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Involving Patients and Consumers in Research: New Opportunities for Meaningful Engagement in Research and Quality Improvement

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Issue Brief

Involving Patients and Consumers in Research: New Opportunities for Meaningful Engagement in Research and Quality Improvement

About the EDM Forum

The Electronic Data Methods (EDM) Forum is a three-year grant from the Agency for Healthcare Research and Quality (AHRQ) to facilitate learning and foster collaboration across a set of eleven comparative effectiveness research (CER) projects. Collectively, these projects are designed to build infrastructure and methods for collecting and analyzing prospective electronic clinical data. Specific areas of focus include the governance, clinical informatics, and analytic issues that are crucial to the design and use of electronic clinical data for CER and PCOR. The EDM Forum, and the connected research projects, are funded by the American Recovery and Reinvestment Act (ARRA).



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Introduction

Engaging patients and consumers in health research has been a long-held yet largely elusive goal. While desirable, achieving meaningful engagement in research is challenging and often requires a sustained commitment that can be resource intensive. Furthermore, the term means very different things to different people, so application of the concept is highly inconsistent and difficult to evaluate.

Despite these challenges, a handful of research initiatives—building on substantial federal investments and national efforts to transform care delivery—are involving patient and consumer communities. This issue brief examines the rationale for engaging patients and consumers in health care research, and discusses several opportunities and challenges based on the experiences of several efforts to leverage electronic clinical data (ECD) for comparative effectiveness research (CER), patient centered outcomes research (PCOR), and quality improvement (QI). It also identifies a number of challenges to meaningful engagement of patients and consumers in the research process.

Finally, this brief raises new possibilities for thinking more holistically about ways to engage communities in evidence generation—expanding the continuum of activities potentially benefiting from patient and consumer involvement—so that technology and infrastructure development are included. (A forthcoming publication will further describe the expansion of the continuum).

A New Environment for Engagement

Significant investments in CER¹ and PCOR have focused on conducting research to discover “what interventions work best, for which patients, under what conditions.” Parallel developments in clinical informatics – including expanded deployment of electronic health records (EHRs) – are making large amounts of data available for a broad spectrum of inquiry, from QI to research. While issues of how and under what circumstances these data are to be accessed and interpreted remain unresolved, efforts to further expand access to federally-supported data resources, the increasing use of mobile technologies to capture and share health-related information, and the “meaning-

ful use” requirements for EHRs, will only expand the volume of potential information available to researchers as well as patients and consumers.

Simultaneously, delivery system innovations (e.g., patient centered medical homes) and market developments (e.g., value-based reimbursement) are re-orienting from more traditional provider-centric models to those that focus more directly on patient needs. This shift has the potential to facilitate greater integration of patient-contributed data into routine care, and also to collect more information from patients with respect to their needs and preferences for health services.

Several additional factors are both enabling and accelerating this transformation, including: (1) common use of the internet to search for health information;² (2) patient and consumer participation in online communities designed to foster peer-to-peer learning and support;³ and (3) use of technologies (e.g. sleep or activity trackers) that can help link biometric or other patient-reported information back to health records or other tools used to manage health and health care.⁴ These sources of information, if appropriately leveraged, could significantly enhance health research and increase opportunities to engage patients and consumers.

Public awareness and interest in expanded and more direct engagement is also growing. Health advocate and activist Dave deBronkhardt (e-patient Dave) encourages the biomedical enterprise to “let patients help”⁵ in a meaningful way. A cadre of vocal advocates has amplified this message with their own stories, but some of the trends noted above suggest that there is broader support. Recently published frameworks for achieving, maintaining, and defining engagement support this notion.^{6,7,8} For example, historically, patient-reported outcomes (PROs) were more limited to research contexts (largely due to available modes and mechanisms of collection); however, new opportunities now exist to look at quality of life, observations of daily living (ODLs) and patient satisfaction

in a way that is not (necessarily) tied to the process of care delivery and is more reflective of patients’ perspectives on their health, conditions, and care. The expectation is that these sources of information will provide a more comprehensive view of the effectiveness of treatments and services, and their impact on patients more broadly.

All of these developments signal the potential for researchers to partner with patients and consumers in an effort to better understand priorities and improve patient outcomes.⁹ There is now an opening to explore a broader spectrum of opportunities for meaningful engagement. Whereas prior approaches have involved patients and consumers at different points in the research process (e.g., prioritization and submission review), the issue of whether and how to incorporate patient and consumer perspectives in the design of data resources and other infrastructure components also warrants consideration.

Why Patient and Consumer Engagement Matters to Research

As individual participants in the health care enterprise, patients and consumers bring unique and critically important perspectives to the care experience and are important partners in generating new evidence. This may be reflected in their preferences for treatment, in their expectations for shared decision making, or in their assessment of what constitutes a “successful” outcome. Inherent in the definitions of CER and PCOR is the goal that the research is *useful* to patients, consumers, and other decision-makers. Furthermore, patients, consumers, and researchers all want high-quality research that adheres to standards of ethical behavior; this not only supports the objective of improving health and healthcare, but also helps to ensure continued participation in and support for research activities.

Both ethical, and instrumental - or practical - reasons have been articulated in support of engaging patients and consumers in health research:

- The ethical, or values-based perspective is best reflected in the responsibility of researchers to conduct studies that uphold the basic principles of respect for persons, beneficence, and justice.¹⁰ In addition, embracing patient and consumer engagement in research can help respond to the request frequently articulated by patient advocates: “nothing about us without us.”
- Practical or instrumental considerations incorporate the notion that – as ultimate end users of the research - patients and consumers should have a voice in shaping such endeavors because engagement will lead to research that is better targeted and more useful. The expectation is that researchers will evaluate what actually works in practice, and consider programmatic reforms to improve patient outcomes. Patient and consumer engagement and buy-in are also critical for broader application and acceptance of research findings.¹¹ When these perspectives are excluded, proponents of research – CER in particular – may risk opposition to their efforts.^{12,13,14} Patient and consumer engagement can also contribute to more rigorous or higher-quality studies; these perspectives may help identify key mediators, moderators, or even causal pathways that are most relevant to patients and consumers, and their outcomes, and that might not otherwise be considered. Finally, though less well understood, it is possible that the systematic and meaningful engagement of patients and consumers in the research process will engender greater interest in participating in research studies as subjects and/or in making their data available for research.

These same arguments also warrant consideration when developing new infrastructure to support research (e.g., data resources). If the expectation is that the infrastructure

will be leveraged to support research, patients and consumers will want some assurance that their needs and preferences have been “baked in” to the goals of the project. Essentially, new infrastructure should be technically, procedurally, and otherwise able to support the types of research efforts that patients and consumers perceive as important, and should be designed to reflect their values and preferences. It is also important that any components of the infrastructure that interact with patients be designed with their participation in mind.

Challenges to Meaningful Patient and Consumer Engagement

One consistent request from members of patient and consumer communities is that their needs, concerns, values, and expectations be considered *early* in the process - not as an afterthought or at a point where action on that input is no longer feasible. As expressed by Musa Mayer, a 20-year breast cancer advocate, “Being invited to endorse or recruit for research studies without participating in their creation is a familiar complaint.”¹⁵ Developing strategies for including patient perspectives has proved challenging, however, as it is not always obvious, intuitive, or feasible (given time and resource constraints) for members of the research community to be adequately attentive or responsive to such requests. Early engagement in infrastructure development may prove to be even more challenging, as the full set of potential uses for the data resource is likely to be broader than a single research study. Thus, determining who to involve, and at what level, is not obvious. Several members of the research community also have expressed frustration with the lack of opportunity, time, and resources provided to support such endeavors.¹⁶

Even where there is opportunity, patients and consumers may not be well equipped to engage in research and/or infrastructure projects without some level of training and support. Furthermore, many of the studies leveraging ECD involve using tools (e.g., EHRs) not purposefully designed for research. As a result, the ability to capture

data with the level of precision assumed for research may not be feasible, and various complex statistical methods are often used to account for unknown factors.¹⁷ Such analysis also involves a range of disciplines including health services research (HSR), clinical informatics, statistics, and others. In light of the complexity, researchers and others working to develop supporting infrastructure may struggle with how and when to engage patients and consumers. Both time and resource constraints are often an issue, as are concerns about adequate training and other supports that likely would be required.

Other challenges include the relatively limited opportunities for collaboration between researchers and end-users (i.e., patients); the perceived or real lack of appreciation for new and different perspectives in research; and lack of a clear pathway for engaging interested patients and consumers. Perhaps as a result, opportunities for patients and consumers to engage with the research enterprise are often limited to participation as study subjects. To the extent that other opportunities exist, most patients and consumers are not aware of them. In addition, some may be concerned that their perspectives are not respected, or may perceive that the research community views their contributions as having relatively limited value.¹⁸

Opportunities for Meaningful Engagement in CER and PCOR

Notwithstanding existing and anticipated challenges, building lessons learned and developing new approaches to engage patients and consumers is especially critical at this juncture. There are many important opportunities for engagement throughout the full evidence generation spectrum that have the potential to improve patient outcomes (see box on the ‘Evidence Generation Process’). In the process of building infrastructure and conducting research activities that are crucial to CER, PCOR, and QI, patients and consumers can be important partners. For example, conceptualizing research activities so that key goals and objectives resonate with patients and consumers

Evidence Generation Process

Throughout the entire evidence generation process, patients and consumers can be important partners in:

- Conceptualizing the research activity to ensure studies are well targeted and responsive to community-based priorities; and
- Developing and monitoring governance policies and processes to manage relationships between various stakeholders and institutions – ensuring data security, privacy, and access issues, as well as conflicts of interest, are addressed.

In the process of technical infrastructure development¹⁹ potential opportunities for engagement include:

- Assessing needed infrastructure to address patient and consumer priorities;
- Considering appropriate software and hardware solutions;
- Defining data requirements;
- Identifying core applications; and
- Monitoring the infrastructure and recommending changes as needed.

In research and analysis²⁰ potential opportunities for engagement include:

- Assisting in identification of relevant data sources, exploring funding sources or partners, developing the research plan and proposal, and conducting the organizational and administrative preparation necessary to carry out the research. This step also provides an opportunity to evaluate the feasibility and utility of the proposed research;
- Providing input on research methods appropriate to the question and context, including stakeholder values;
- Selecting sample population(s);
- Selecting or developing data collection tools;
- Collecting, processing, and analyzing data;
- Interpreting findings;
- Applying lessons learned; and
- Disseminating findings.

is perhaps the most critical step. Once a research project is underway, it is nearly impossible to revisit the questions of purpose, population(s), and key outcomes that matter most. Patients and consumers can also have important roles in developing and monitoring governance policies, which inform the relationships between various stakeholders and institutions to ensure data security, accountability, and privacy, and also in considering issues of data access and conflicts of interest.

Activities for Engaging Patients and Consumers

There are a variety of possible ways to engage patients and consumers in the evidence generation process. Though activities will differ considerably depending on the context and phase of the research, specific activities may include:

- Contributing public input/comment (e.g. to formally-released calls for comments or informally-presented requests for feedback);
- Serving as external advisors on specific patient/consumer issues;
- Serving in leadership roles (e.g. governance board);
- Serving as a community liaison between researchers and community members;
- Participating as a research team member (investigator, project manager, workgroup leader);
- Participating in a research study;
- Designing, testing, and validating informatics tools and/or research instruments (e.g. contributing input on the design and function of social media tools and portals or helping to design research questions to ensure they capture outcomes of interest to patients);
- Serving as a reviewer (e.g. protocol documents, grant proposals);

- Participating in virtual networks (e.g. participatory sensing, “Asthmapolis”);
- Participating in oversight, monitoring, and evaluation; and
- Educating other stakeholders on the research process.

In working to define roles and opportunities for engagement, it is also important to consider that different skills and perspectives may be needed depending on the particular activity. For example, patients and consumers involved in defining the research question should ideally be familiar with the condition being studied, but those engaged to provide input on research methods likely would require a different kind of expertise. Additionally, different skills, perspectives and resources may be needed depending on the type of activity within these broader categories; expectations of time and expertise can also differ depending on the level and duration of engagement (i.e., long-term service on a governing board versus one-time focus group participation).

Training

Members of the advocacy community are well aware that training and support are required to ensure that patients and consumers can have a place at the decision-making table. Because CER using ECD incorporates a range of research approaches, including experimental (e.g., randomized controlled trials, or RCTs) and observational studies, the “lift” for patient and consumer participants could be even heavier since they may need to understand a range of study designs. While training programs exist to prepare patients and consumers to sit on review boards for the federal government and to understand, for example, randomized controlled trials and systematic reviews, additional efforts will likely be necessary to train consumers and patients to participate meaningfully in all phases of CER and PCOR.

Examples of Efforts to Engage Patients and Consumers

To date, efforts to meaningfully involve patients and consumers have largely focused on their participation in certain aspects of randomized clinical trials and systematic reviews. These experiences can be instructive and illustrate the practical considerations and potential of engaging patients and consumers.

Early examples include the Department of Defense’s (DoD) Breast Cancer Research Program, FDA advisory committees, training efforts from the National Breast Cancer Coalition, and collaborations between Consumers United for Evidence-Based Healthcare and the US Cochrane Center. Specific projects based on these existing models of engagement are provided in the box on page 5, Programs That Engage Patients and Consumers in Clinical Research and Systematic Reviews.’

More recent efforts to engage stakeholders include the Agency for Healthcare Research and Quality (AHRQ) Community Forum, which is focused on identifying, evaluating, and implementing best practices for broad stakeholder (e.g., clinician, patient, caregiver, researcher, and payer) engagement and public deliberation practices for CER and PCOR.²¹

The recently established Patient-Centered Outcomes Research Institute (PCORI) also has a stated goal of soliciting feedback from and directly engaging with patients and consumers. PCORI-supported research will focus on the “effectiveness, benefits and harms of different treatment options”²² and will be translated and disseminated to help patients and providers make informed health decisions. The commitment to stakeholder engagement has been reflected in the development of the organization’s national priorities and a research agenda that aims to study a broad range of conditions and decisions, and requires patient and stakeholder engagement in those processes. The national priorities

Programs That Engage Patients and Consumers in Clinical Research and Systematic Reviews and Associated Training Provided

Congressionally Directed Medical Research Programs²³

Role for Patients and Consumers: Trained consumers participate in this Department of Defense program's research proposal process by reviewing submissions for scientific quality and programmatic relevance; they have full voting member status.

Training: Participants receive orientation materials (handbook on policies and guidelines); attend an orientation session; and are paired with an experienced consumer reviewer who mentors them throughout the review process.

Food and Drug Administration (FDA) Advisory Committee Consumer Representatives²⁴

Role for Patients and Consumers: As both voting and non-voting members of FDA advisory committees, patient representatives provide input on new drugs under review.

Training: No training is explicitly provided. Eligible participants must be able to "analyze scientific data, understand research design, discuss benefits and risks, and evaluate the safety and efficacy of products under review."

Consumers United for Evidence-based Healthcare (CUE) and the US Cochrane Center (part of the Cochrane Collaboration)²⁵

Role for Patients and Consumers: Members of CUE (a national coalition of health and consumer advocacy organizations that partners with the US Cochrane Center) can participate in CUE meetings and projects, receive training about evidence-based healthcare, and provide input into the Cochrane Collaboration's systematic reviews of healthcare interventions.

Training: CUE and the US Cochrane Center developed a free online course for consumer advocates that provides an overview on the value of evidence generation, and information about how to understand research design, bias, and results.

American Thoracic Society (ATS) Public Advisory Roundtable (PAR)²⁶

Role for Patients and Consumers: Consumer advocacy organizations (representing respiratory diseases, sleep-related conditions, or related critical illnesses) work in collaboration with the American Thoracic Society on policy and research development.

Training: The ATS PAR Patient website provides educational materials, including detailed fact sheets and condition-specific education material.

James Lind Alliance (JLA)²⁷

Role for Patients and Consumers: The organization brings together patients, caregivers, and clinicians to collectively "identify and prioritize the top 10 uncertainties, or 'unanswered questions', about the effects of treatments" of greatest importance. This information helps to ensure that those who fund health research are aware of what matters to both patients and clinicians.

Training: No training is explicitly provided. However, the JLA works closely with patients and clinicians to develop Priority Setting Partnerships and ensure representation of patient perspectives in the process.

National Breast Cancer Coalition (NBCC)²⁸

Role for Patients and Consumers: The NBCC offers a variety of opportunities for engaging patients and consumers to promote research and improve access to quality breast cancer care.

Training: Training is provided through the Annual Advocate Summit and a number of Project LEAD® training courses. Patients and consumers learn about the science of breast cancer and breast cancer research, and receive training in the design of clinical trials and research proposal review. They also learn about key aspects of serving effectively on governing bodies, and disseminating research findings.

and research agenda were informed by a public comment period that collected input through an online survey and focus groups.²⁹

Examples from the PROSPECT, DRN, and Enhanced Registries Projects

Among the research projects participating in the EDM Forum, several have successfully engaged patients in various aspects of research using a variety of mechanisms. The approaches in the following examples include patient and consumer participation in workgroups; solicitation of patient input when designing, testing, and validating informatics tools; and, building

partnerships with community health education centers to provide a location where researchers can interact with patients and consumers.

Surgical Care and Outcomes Assessment Program CER Translation Network (CERTAIN)

The Surgical Care and Outcomes Assessment Program CER Translation Network (CERTAIN) Enhanced Registry is focused on improving the effectiveness, quality and safety of surgical and interventional care for peripheral arterial disease (PAD), which is sometimes referred to as "angina of the leg." CERTAIN incorporates patient and other

stakeholder perspectives - and real world clinical practice - to address questions of comparative benefit and costs for clinicians, patients, payers, industry and policymakers. CERTAIN is working to build an automated flow of electronic health information using cutting edge informatics (e.g., text mining) tools, and to evaluate the utility and validity of automated data retrieval from across diverse healthcare settings. The project aims to enhance existing QI efforts by delivering more comprehensive and timely data about performance of evidence-based care, and by minimizing the staff and resource burden to participating hospitals.

A set of workgroups was established to help guide the project, one of which focuses on PROs. The PRO Core selects and incorporates PRO measures, helps define instruments, helps develop methods, and conducts PRO analyses. This effort is considered critical to the project because the investigators consider patients' perceptions of favorable outcomes as being critical to assessing the success of treatment for PAD. To achieve this goal, the PRO Core commissioned a number of patient focus groups to help inform the design and development of PRO tools used in the study. Their input was particularly solicited in considering the definition and design of quality of life measures included in the study. More information can be found at www.becertain.org.

Cincinnati Pediatric Enhanced Registry

The overall goal of the Cincinnati Pediatric Enhanced Registry project is to build an open-access data sharing network focusing on a pediatric population to improve care and increase patient participation for inflammatory bowel disease (IBD), including Crohn's Disease. The expectation is that a modular, versatile, and scalable registry will be populated by EHRs and used to support both QI and CER.

Investigators are working with IBD providers across the country to develop and test patient activation management (PAM) tools (e.g. reminders, checklists, and prompts to improve patient management of IBD) and a social networking tool aimed at encouraging patients and their families to actively participate in their care.

To achieve the goal of understanding which PAM and social networking tools are most effective, investigators conducted a series of activities to improve the infrastructure and technological tools as part of the research activity. Investigators first conducted qualitative research (interviews and focus groups) in which patients and families were asked a series of questions related to their methods of care and communication. Questions probed about knowledge of guidelines, preferences for

electronic communication with their care team, barriers to asking questions about needed care delivery, and how IBD care centers can more actively engage patients and families during their visits and collect information pre and post care to improve preparation for encounters and follow-up.³⁰ Based on research findings, investigators and application programmers designed the content and format of the registry-based PAM tools and developed the features and functions of a social networking portal (www.c3nproject.org) to interact with patients on an ongoing basis. More information can be found at www.enhancedregistry.org.

Washington Heights/Inwood Informatics Infrastructure for Community Centered Comparative Effectiveness Research (WICER)

The WICER PROSPECT study is working to create a robust, community-focused data infrastructure that supports innovative studies of hypertension and other pressing public health problems at a local level. WICER is built on an existing institution-focused data foundation at Columbia University. WICER contains a research data warehouse that integrates patient-level data, including clinical data from multiple facilities, settings and sites of care, with self-reported information collected via community survey.

Because the project is engaging the community to improve patient outcomes around hypertension, investigators are working closely with the Washington Heights/Inwood community to design research instruments and engage them in study recruitment. The degree of collaboration between investigators and community liaisons is demonstrated by community members' participation on a stakeholder advisory workgroup that was formed as part of the project. These community liaisons:

- Informed the conception of the research activity;
- Helped shape the design and implementation of the initial community survey to ensure it could capture out-

comes of interest to patients (e.g., the role of stress, self-perception, and social networks on health); and was culturally and linguistically appropriate; and

- Conducted outreach and encouraged community involvement.

Data for the study were collected via tablets in households, Ambulatory Care Network Clinics, and the Columbia Community Partnerships for Health Center in the Northern Manhattan Washington Heights/Inwood community. Each participant's blood pressure measures, height, and weight were then recorded on a take-away Personal Health Screening Form and additional health education was provided to ensure that the results are clearly understood. WICER survey data will be shared with community-based organizations and community members. More information can be found www.wicer.org.

Conclusion

Current investments to build infrastructure for CER, PCOR, and QI provide a unique opportunity for the research community to build on prior efforts and substantially strengthen engagement with patients and consumers. This can be achieved both by increasing participation in all possible phases of the research process, and by striving to incorporate patient and consumer perspectives in the development of new infrastructure, much of which will involve leveraging recent investments in clinical informatics systems. Careful consideration will be needed to prioritize the activities of most interest and relevance to both the research community and the patients and consumers affected by their work. In addition, education and training opportunities and other types of supports will likely be necessary to ensure that patient and consumer interests are adequately represented.

As the case examples illustrate, many comparative effectiveness researchers already are making efforts to engage patients and consumers, but most are still in the early stages of identifying the most successful strategies for including these perspectives. There are

substantial opportunities to build on the lessons learned from successful programs – particularly as new efforts grow and mature – and to expand the range of activities that can bring patients, consumers, and researchers together with the shared objective of optimizing health and health care.

Methods

The background for this brief is based on a comprehensive environmental scan conducted by the EDM Forum in 2011. Activities included a set of structured reviews of the peer-reviewed literature and the grey literature, six site visits with projects participating in the EDM Forum, interviews with key stakeholders, ongoing discussions and input from the community through a set of symposia held by the EDM Forum, and input from a variety of relevant stakeholders. Collectively, this process provided a current view of the various challenges and innovations associated with analysis, informatics, and data governance for electronic clinical data, and informed the proposed framework for engaging patients and consumers. Several members of the EDM Forum Steering Committee and the Consumer Patient Researcher Roundtable reviewed the brief and provided comments.

About AcademyHealth

AcademyHealth is a leading national organization serving the fields of health services and policy research and the professionals who produce and use this important work. Together with our members, we offer programs and services that support the development and use of rigorous, relevant and timely evidence to increase the quality, accessibility, and value of health care, to reduce disparities, and to improve health. A trusted broker of information, AcademyHealth brings stakeholders together to address the current and future needs of an evolving health system, inform health policy, and translate evidence into action.

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