

From Principles to Practice: Real-World Patient and Stakeholder Engagement in Breast Cancer Research

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ABSTRACT

The Patient-Centered Outcomes Research Institute (PCORI) in Washington, DC, has catalyzed a meaningful shift in the composition of research project teams since its initial research funding cycle in 2011. Despite the influx of funding in the research community for patient-centered research, research on how to effectively engage patients and stakeholders in the research process is still relatively nascent. Kaiser Permanente Washington Health Research Institute (KPWHRI) in Seattle, WA, was an early recipient of PCORI research funding and, as of December 2017, has received 8 PCORI research awards totaling nearly \$15 million. Anticipating the pivotal importance of PCORI's patient-focused approach, KPWHRI developed a set of 8 principles to guide how research teams should work with patients and other stakeholders to simultaneously achieve research aims and embrace this new paradigm in how research teams collaborate. With a goal of assisting other research teams, this article describes the genesis of the KPWHRI principles, their relevance to patient- and stakeholder-engaged research, and how these principles were brought to life in the context of a specific PCORI-funded project on surveillance imaging in women after a breast cancer diagnosis.

INTRODUCTION

The Patient-Centered Outcomes Research Institute (PCORI) in Washington, DC, catalyzed a meaningful shift in the composition of research project teams by requiring that patients and stakeholders—clinicians, policymakers, caregivers, health care leaders, and others—be involved in the research team in a meaningful and intentional way. As of December 2017, PCORI has funded 568 projects totaling \$2 billion. Despite the influx of PCORI funding, evidence on effectively engaging patients and stakeholders in research is relatively nascent.^{1,2} Drawing on principles of community engagement,³ the science of team science, and practical experience, many research teams have crafted approaches to working with patients and stakeholders. Early reports^{4,5} indicate that patient/stakeholder engagement has many manifestations, and its overall impact on the health research enterprise is still unfolding.

Among PCORI's strategic goals is to influence the broader research community, including funders, and already this is manifesting. The US Food and

Drug Administration and the National Institutes of Health (NIH) are involving patients and stakeholders in key efforts, such as the Patient Focused Drug Development and Precision Medicine initiatives. Moreover, entities such as the Clinical Trials Transformation Initiative in Durham, NC, and Faster Cures, a Washington, DC-based think tank, are offering conceptual and practical guidance for research collaborations involving patients. Research teams can benefit from this guidance, but it should be complemented by actual examples of how engagement occurs in the context of funded studies.

From 2011 to 2017, Kaiser Permanente Washington Health Research Institute (KPWHRI) in Seattle, WA, has received \$14.6 million in PCORI funding on topics including cancer surveillance, back pain, and reducing opioid misuse. Anticipating the pivotal importance of PCORI's patient-focused approach, KPWHRI developed a set of principles to guide research teams in working with patients and stakeholders to simultaneously achieve research aims and embrace this new collaboration paradigm. This

article describes these principles, their relevance to interactions with patients and stakeholders, and how they were expressed in a specific PCORI-funded project on surveillance imaging in women after breast cancer.

The Comparative Effectiveness of Surveillance Modalities in Breast Cancer Survivors study⁶ was launched in 2013. Known as SIMBA, this study has three aims:

1. Qualitatively assess and understand patients' and physicians' experiences in the use of surveillance breast imaging.
2. Generate evidence about differences between magnetic resonance imaging of the breast compared with mammography for all women and subgroups of women by measuring test performance.
3. Develop decision aids comparing outcomes important to patients and physicians in surveillance breast imaging for use in clinical practice.

PATIENT AND STAKEHOLDER ENGAGEMENT PLAN

KPWHRI principles of patient/stakeholder engagement in research originated in the organization's Patient-Centered Care Interest Group⁷ and reflected general tenets of engaging patients in their care.⁸⁻¹⁰ These principles also evoke the aims of the Institute of Medicine (now the National Academy of Medicine) report, "Crossing the Quality Chasm,"¹¹ in that KPWHRI seeks to conduct research that provides an equitable voice for patients, safe space for patients' contribution, timely input, efficient and effective methods, and a patient-centered orientation.

The Patient and Stakeholder Engagement Plan from SIMBA reflected the KPWHRI principles as well as PCORI's principles of trust, transparency, co-learning, respect, and partnerships. Here we

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describe the philosophical intent behind each of the eight principles and how each played out in SIMBA.

Authenticity

1. KPWHRI's PCORI-funded research will embody authentic engagement of patients, members, and other community stakeholders, meaning that these stakeholders are equal members of the research team.

This first principle, centered on authenticity, is the primary driver for KPWHRI's patient-engaged research. Collaboration cannot amount to token participation or "checking a box" to include various stakeholders; it entails a culture change that removes silos, hierarchies, and paternalism that have pervaded the research enterprise. Furthermore, "equal" is not synonymous with "identical." That is, everyone on SIMBA's study team participates in the dialogue representing *their* voice and expertise—an integral part of the project's culture from the outset. When research teams create shared culture from the beginning, trust develops among team members, and different viewpoints are balanced as part of team ethos. For example, patients' input on methods may not have the same weight as input from the study's biostatistician. Similarly, the determination of what patients value must be thoughtfully considered in light of what clinicians regard as important or optimal practice of medicine. The research life cycle means that as a practical matter, patient/stakeholder input will also be on a different cadence. Nevertheless, ensuring that input is genuinely considered throughout the study entails a proactive approach to engagement. The research team leaders have modeled bidirectional communication and active listening as cornerstones of SIMBA.

Real-World Perspective

2. In the process of designing, developing, implementing, and disseminating research in partnership with patients/members/community stakeholders, we recognize and embrace the fact that a research-centric model will not serve the larger goals of PCORI-funded research. We will strive for high-quality science, but we recognize that real-world needs and iterative processes are inherent in patient-centered research.

Historically, research teams have been made up of scientific experts, project

operations staff, and occasionally advisory panels with various stakeholders but typically composed of other experts in the scientific subject matter. Isolated from real-world needs of patients, clinicians, and other "consumers" of research, implementation of research findings tended to fall short. Study results may not reflect the real-world perspective outside academia, limiting their adoption into practice.¹²

In contrast, the patient-oriented research paradigm reflects constructs of user-centered design. Patients and researchers collaborate on study questions, data collection, and appropriate dissemination tactics. This iterative work may be less methodical and more improvisational, and it may run counter to researchers' temperamental inclination toward rigor and order. However, it also reflects real-world constraints and considerations.

A poignant example of the impact that patient partners had on the research took place early in SIMBA's design phase: The planned sample size did not provide enough statistical power to look at mortality as an outcome. Moreover, SIMBA's patient partners asserted that mortality was not as concerning to them as other outcomes such as morbidity and recurrence. Thus, when balancing study design choices, the study team was obliged to consider both statistical and patient-centered issues. Perspectives of patients and researchers related to guideline-concordant care offer another illustrative example. Researchers wanted to gauge receipt of surveillance imaging in accordance with clinical guidelines and put the data into "boxes." However, patients reported that they received surveillance imaging on schedules that did not conform precisely to clinical guidelines, which led the project team to be more flexible in the definition of "surveillance imaging."

Mutual Trust

3. We acknowledge that perceptions of research may be positive or negative, and that at times, communities and groups have been unfairly exploited by research or may harbor feelings of being "experimented on." In the event that these perceptions are voiced in the context of our research, we will actively partner with the patient/member/community to address these perceptions.

Because of several incidents¹³⁻¹⁵ over many years, research may be perceived in a negative light, especially by communities that were targets of exploitation. Given that SIMBA is an observational study, not a trial, that sense of experimentation may have been mitigated. However, the need for mutual trust between researchers and patient partners is bedrock. Patient collaborators in SIMBA explicitly indicated that they were assessing whether the study team was genuinely committed to a patient-partnered study team with mutual goals and shared values, reflecting the importance of both sides feeling comfortable with the relationship. Additionally, when the SIMBA team was composing the advisory panel, they actively recruited panel members from diverse racial/ethnic backgrounds, rather than relying on easier recruitment methods that often yield homogeneity.

Plain Language

4. KPWHRI has a long-standing commitment to health literacy and plain language. We will uphold this commitment by ensuring that all research study materials are written in plain language and that our research teams use plain language in their verbal communications.

Research has its own language. Study teams that aspire to be truly patient-centered must adroitly facilitate and translate the research vernacular in the moment. It is often difficult for researchers to "switch" to plain language, especially in oral communication. But if patients/stakeholders do not understand, information asymmetry and power imbalance may result. In all circumstances, patients should feel comfortable speaking up, which can be aided by training and tools throughout the project life cycle.

The SIMBA study created a climate in which participants feel empowered to comment when they do not understand orally presented information. The principal investigator has modeled the desirable ethos in the study team, encouraging patience when questions arise. The project manager facilitates in-person interactions, observing body language that may indicate incomplete understanding of research activities. A plain language expert has been on the team since inception and ensures that project communications are accessible

to all study team members, not just those with scientific backgrounds. These practices are scalable and extensible to other projects. KPWHRI makes the Readability Toolkit¹⁶ and online training freely available to the research community, along with customized training in plain language communication.

Furthermore, SIMBA facilitated deeper understanding and awareness of research by giving patients and stakeholders undergraduate-level books on statistics and research method tutorials during team meetings. Consequently, patients and stakeholders comprehended the long trajectory of many research studies and became more thoughtful consumers of health research news.

Equitable Partnerships

5. We regard patient/member/community participation as a valued asset to our research, and pledge to build equitable partnerships, respecting what each team member brings to the table.

Equitability is not a gratuitous or empty promise. Patients bring content expertise from being a patient—the lived experience. Involving all collaborators (patients, clinicians, researchers) led to a fuller conversation about important design considerations and desired outcomes of the SIMBA project. Here, the concept of “outcomes” was multifaceted, referring to both the actual outcomes of the study, and the outcomes of collaborating with a diverse constituency.

The relationship with patients who were patients of clinicians on the study team was an important consideration. Although clinicians could recommend patients who might be suitable for an advisory council or project team, SIMBA does not have patients in an advisory capacity who had prior clinical relationships with clinicians on the team. Prior research has shown the challenges patients face in cancer communication,^{17,18} and the team believed that patient-partners would be unlikely to speak candidly about their cancer experience if their oncologist was present. This model (no direct patient-physician relationships) enabled the SIMBA team to have frank conversations about patients’ care experiences during their posttreatment and recurrence journey. Depending on the study, other permutations of study

teams might lead to imbalanced partnerships or impede communication, such as a study on adolescents that involves both teenagers and parents.

Relationship Building

6. In the same way that patient-centered care is rooted in listening, patient-centered research must adopt a similar orientation. KPWHRI research teams will value active listening and relationship building with patients/members/community stakeholders on our research teams.

Developing relationships with patients required dedicated time and enriched the SIMBA project by strengthening the relevance of the research and enhancing our patient-partners’ trust in the project and team. For SIMBA patient-partners, in-person interactions were essential, including premeeting preparatory discussions, postmeeting debriefs, team lunches, and travel time. For study teams not colocated, developing strategies to emulate in-person interaction (eg, “share and tell,” conversations), can build trust.¹⁹ Concerns might arise that intensive focus on relationship building may slow study progress or efficient decision-making, but that did not manifest here. Study pace can be preserved by setting up ground rules for deliberative discussions and processes for nimble decision making by a subset of the larger team.

Discussions about health and health care that directly affect patients can spark intense emotion, and active listening can give way to activism or domination of a conversation. Similarly, researchers accustomed to leading and decisiveness may need to buffer their natural tendencies in order to create a shared locus of control. Patient-centered research entails subtle and sometimes fundamental shifts in temperament, acknowledging that all contributors bring a perspective worthy of consideration, despite their background, discipline, or training.

Community Engagement

7. We will uphold general principles for working with community groups and patients as articulated in the Department of Health and Human Services’ Principles of Community Engagement booklet,³ the PCORI Methodology Committee report,²⁰

and the Clinical and Translational Science Awards’ Best Practices in Community Engagement report.²¹

This principle originates in seminal work by the Centers for Disease Control and Prevention (CDC) and NIH pertaining to community engagement and community-based participatory research.³ When SIMBA was initiated in 2013, the science of patient engagement was in its infancy, and it remains a nascent, if fertile, space in which to examine and optimize collaboration. The SIMBA team viewed its work with the patient partners through the dual lens of *observing* rapid developments and new approaches to patient engagement, and simultaneously *contributing* to this field. The team kept an open mind about how patient engagement would manifest, and this state of innovation and mindfulness has benefited the project both scientifically and interpersonally. SIMBA has been recognized for its efforts via appearances at PCORI’s first annual meeting and Stanford MedX 2015, where team members described SIMBA’s patient partnerships in a panel presentation and exchanged state-of-the-art tactics to collaborate with patients, designers, and others for health care improvement.

Feedback

8. We will regularly seek feedback from nonscientists on our study teams to ensure that communication is bidirectional, trust is maintained, and that equitable partnerships are upheld.

SIMBA collaborators learned throughout the project that engagement is dynamic and variable. As the study moved from design to implementation and dissemination, tactics for engaging patients evolved. Hence, approaches needed to sustain engagement are different from the approaches used to catalyze it at the outset. The SIMBA patient advisory board and stakeholder panel complete anonymous surveys at semiannual in-person meetings to assess communication, inclusion, comprehension, and durability of the partnership. Participants can share whether they believe their contributions were recognized and whether they felt included. This tactic is instrumental and complements in-person interactions and

nonverbal communications. It is likely that a patient partner may feel his/her input is less salient during the analysis phase yet may not broach this with the study team directly, so such surveys give participants another opportunity to be heard.

CONCLUSION

The experience with patient engagement in SIMBA has illuminated three vital aspects of patient-partnered research. First, there are *cognitive and affective dimensions to engagement*, and researchers should attend to both these dimensions—how patients think and feel—to effectively integrate patients on a research team. Second, we believe there are *personality attributes that may lend themselves to success*. Both researchers and patient-partners will be more effective if they approach collaboration with openness, curiosity, and humility. Contrasting attributes—rigidity, indifference, and arrogance—may interfere with the research progress and partnership viability. Finally, given the natural life cycle of research, project teams should note that the *engagement process itself has a life cycle*, including variability in patients' interactions. Sustaining engagement may be challenging, especially during lengthy data collection and analysis.

The study topic is a key aspect of engagement, and patient-partners may contribute to a study team for different reasons. Nevertheless, we hope these principles may be generalizable and applicable, irrespective of the research topic. The literature and experiences of patients as research partners is evolving, and the research community will learn more as project teams share both empirical and experiential findings. As this new research era evolves, this quote from the *Principles of Community Engagement* resonates: "When researchers and organizers work collaboratively with community organizations throughout a project, they can produce effective, culturally appropriate programs and [emphasis added] robust research results."^{3p12} ❖

Disclosure Statement

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