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Patient Engagement In Research: Early Findings From The Patient-Centered Outcomes Research Institute

ABSTRACT **Charged with ensuring that research produces useful evidence to inform health decisions, the Patient-Centered Outcomes Research Institute (PCORI) requires investigators to engage patients and other health care stakeholders, such as clinicians and payers, in the research process. Many PCORI studies result in articles published in peer-reviewed journals that detail research findings and engagement's role in research. To inform practices for engaging patients and others as research partners, we analyzed 126 articles that described engagement approaches and contributions to research. PCORI projects engaged patients and others as consultants and collaborators in determining the study design, selecting study outcomes, tailoring interventions to meet patients' needs and preferences, and enrolling participants. Many articles reported that engagement provided valuable contributions to research feasibility, acceptability, rigor, and relevance, while a few noted trade-offs of engagement. The findings suggest that engagement can support more relevant research through better alignment with patients' and clinicians' real-world needs and concerns.**

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Engaging consumers, patients, and other health care stakeholders as research partners offers great promise in producing evidence that is more relevant to patients' needs. Thus, identifying, understanding, and supporting engagement practices that contribute to the design, conduct, and uptake of research is an important policy issue. This knowledge can inform best practices, policies, and resource allocation related to the types, intensity, and circumstances of patient and other stakeholder engagement in health research.

The authorization of the Patient-Centered Outcomes Research Institute (PCORI) in 2010[1] offers an unprecedented opportunity to examine engagement practices and contributions. PCORI is unique among large clinical US research funders in requiring engagement—particularly from patients or consumers—in study design, conduct, and dissemination. PCORI has funded hundreds of projects that operationalized engagement in different ways, ranging from community forums to advisory panels and patient coinvestigators. PCORI's requirements and general guidance about the purpose and principles of engagement[2] provide a shared context for studying the contributions of engagement on a larger scale than has been done before. Furthermore, PCORI was created to fund comparative effectiveness research that compares the benefits and harms of clinical interventions in real-world settings, so engaging people who will receive those interventions is particularly salient.

Previous efforts to aggregate the literature on engagement include both analyses of descrip-

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tions of engagement in the context of studies on other health topics[3–5] and a meta-analysis of studies about the association between engagement and participant recruitment.[6] This literature suggests that engagement contributes to research questions and outcomes that are important to patients and their caregivers, as well as enhanced enrollment and retention of study participants.[3–6] However, these earlier studies are limited because published descriptions of engagement are relatively uncommon and highly variable in depth and content.[3,5] Also, randomized trials of engagement are narrowly conceptualized and focus only on a specific aspect, such as recruitment, rather than broader research engagement. Many PCORI comparative effectiveness research project findings are published in peer-reviewed journal articles, and—although not studies of engagement—many describe engagement approaches and views of how engagement affected the research. These articles provide information about the contributions of engagement based on PCORI research teams' real-world experiences.

This article analyzes 126 peer-reviewed articles that include descriptions of PCORI research teams' experiences with engagement. The questions guiding this review were: What are the contributions of engagement to PCORI-funded comparative effectiveness research? What engagement approaches did research teams use to achieve these contributions? How did research teams assess the contributions of engagement?

Study Data And Methods

We conducted a qualitative analysis of descriptions of engagement in PCORI-funded research published in peer-reviewed journals. Systematic review methods were inapplicable because we analyzed descriptions of partner engagement in the context of studies—not findings from studies of engagement. Nonetheless, we followed relevant guidance for consistency and quality control to identify and select articles and to extract relevant text.[7] We also used the terms *projects* and *articles* to describe our sample, rather than *studies*, to reflect the type of information we analyzed.

ARTICLE IDENTIFICATION We identified articles published through February 27, 2018, that were associated with PCORI funding by searching PubMed, Google Scholar, Web of Science, EBSCO Discovery Service, and PCORI's system for monitoring funded studies. The search strategy is presented in online appendix exhibit A1.[8]

ARTICLE SELECTION We included peer-reviewed articles that acknowledged full or partial PCORI funding and were directly related to a PCORI comparative effectiveness research project. We excluded meeting abstracts and articles on non–comparative effectiveness research projects, such as projects intended to improve research methods. Next, two reviewers independently screened the full text of articles to identify those describing the contribution or contributions of engagement to the project. Disagreements about inclusion were discussed and resolved with an independent third reviewer.

We defined *research engagement* as the involvement of patients, caregivers, and other stakeholders (such as clinicians, payers, and policy makers) in the planning, conduct, or dissemination of research.[2] On a continuum, engagement practices ranged from one-way input to shared leadership[9] (see exhibit 1 for definitions and examples of engagement approaches on a continuum). Qualitative methods, such as focus groups, were classified as engagement (one-way input) when articles described these practices as engagement rather than research.[9,10] Contributions were defined as the incorporation of learnings, insights, or priorities of partners into the project; changes in project plans; or confirmation of the value of planned approaches. We looked for explicit language aligned with this definition (for example, *selected, developed, refined, informed*, and *co-led*) rather than ambiguous descriptions of engagement activities (such as *participated* or *reviewed*).

EXTRACTION For the 126 articles that met our inclusion criteria, all text descriptions of engagement contributions, practices, and measurement (whether positive or negative) were extracted verbatim from the articles, including supplemental materials, using a standardized form in an Excel database (appendix exhibit A2).[8] Plans for engagement and theoretical discussions of engagement were not extracted. Articles could describe multiple unique contributions of engagement or multiple discrete engagement techniques.

QUALITATIVE ANALYSIS We followed Elizabeth Bradley and coauthors'[11] techniques to iteratively develop and apply codes and conduct content and thematic qualitative analyses of extracted text—except that in applying the final code set, we used single coding with quality checks for all codes by Laura Forsythe. Our main content codes addressed project phases -from defining the research question through dissemination, as well as engagement practices and contributions, partner types (appendix exhibit A2),[8] and alignment with the engagement continuum (exhibit 1). We also coded articles on the amount of information about engagement contributions and practices. Our analysis focused on specific or measured contributions rather than general

Continuum of engagement practices

	Input	Consultation	Collaboration or shared leadership
Use in sample	12% of projects described only input	46% of projects described consultation, either exclusively or in addition to input	37% of projects described collaboration or shared leadership, either exclusively or in addition to other practices
Defining characteristics	Patient and other stakeholder partners provide information researchers use in defining agendas and making decisions Information typically flows unidirectionally Partners have no decision-making ability	Patient and other stakeholder partners provide support or advise on specific study attributes on an ongoing basis or as needed Information flows both uni- and bidirectionally Decision-making authority is limited to activities defined by research team	Patient and stakeholder partners actively define agendas and make decisions Information flows bidirectionally Decision-making responsibility is shared
Examples	Focus groups In-depth interviews Surveys User-experience testing Crowdsourcing Conferences/forums	Advisory panels Working groups External advisers	Co-investigators Research team members Embedded advisers Steering committees Community-based participatory research (CBPR)/participatory approaches

SOURCE Authors' analysis of peer-reviewed journal articles with descriptions of the contributions of engagement to comparative effectiveness research funded by the Patient-Centered Outcomes Research Institute. **NOTE** The location on the engagement continuum is unknown for an additional 4 percent of projects that provided minimal description of engagement.

statements lacking detail (see appendix exhibit A3 for definitions).[8] Using engagement contributions to recruitment as an example, a statement that partners helped "craft the recruitment strategy" was classified as general, while a statement noting that "stakeholders recommended utilizing a multipronged approach of clinic recruitment, church-based recruitment, and social media recruitment, to allow for the most representative sample"[12(p7)] was coded as specific. Additionally, if an article, for example, compared recruitment rates before and after implementing partners' recommendations, we classified the engagement contribution as measured. We organized thematic analyses of types of engagement contributions by project phase and analyzed by project, rather than by article, to avoid duplicating information from projects with multiple articles.

STAKEHOLDER ENGAGEMENT We collaborated with PCORI's Advisory Panel on Patient Engagement through a series of meetings (appendix exhibit A4 includes details).[8] We first solicited input on the project goals and approach and then elicited iterative feedback. Specifically, the advisory panel provided guidance on applying a continuum to engagement approaches, recognizing challenges in identifying engagement contributions for more integrated teams, identifying important analytic questions, interpreting findings, and planning dissemination.

LIMITATIONS Our analysis had several limitations. First, it represented PCORI-funded comparative effectiveness research projects with the interest in publishing in peer-reviewed journals and ability to do so. Projects in our sample may be more likely to have been completed, have more compelling findings, or have more impactful engagement experiences.

Second, we analyzed what authors (typically, but not exclusively, researchers) reported about engagement, so our analysis rested on their perceptions, as well as journals' interest in engagement. In particular, our ability to detect negative or unintended consequences of engagement could have been limited by authors' desire to describe positive experiences more than negative ones.

Third, descriptions of engagement varied greatly in level of information and language used. Some articles, including those focused on research methods or findings, provided great detail about engagement.[13–15] Excluded articles may reflect a lack of engagement, minimal engagement impact, or unclear or underreporting of explicit contributions. This analysis could underreport engagement contributions for projects that truly shared leadership and did not distinguish the source of contributions.

Fourth, we were also unable to assess the quality of engagement processes or whether engagement was authentic versus tokenistic.

Finally, our analysis was based on PCORI's earliest comparative effectiveness research proj-

ects, many of which were funded before formal engagement guidance and PCORI's shift toward larger, more targeted projects. More recent projects could have different engagement experiences.

Study Results

SAMPLE DESCRIPTION We included 126 articles (appendix exhibits A5 and A6 present a flow diagram and list of included articles).[8] Most articles were reports of original research (52 percent) or descriptions of study protocols (39 percent) (appendix exhibit A7 includes more detail about the sample),[8] and collectively they represented more than one-third of PCORI-funded comparative effectiveness research projects during the relevant period. Thirty percent of the articles included an aim to describe engagement. Nearly all articles (98 percent) were written about a single PCORI comparative effectiveness research project. Projects in the sample were commonly randomized trials (83 percent), and they covered conditions from breast cancer to diabetes and serious mental illness. Nineteen percent specifically tested strategies to reduce health disparities.

WHAT ARE THE CONTRIBUTIONS OF ENGAGEMENT? We identified two sets of themes: the contributions of engagement to PCORI-funded comparative effectiveness research projects and the effects of engagement contributions. Exhibit 2 summarizes the two sets of themes, including the number of projects reporting each theme, by project phase. We found engagement contributions in all project phases, and 73 percent of

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EXHIBIT 2

Summary of contributions of engagement and effects of contributions described in included articles, by project phase

Project phase	Themes for contributions of engagement	Themes for effects of contributions
DESIGN		
Research focus (41)	Identification or expansion of topic (5) or aims or research questions (5) Determination of outcomes (35) Choice of comparator(s) (6)	Research focus that is meaningful for patients (36) Comparators that are acceptable, feasible, or most relevant (4)
Research design (19)	Practical aspects (for example, setting or timeline) (7) Broader inclusion/less restrictive exclusion criteria (7) Choice of designs, including numbers/types of arms (9) and participant allocation/randomization (3)	Address real-world barriers to implementation (6) Alignment with patients' preferences or practical realities (4) Maximize participation of real-world patients (8)
Interventions (54)	Adaptation of intervention elements, including delivery (20), materials or tools (14), and topics or content (18) Training for intervention providers (4)	Less burden for patients or providers (12) Alignment with participants' culture (6) and preferences (21) Enhanced intervention usability (14) Greater adherence to or retention in interventions (6)
CONDUCT		
Recruitment/enrollment (24)	Optimal strategies to find or recruit for specific populations or settings (11) Appropriate recruitment and consent materials (7)	Effective communication to the target population (4) Strong/enhanced enrollment (7) More generalizable findings (3)
Retention (7)	Frequency or timing (3) and modes of follow-up (4) Incentives for study participants (3)	Alignment with patients' preferences or practical realities (5)
Data collection/measures (25)	When or how to collect data (7) Selection (6) or assessment (4) of measures Reorder, shorten, or add items (10)	Quality of the data (3) Enhanced participant experience (for example, less burden, greater comfort) (6) Findings based on relevant, important measures (5) Measures aligned with participants' culture (4)
Data analysis/results review (9)	Specific aspects of analytic approach (for example, suggest covariates) (4) Interpretation of results (6)	Inform real-world use of the results (3)
DISSEMINATION		
Dissemination (8)	Plans (4), products (5), and activities (3)	Wider reach (4) More effective communication for target audiences, especially consumers and policy makers (5)

SOURCE Authors' analysis of peer-reviewed journal articles with descriptions of the contributions of engagement to comparative effectiveness research funded by the Patient-Centered Outcomes Research Institute. **NOTES** The themes listed are those that were described by at least three projects. See appendix exhibit A9 for supporting citations (see note 8 in text). The numbers in parentheses are the numbers of projects with contributions by phase or theme.

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projects reported engagement contributions during multiple phases.

Nearly all contributions were framed positively. While no articles labeled contributions of engagement to the projects as negative or undesirable, three projects acknowledged the time and resource investment required for engagement.[16–18] Furthermore, two projects noted that partners' recommendations introduced trade-offs, such as using unvalidated measures to assess high-priority outcomes or alternative randomization schemes to align with partners' desires to maximize the number of people receiving a clinical intervention.[12,19] Also, four projects noted that partners' recommendations—such as examining specific outcomes, covariates, or measures—could not be implemented because of study constraints, including follow-up time, data collection mode, and data availability.[20–23]

STUDY FOCUS: DEFINING RESEARCH QUESTIONS, COMPARATORS, AND OUTCOMES Partners contributed to identifying the topic, defining research questions or aims, selecting comparators to examine, and establishing study outcomes (that is, constructs to study). Authors wrote that because of engagement, projects selected, prioritized, added, or modified primary or secondary outcomes—including health status and well-being, knowledge and understanding, and evaluation of care. Four projects explicitly noted that patient partners overturned assumptions about important outcomes to study.[14,17,24,25] For example, one project studying stroke patients described how patient partners helped refocus research aims, saying: "We knew regaining functional status was an important component of recovery, but we did not realize how much depression, anxiety, and fatigue weighed on many stroke survivors' minds. So, we revisited our aims, overhauled our data collection plan, and ensured that our goals were not only informed by patients but also aligned with the issues that patients cared about the most."[25(p1)]

RESEARCH DESIGN Partners contributed to research design by influencing inclusion or exclusion criteria; the designs selected, such as noninferiority designs, numbers and types of arms, and mixed methods; and decisions about assignment of participants. Partners in some cases wanted more people in the study or interventions, which can lead to broader inclusion criteria; selection of designs, such as delayed start;[13] or use of different participant assignment techniques, such as unequal randomization.[12] Such considerations demonstrate that nontechnical input can inform technical decisions about how to carry out research.

INTERVENTIONS: TAILORING AND DELIVERY The most common contribution theme across all project phases was tailoring interventions for specific populations or settings, including intervention delivery (for example, format or number of sessions), materials or tools (such as handouts and decision aids), and content (for example, increased emphasis on patient-provider communication).

RECRUITMENT AND RETENTION The contributions described for recruitment/enrollment and retention included planning (for example, developing recruitment and consent materials and setting participant compensation) and anticipating barriers (such as addressing factors to improve participation rates among hard-to-reach populations). Contributions also included solving unanticipated problems. For example, partners helped overcome hospital administrators' concerns about participating with competitors in a large pragmatic study by understanding complex local market dynamics and identifying champions who allayed the concerns.[26] Partners also helped revise recruitment scripts when enrollment was low or potential participants were unreceptive to the approach.[27,28] For example, one article noted how partners recommended changing the enrollment script to emphasize that the research was designed with involvement from patients and families and would test a tool aimed at improving physician-patient communication and encouraging shared decision making about appendicitis treatments. Following the change, enrollment increased from 65 percent to 95 percent.[28]

DATA COLLECTION, MEASURES, AND ANALYSIS Authors noted contributions to when and how to collect data from study participants, such as data collection timing relative to clinical events and data collection mode; measure selection, such as selecting a specific patient-reported outcome instrument; adaptation of measures such as reordering, adding, or removing items; and assessment of measurement properties (for example, face validity and usability). Further, some articles described specific contributions to specific aspects of the analytic plan (such as covariate selection and defining clinical significance) and interpretation of results.

DISSEMINATION Partners contributed to plans for when, where, and how to share findings and to specific dissemination products (for example, manuscripts, presentations, and patient materials) and activities (such as giving presentations and educating policy makers).

SUMMARY OF THE EFFECTS OF ENGAGEMENT Across all phases of research, authors reported effects of engagement contributions on research design and conduct, study participants, or patients and clinicians who will use the findings (exhibit 2). For example, authors reported that

adaptations to interventions led to minimal burden for patients or providers, alignment of interventions with patients' preferences, and greater intervention adherence. Descriptions of the diverse engagement effects can be grouped into four interdependent themes: acceptability, feasibility, rigor, and relevance. *Acceptability* relates to research designs, procedures, and interventions intended to be well received by patients or clinicians based on burden; usability; and alignment with preferences, values, and needs. *Feasibility* relates to mitigating potential or actual roadblocks—particularly to making interventions, enrollment, retention, and data collection more doable in real-world settings. *Rigor* pertains to choices that minimize bias and enhance data quality. *Relevance* reflects the applicability and importance of the research for patients and clinicians making decisions, including the importance of research questions and outcomes, generalizable study samples, interpretations of findings in a real-world context, and more effective dissemination.

WHAT ENGAGEMENT APPROACHES AND PRACTICES DO RESEARCH TEAMS USE TO ACHIEVE CONTRIBUTIONS? Nearly two-thirds of projects described using multiple engagement approaches and practices. Few projects (12 percent) relied exclusively on one-way partner input, such as focus groups or one-time forums (exhibit 1). Nearly all projects reported using engagement practices consistent with consultation (46 percent) or collaboration or shared leadership approaches (37 percent). For example, one article described having "met frequently and shared editorial control over the project" with partners.[16(p3)]

The partner role often was described as helping adapt aspects of the research and sometimes described as development or codevelopment, or as articulating experiences, preferences, or insights to inform researchers' decisions or solutions. For example, researchers selected outcome measures to reflect patients' greatest concerns. Occasionally the partner role was described as implementing the research strategy, such as recruiting participants and conducting focus groups. Few contributions were described as purely endorsement of researchers' plans.

Projects most commonly reported engaging patients (88 percent), clinicians (68 percent), and caregivers (46 percent) and less often reported engagement with health systems (18 percent), payers (16 percent), and policy makers or governmental representatives (13 percent) (data not shown). Patient partners were most frequently described as individual patients, though patient advocates and groups were represented. Clinicians were mostly physicians, followed by

nurses and other allied health care professionals, such as physical therapists. Descriptions were seldom sufficient to distinguish between practicing and researcher clinicians. Authors explicitly attributed most contributions to patients or caregivers, sometimes alongside other stakeholders—who overall were less explicitly credited.

HOW DO TEAMS ASSESS CONTRIBUTIONS OF ENGAGEMENT? Nearly all extracted engagement contributions were based on the personal reflections of authors who were members of comparative effectiveness research teams funded by PCORI. However, a few projects measured the contributions of engagement systematically. Measurement strategies included user feedback on adapted intervention elements (three projects) and various indicators of enrollment or retention (six projects) (see appendix exhibit A8 for details).[8]

Discussion

We have described varied, widespread, and practical ways that patient and stakeholder engagement contributed to PCORI-funded comparative effectiveness research. Compared to past studies, we found more engagement of patients specifically[3,4] and an emphasis on engagement contributions to intervention tailoring and research design decisions. Because comparative effectiveness research examines the effectiveness of clinical services in real-world settings and populations—especially those subject to health disparities—such tailoring is important. We also found that engagement contributes to identifying research questions and outcomes important to patients and clinicians, recruitment and retention of study participants, data collection processes, interpretation of results, and dissemination. These findings extend previous research[3–5] in a larger sample and with greater detail, particularly for the perceived effects of contributions on the research, participants, or research end users. Overall, our findings suggest that engagement contributes to research that is better aligned with patients' and clinicians' needs.

Descriptions of the effects of engagement contributions fall into four important, highly interconnected groups: feasibility, acceptability, rigor, and relevance. The inability to complete studies, examination of low-priority research questions, and inadequate study designs are major sources of wasted research resources.[6,29] Thus, feasibility, acceptability, rigor, and relevance of findings for patients and clinicians are important steps toward ultimately producing useful evidence that more quickly affects health

care delivery and ultimately patient outcomes.

While we did not find contributions of engagement labeled as negative, we did find partner recommendations that could not be implemented because of study constraints; input that sometimes introduced trade-offs among feasibility, acceptability, rigor, and relevance; and acknowledgment of the time or resource investments associated with engagement. Engagement adds to ever-present, real-world research circumstances including time, budget, and recruitment challenges and funder requirements. With consumers and other stakeholders involved, conversations about research design priorities can address both technical issues and broader issues of what research is relevant and valued—and by whom. Importantly, engagement is just one factor in research completion and success and can neither solve every problem nor be the sole reason that projects fail.

Among the contributions summarized, some influenced the entire research course, such as when partner input drove primary outcomes and comparators. Others were more modest, such as refining written materials for an intervention. Yet even modest contributions can substantially affect research—for example, when changing an enrollment script to better describe the purpose of the research and the role of families increased enrollment by 30 percentage points.[28]

While there is great interest in knowing more precisely the impact of engagement on research conduct and uptake, few projects in our sample reported systematically measuring engagement effects. Additionally, we could not gauge the exact magnitude of engagement contributions, because of both the subjective nature of the descriptions and the lack of a control group.

Finally, regarding how researchers engaged partners, PCORI's provision of general guidance rather than prescription of specific engagement activities allowed research teams to pursue multiple, sometimes innovative, engagement approaches. As the definition of *engagement* evolved from passive input and endorsement to reshaping or coproducing research, many PCORI projects reported more collaborative approaches and prominently noted patients and caregivers as contributors. Our findings also underscore the fact that diverse forms of engagement offer the potential to better align research with the priorities of relevant partners.

Implications
Our findings that patients and stakeholders are engaging as consultants and collaborators and contributing to research that is more aligned with patients' and clinicians' needs have implications for research policy and practice. Funders and research institutions need to establish engagement policies and provide resources to support research that is more fully responsive to end users' needs. For example, PCORI developed and will continue to refine the engagement rubric,[2] templates for planning engagement, and project milestones that document specific engagement achievements, as well as providing engagement officers to deliver technical assistance. Since the contributions we identified occurred in early PCORI projects with more limited support for engagement, increased emphasis and resources could accelerate engagement and its impact. Furthermore, research teams conducting engaged research should consider conceptualizing engagement as two-way communication about the diverse factors that affect research decisions, rather than as just a process to obtain one-way input. Finally, incomplete descriptions of how specific engagement practices affect research, even in the context of PCORI projects, are common. Therefore, our findings support the need to prioritize the inclusion of information on engagement and its implications in peer-reviewed articles and contribute to international conversations about reporting on engagement.[30] Journal editors, researchers, and consumers will need to collaborate to ensure that important scientific and engagement information is communicated.

This review also highlights the need to develop innovative research designs and validated measures to assess engagement processes and outputs from multiple perspectives. Evaluating how engagement affects research is particularly challenging in the context of ongoing, relational engagement with true, complete integration of partners. This challenge will only grow as research teams increasingly adopt more collaborative engagement approaches.

Given the rapid evolution in engagement practices and the fact that a sizable proportion of our sample (39 percent) consisted of protocols focused on earlier phases of research, it will be important to update this review and systematically examine how engagement in research affects the uptake of findings in health care decision making. As engagement practices spread but resources remain limited, we are at an important juncture for understanding the critical elements of optimal engagement practices and circumstances and the challenges to implementing effective engagement. We also need to understand more about the characteristics of engaged partners beyond the type of stakeholder they represent and how more diverse representation affects engagement contributions. PCORI is in-

vesting in additional research, including qualitative case studies and comparisons of PCORI-funded projects to projects from funders that do not require engagement. Notably, as much can be learned from studies that do not report contributions of engagement as from those that do.

Conclusion

This study looked, in near real time, at the contributions of partner engagement in PCORI's earliest funded comparative effectiveness research. The engagement contributions shared likely represent for authors the most explicit and impactful aspects of engagement. The examples represent the beginning of a shift from an investigator-driven research enterprise to one that more fully collaborates with patients, consumers, and other stakeholders. While additional evidence about the conduct and impact of engagement in research on health outcomes is needed, these early findings begin to show the perceived value of engagement for patient-centered comparative effectiveness research and may catalyze a stronger shift toward a culture of engagement. In fact, culture change is under way in both health research and health care as other funders, research entities, and health care systems emphasize engagement. Ultimately, evidence will be more useful and relevant to decision making when patients and stakeholders are fuller participants in the research process. This can only help improve both health and health care. ∎

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