts, however, are generally in the preliminary stages, and respondents declined to share their draft policies publicly. It is a minority of institutions in our sample that have or are developing such policies.

Other strategies were offered as either complements or alternatives to formal policy development. For instance, multiple IRB members and investigators reported that their institutions encourage PCORI-funded investigators to talk to one another and share best practices. Several IRB members and investigators described the benefits of scheduling regular meetings between the study team and the IRB to begin before a research proposal is submitted to PCORI and continue through IRB-approval. Such meetings allow investigators to anticipate and address problems in a manner satisfactory to the IRB and ideally to avoid delays that could threaten PCORI-imposed deadlines. Several IRB members also described having a single IRB member or staff person who could act as a point-person for PCOR-related issues.

Finally, a handful of respondents stated that their institutions have policies on use of social media and mHealth in research (i.e., not limited to PCOR), and several more reported having such policies in development. Drafting such policies was characterized as "challenging" and

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"not straightforward": in particular, the technological landscape changes so fast that policies can quickly become outdated. Some respondents explained that their institutions rely on information technology (IT) experts to review research-related use of technology and expressed the value of having an identifiable expert to approach with questions and concerns. This was the exception, however, and many lamented not having access to such resources.

DISCUSSION

Our initial motivation for this project was anecdotal evidence suggesting that ethical and regulatory oversight of PCOR studies was proving burdensome for IRBs and—by extension—for other stakeholders. Our qualitative data reflect that IRB review can be time-consuming and challenging in this context. Yet, our preliminary findings caution against assuming that this burdensomeness is the outgrowth of novel ethical and regulatory challenges inherent to the PCOR approach. Rather, there are many familiar issues in PCOR studies, and we are generally optimistic that existing frameworks can be adapted to facilitate its conduct.

THEME 1

Because the term PCOR was neither commonly used nor formally defined at the time of PCORI's creation, a "foundational" task for PCORI "was to clearly describe the field of patient-centered outcomes research."[18] A transparent, iterative process yielded the definition that PCORI uses today, which emphasizes asking and answering patient-centered questions. With this background in mind, we sought to understand how respondents define PCOR. While most respondents correctly emphasized the importance of the patient perspective, only a minority seemed truly confident in their proffered definitions.

Despite appreciating the importance of patient-centeredness, few non-investigator respondents defined PCOR in terms of its research methods. There was not widespread familiarity, for example, with PCORI's view that PCOR "is a type of comparative clinical effectiveness research."[19] This is not to say that responses excluding CER are necessarily wrong; they may, however, be meaningfully incomplete. Although it is unsurprising that investigators who have successfully competed for PCORI contracts and are conducting PCOR studies are the most conversant in PCOR methods, an understanding of methods is a necessary building block of sound ethical and regulatory oversight.

We speculate that the lack of definitional clarity surrounding PCOR, particularly on the part of IRB members, may be due in part to the fact that PCOR still makes up a small percentage of the studies IRBs are charged with reviewing even at institutions with relatively higher levels of PCORI funding. A lack of familiarity with PCOR may manifest in definitional uncertainty and could also make PCOR seem more novel than it actually is. Indeed, this may explain some of the anecdotal evidence about perceived burdensomeness that motivated this project. We suggest that more education is needed to familiarize stakeholders with the aims and methods of PCOR and to facilitate ethical and regulatory oversight.

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THEME 2

Respondents were generally skeptical that PCOR raises new ethical or regulatory issues beyond the engagement of patients in non-traditional roles. They identified a number of open questions regarding what, if any, protections patients in non-traditional roles need from IRBs and what protections institutions might need as the line between investigators and patients is blurred. Yet, we resist the conclusion that these are novel oversight questions—even if they are new to many of our respondents.

In fact, such questions have been raised and explored in other areas of research.[20] For example, community-based participatory research (CBPR), which engages community members in developing and evaluating strategies for health improvement, has long encouraged sharing of power and decision-making between investigators and community representatives.[21] CBPR researchers have previously identified many of the challenges flagged by our respondents as ethical issues in their own research. For instance, a 2013 review of literature on ethical CBPR identified both obtaining consent from individuals who occupy dual roles as researchers and participants and perceived inflexibility of investigators who may appear to prioritize the needs of their research over participants' needs as challenges of CBPR. PCOR stakeholders could doubtlessly benefit from interdisciplinary dialogue with CBPR stakeholders. However, there are caveats: IRBs generally "are unfamiliar with CBPR"[22] (a claim which seems consistent with our findings) and "a noticeable theme in some of the [CBPR] literature is the difficulty of fitting CBPR into the process and procedures for institutional ethical review."[23] Additionally, not all of these issues have been satisfactorily resolved in CBPR, despite the attention given over to them. Therefore, we suggest that lessons can be drawn from CBPR but will need to be further developed and adapted to PCOR.

THEME 3

We found wide variation in the extent to which patients were involved in the conduct of PCOR, and in some instances, patient engagement seemed mostly to be window dressing. This is at odds with the goal of PCOR, and of PCORI more specifically, to promote meaningful patient engagement in research so as to facilitate creation of a more patient-centered healthcare system. Yet, we agree with the majority of respondents that ensuring high-quality patient engagement is not appropriately IRBs' role. IRBs should be mission-focused on protecting research participants. It is, therefore, necessary to consider both who should hold investigators accountable for the quality patient engagement and how this will be achieved.

Our findings raise a number of questions deserving of further empirical study, of which we will highlight three. First, an important threshold issue in PCOR is *which* patients are selected to participate in non-traditional roles. (Here again, comparisons to the CBPR literature are insightful.[24]) While it has been commonplace to worry about, and require disclosure and review of, investigator conflicts of interest (COI), we found no such attention paid to the question of *patient* COI.[25] It was not clear an IRB or institutional official would be aware of a situation where a particular patient serving in a research role was trained by, or even employed by, a disease advocacy organization or a drug company. But the problem runs

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deeper than such direct COI. If PCOR is to meet its goals, the patients selected for non-traditional roles must be, in some measure, truly *representative* of the patient community. While our data is preliminary, it does suggest that for several reasons—availability, cultural synergy with the non-patient investigators, etc.—the patients selected for these non-traditional roles tend to be more educated, more vocal, and more familiar with the healthcare system than the typical patient might be. PCORI and those studying PCOR should undertake a more systematic examination as to which patients are serving in non-traditional roles and whether they are disjunctive from the target patient populations for particular PCOR studies. It should also consider putting in place COI reporting for patients serving in non-traditional roles and potentially requiring benchmarks for not only patient participation but representativeness as well.

Second, how should patients be prepared to assume non-traditional roles so that they can become true partners while maintaining their distinctive patient perspective? Numerous studies suggest shortfalls in research participants' understanding of key terms.[26] Thus, it is predictable that patients in non-traditional roles might need help when taking a seat at the table, but it is unclear how best to achieve this. Relying on advocacy organizations to provide training, as often seems to happen now, can perpetuate the COI issues just discussed. Third, how should patient-engagement be measured? Many of our patient-respondents claimed to be satisfied with their own levels of participation; this was in sharp contrast with investigators' candid admissions that patients in non-traditional roles had little to no substantive impact on their research. This suggests that patient self-report may be insufficient to capture the quality of patient engagement, and alternative approaches need to be identified and evaluated.

THEME 4

Complaints about the burdensomeness of IRB review are not new.[27] It was, therefore, unsurprising that respondents identified ethical and regulatory oversight challenges and burdens that PCOR shares in common with other types of research. PCOR studies are, for instance, often carried out at multiple sites, a practice that has become an increasingly common feature of non-PCOR studies as well. At present, IRB approval is typically required at each study site, although this is changing. The National Institutes of Health (NIH) has issued a policy requiring the use of single IRBs in multi-site clinical research studies,[28] and the recent revisions to the Federal Policy for the Protection of Human Subjects or "Common Rule" require participating U.S. institutions engaged in cooperative research to rely on a single IRB.[29] A common criticism of the current redundant review process is that it can create inefficiencies and add delays.[30] These critiques were echoed by many PCOR investigators we interviewed, as well as by IRB members who discussed the challenges of multi-site review. Current trends in research oversight may, therefore, have incidental benefits for PCOR.

THEME 5

Our findings strongly suggest that PCOR does not demand wholly new approaches to research oversight. Rather, existing ethical and regulatory frameworks can facilitate oversight if further developed, appropriately adapted, and made available to PCOR

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stakeholders. The literature on ethical CBPR offers a prime example. By extension, it appears unlikely that IRBs need to develop PCOR-specific oversight policies. That said, we encourage stakeholders to continue identifying strategies (such as sharing best practices among PCOR investigators and routinizing meetings between IRBs and investigators) to make oversight both more efficient and more effective. Strategies like these may be particularly useful given PCORI's emphasis on milestones—project objectives and deliverables to be accomplished at specific times during the study.[31] Finally, we are optimistic that the perceived burdensomeness of oversight may decline as IRBs and other stakeholders gain increasing familiarity (and comfort) with PCOR.

A notable exception to this adaptation of "off the shelf" guidance, however, pertains to the use of social media and mHealth in PCOR. Social media platforms and the Internet have created major shifts in how patients connect with healthcare providers, and subsequently with clinical researchers.[32] PCOR investigators, patient and family advocates, and research participants appear largely to have embraced these opportunities. Yet, these new technologies have created ethical and regulatory oversight challenges that have yet to be satisfactorily resolved, although notable efforts are underway.[33] There is a need for guidance on how IRBs should review protocols incorporating these technologies, as well as to consider who beyond IRBs should be involved in approving their use. Institutional resources for such review appear uneven, but it would be useful to have further empirical research to characterize institutional practices. Development and adoption of guidance on best practices for ethical and regulatory oversight of these technologies will have the dual benefits of addressing an oversight challenge that commonly arises in PCOR and of addressing a challenge in clinical research more broadly.

LIMITATIONS

The primary goal of our qualitative data collection was to inform the design of a national survey of IRB chairpersons about oversight of PCOR. As such, it was not designed to achieve saturation on all themes. Rather, it was intended to identify issues for survey development. Moreover, though we aimed to have diverse institutions represented in our sample, our numbers were insufficient to compare and contrast differences between institution types, and our findings may not generalize to a broader group. While our data identify important emergent themes, additional empirical data will help clarify and confirm our observations.

CONCLUSION

PCOR is increasingly common; yet, to date, the ethical and regulatory oversight issues associated with PCOR have not been well defined. Ours is the first qualitative study to ask stakeholders about oversight challenges they associate with PCOR. Our data suggest that the key areas of interest are engagement of patients in non-traditional roles and the potential exacerbation of oversight issues that also arise in other types of clinical research. In order to realize the potential of PCOR, further work is needed to educate stakeholders about the aims and methods of PCOR and to allow these issues to be explicitly addressed through policy

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guidance, scholarship, and empirical research. Nevertheless, we suggest that existing ethical and regulatory frameworks can be adapted for use in PCOR.

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TABLE 1.

Overview of Study Participants

	INSTITUTIONAL CASE STUDIES			FOCUS GROUPS	INDIVIDUAL INTERVIEWS	TOTAL
	Site 1 Academic Medical Center	*Site 2 School of Public Health*	*Site 3 Hospital System with Significant Research*			
IRB Members and IRB Chairs	2	6	3	19	2	32
PCOR Investigators	6	2	1	17	5	31
PCOR Project Managers	7	3	5	0	0	15
Patient and Family Advisors/Patient Engagement Advocates	0	0	1	14	1	16
Research Ethicists	1	0	0	0	3	4
High-Level Administrators	2	1	0	0	0	3
Regulators	0	0	0	0	2	2
TOTAL	18	12	10	50	13	103

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Table 2.

Main Themes Identified

- THEME 1: Respondents emphasized the patient perspective in their definitions of PCOR but many remain uncertain about what exactly PCOR is and what methods are entailed.
- THEME 2: Respondents identified widespread engagement of patients in non-traditional roles as the one novel aspect of PCOR from an ethical and regulatory oversight perspective.
- THEME 3: Respondents perceived many barriers to the meaningful engagement of patients in non-traditional roles but did not widely view lack of meaningful engagement as a problem for IRBs to resolve.
- THEME 4: Respondents reported that, although the ethical and regulatory oversight issues associated with PCOR are largely familiar, PCOR oversight is nevertheless relatively challenging as compared with traditional clinical research.
- THEME 5: Respondents explained that IRBs and institutions are still identifying best practices for ethical and regulatory oversight of PCOR.